

Drug Utilization Review Board

Oklahoma
Health Care
Authority

Wednesday,
December 13, 2017
4 p.m.

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 Meeting – December 13th, 2017

DATE: November 29th, 2017

NOTE: The DUR Board will meet at 4:00 p.m. The meeting will be held at 4345 N. Lincoln Blvd.

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

Call to Order

Public Comment Forum

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

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

Action Item – Vote to Prior Authorize Mavyret™ (Glecaprevir/Pibrentasvir) and Vosevi® (Sofosbuvir/Velpatasvir/Voxilaprevir) – Appendix C

Action Item – 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) – Appendix D

Action Item – Vote to Prior Authorize Duzallo® (Lesinurad/Allopurinol) – Appendix E

Action Item – Annual Review of Phosphate Binders – Appendix F

Action Item – Annual Review of Soliris® (Eculizumab) – Appendix G

Annual Review of Duchenne Muscular Dystrophy (DMD) Medications and 30-Day Notice to Prior Authorize Emflaza® (Deflazacort) – Appendix H

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 Fasentra™ (Benralizumab) – Appendix I

Annual Review of Anti-Emetic Medications and 30-Day Notice to Prior Authorize Varubi® IV (Rolapitant) and Cinvanti™ (Aprepitant) – Appendix J

30-Day Notice to Prior Authorize Zilretta™ (Triamcinolone Acetonide Extended-Release Injectable Suspension) – Appendix K

Annual Review of Ophthalmic Allergy Medications and 30-Day Notice to Prior Authorize Zerviate™ (Cetirizine Ophthalmic Solution) – Appendix L

Industry News and Updates – Appendix M

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board (DUR Board)

Meeting – December 13, 2017 @ 4:00 p.m.

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

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

1. Call to Order

- A. Roll Call – Dr. Cothran

Items to be presented by Dr. Muchmore, Chairman:

2. Public Comment Forum

- A. Acknowledgment of Speakers for Public Comment

Items to be presented by Dr. Muchmore, Chairman:

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

- A. November 8, 2017 DUR Minutes – Vote
- B. November 8, 2017 DUR Recommendations Memorandum

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

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

- A. Medication Coverage Activity for November 2017
- B. Pharmacy Help Desk Activity for November 2017
- C. SoonerPsych Program Update

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

5. Action Item – Vote to Prior Authorize Mavyret™ (Glecaprevir/Pibrentasvir) and Vosevi® (Sofosbuvir/Velpatasvir/Voxilaprevir) – See Appendix C

- A. Introduction
- B. College of Pharmacy Recommendations

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

6. Action Item – 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) – See Appendix D

- A. Introduction
- B. College of Pharmacy Recommendations

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

7. Action Item – Vote to Prior Authorize Duzallo® (Lesinurad/Allopurinol) – See Appendix E

- A. Introduction
- B. College of Pharmacy Recommendations

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

8. Action Item – Annual Review of Phosphate Binders – See Appendix F

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

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

9. Action Item – Annual Review of Soliris® (Eculizumab) – See Appendix G

- A. Current Prior Authorization Criteria
- B. Utilization of Soliris® (Eculizumab)
- C. Prior Authorization of Soliris® (Eculizumab)
- D. Market News and Updates
- E. Soliris® (Eculizumab) for Myasthenia Gravis (MG) Summary
- F. College of Pharmacy Recommendations

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

10. Annual Review of Duchenne Muscular Dystrophy (DMD) Medications and 30-Day Notice to Prior Authorize Emflaza® (Deflazacort) – See Appendix H

- A. Current Prior Authorization Criteria
- B. Utilization of DMD Medications [Exondys 51™ (Eteplirsen)]
- C. Prior Authorization of DMD Medications [Exondys 51™ (Eteplirsen)]
- D. Market News and Updates
- E. Emflaza® (Deflazacort) Product Summary
- F. Guideline Recommendations
- G. College of Pharmacy Recommendations

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

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) – See Appendix I

- A. Current Prior Authorization Criteria
- B. Utilization of Maintenance Asthma and COPD Medications
- C. Prior Authorization of Maintenance Asthma and COPD Medications
- D. Market News and Updates
- E. ArmonAir™ RespiClick® (Fluticasone Propionate Inhalation Powder) Product Summary
- F. Trelegy™ Ellipta® (Fluticasone Furoate/Umeclidinium/Vilanterol Inhalation Powder) Product Summary
- G. Qvar® RediHaler™ (Beclomethasone Dipropionate HFA) Product Summary
- H. AirDuo™ RespiClick® (Fluticasone Propionate/Salmeterol Inhalation Powder) Product Summary
- I. Fasenra™ (Benralizumab Injection) Product Summary
- J. College of Pharmacy Recommendations
- K. Utilization Details of Maintenance Asthma and COPD Medications
- L. Utilization Details of Asthma Monoclonal Antibodies (Pharmacy Claims)
- M. Utilization Details of Asthma Monoclonal Antibodies (Medical Claims)
- N. Utilization Details of Inhaled Corticosteroids

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

12. Annual Review of Anti-Emetic Medications and 30-Day Notice to Prior Authorize Varubi® IV (Rolapitant) and Cinvanti™ (Aprepitant) – See Appendix J

- A. Current Prior Authorization Criteria
- B. Utilization of Anti-Emetic Medications
- C. Prior Authorization of Anti-Emetic Medications
- D. Market News and Updates
- E. College of Pharmacy Recommendations
- F. Utilization Details of Anti-Emetic Medications

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

13. 30-Day Notice to Prior Authorize Zilretta™ (Triamcinolone Acetonide Extended-Release Injectable Suspension) – See Appendix K

- A. Introduction
- B. Zilretta™ (Triamcinolone Acetonide Extended-Release Injectable Suspension) Product Summary
- C. College of Pharmacy Recommendations

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

14. Annual Review of Ophthalmic Allergy Medications and 30-Day Notice to Prior Authorize Zerviate™ (Cetirizine Ophthalmic Solution) – See Appendix L

- A. Current Prior Authorization Criteria
- B. Utilization of Ophthalmic Allergy Medications
- C. Prior Authorization of Ophthalmic Allergy Medications
- D. Market News and Updates
- E. Zerviate™ (Cetirizine Ophthalmic Solution) Product Summary
- F. College of Pharmacy Recommendations
- G. Utilization Details of Ophthalmic Allergy Medications

Non-Presentation; Questions Only:

15. Industry News and Updates – See Appendix M

- A. Introduction
- B. News and Updates

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

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

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

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

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

- A. Injectable and Vaginal Progesterone Products
- B. Potassium Binding Medications
- C. Defitelio® (Defibrotide)
- D. Kanuma® (Sebelipase Alfa)
- E. Zinplava™ (Bezlotoxumab)
- F. Lumizyme® (Alglucosidase Alfa)

**Future business subject to change.*

18. Adjournment



Appendix A



**OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES OF MEETING OF NOVEMBER 8, 2017**

BOARD MEMBERS:	PRESENT	ABSENT
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): David Nguyen	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Melody Anthony, Deputy State Medicaid Director	X	
Marlene Asmussen, R.N.; Population Care Management Director	X	
Burl Beasley, D.Ph.; M.P.H.; M.S. Pharm.; 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:		
Eric Gardner, Vertex	Daniel Stevning, Sunovion	Jeff Steigmeyer, Sunovion
Kari Suttee, Novartis	Marc Parker, Sunovion	Ron Abraham, Sunovion
Lee Stout, Chiesi	Nicole Wilkerson, Novartis	Lee Hennigan, Novartis
Mark DeClerk, Lilly	Dave Harris, Amgen	Matt Forney, Merck
Jason Schwier, Amgen	Joseph Truong, Vertex	

PRESENT FOR PUBLIC COMMENT:	
Joseph Truong	Vertex

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. 17 SPEAKER: JOSEPH TRUONG

ACTION: NONE REQUIRED

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

3A: OCTOBER 4, 2017 DUR MINUTES – VOTE

3B: OCTOBER 4, 2017 DUR RECOMMENDATIONS MEMORANDUM

Materials included in agenda packet; presented by Dr. Cothran

Correction(s) to October minutes were discussed prior to voting. Correction(s) included the removal of Dr. Winegardner from the board member list as he had resigned prior to the October meeting. New minutes were provided and voted on.

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

ACTION: MOTION CARRIED

**AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/
2017 FALL PIPELINE UPDATE**

4A: MEDICATION COVERAGE ACTIVITY FOR OCTOBER 2017

4B: PHARMACY HELP DESK ACTIVITY FOR OCTOBER 2017

4C: 2017 FALL PIPELINE UPDATE

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE KEVZARA® (SARILUMAB), SILIQ™ (BRODALUMAB), TREMFYA™ (GUSELKUMAB), CYLTEZO™ (ADALIMUMAB-ADB), AND RENFLEXIS™ (INFLIXIMAB-ABDA)

5A: INTRODUCTION

5B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Holderread

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE BLINCYTO® (BLINATUMOMAB), BESPONSA® (INOTUZUMAB OZOGAMICIN), BOSULIF® (BOSUTINIB), GLEEVEC® (IMATINIB), ICLUSIG® (PONATINIB), KYMRIA™ (TISAGENLECLEUCEL), SYNRIBO® (OMACETAXINE), SPRYCEL® (DASATINIB), AND TASIGNA® (NLOTINIB)

6A: INTRODUCTION

6B: RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Schmidt, Dr. Borders, and Dr. Medina

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE BAVENCIO® (AVELUMAB) AND UPDATE SKIN CANCER MEDICATIONS PRIOR AUTHORIZATION CRITERIA

7A: INTRODUCTION

7B: RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Schmidt, Dr. Borders, and Dr. Medina
Dr. Hardzog-Britt moved to approve; seconded by Dr. Harrell

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE HAEGARDA® [C1 ESTERASE INHIBITOR (HUMAN)]

8A: INTRODUCTION

8B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nichols
Dr. Munoz moved to approve; seconded by Dr. Harrell

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE AXID® (NIZATIDINE CAPSULES AND SOLUTION), TAGAMET® (CIMETIDINE TABLETS), AND YOSPRALA™ (ASPIRIN/OMEPRAZOLE DELAYED-RELEASE TABLETS)

9A: INTRODUCTION

9B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nichols
Dr. Harrell moved to approve; seconded by Dr. Huddleston

ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE TRULANCE™ (PLECANATIDE), XERMELO™ (TELOTRISTAT ETHYL), SYMPROIC® (NALDEMEDINE), AND MOTOFEN® (DIFENOXIN/ATROPINE)

10A: INTRODUCTION

10B: COST COMPARISON: CONSTIPATION MEDICATIONS

10C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Adams
Dr. Munoz moved to approve; seconded by Dr. Harrell

ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: VOTE TO PRIOR AUTHORIZE MICORT™ HC (HYDROCORTISONE ACETATE 2.5% CREAM) AND UPDATE THE TOPICAL CORTICOSTEROIDS PRODUCT BASED PRIOR AUTHORIZATION TIER CHART AND CRITERIA

11A: INTRODUCTION

11B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nawaz
Dr. Preslar moved to approve; seconded by Dr. Munoz

ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: VOTE TO PRIOR AUTHORIZE NOCTIVA™ (DESMOPRESSIN ACETATE NASAL SPRAY)

12A: INTRODUCTION

12B: COLLEGE OF PHARMACY RECOMMENDATIONS

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: VOTE TO PRIOR AUTHORIZE SPRIX® (KETOROLAC TROMETHAMINE NASAL SPRAY) AND CATAFLAM® (DICLOFENAC POTASSIUM TABLETS)

13A: INTRODUCTION

13B: COLLEGE OF PHARMACY RECOMMENDATIONS

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: VOTE TO PRIOR AUTHORIZE PROMACTA® (ELTROMBOPAG) AND UPDATE PRIOR AUTHORIZATION CRITERIA FOR NPLATE® (ROMIPLOSTIM)

14A: INTRODUCTION

14B: COLLEGE OF PHARMACY RECOMMENDATIONS

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 15: VOTE TO PRIOR AUTHORIZE ODACTRA™ (HOUSE DUST MITE ALLERGEN EXTRACT) AND UPDATE ALLERGEN IMMUNOTHERAPY PRIOR AUTHORIZATION CRITERIA

15A: INTRODUCTION

15B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Abbott
Dr. Harrell moved to approve; seconded by Dr. Munoz

ACTION: MOTION CARRIED

AGENDA ITEM NO. 16: ANNUAL REVIEW OF NUEDEXTA® (DEXTROMETHORPHAN/QUINIDINE)

16A: INTRODUCTION

16B: CURRENT PRIOR AUTHORIZATION CRITERIA

16C: UTILIZATION OF NUEDEXTA® (DEXTROMETHORPHAN/QUINIDINE)

16D: PRIOR AUTHORIZATION OF NUEDEXTA® (DEXTROMETHORPHAN/QUINIDINE)

16E: MARKET NEWS AND UPDATES

16F: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Abbott
Dr. Muchmore recommends must be prescribed by, or in consultation with, a neurologist or psychiatrist and documentation of the secondary neurological condition must be submitted.

Dr. Munoz moved to approve with changes; seconded by Dr. Harrell

ACTION: MOTION CARRIED

AGENDA ITEM NO. 17: ANNUAL REVIEW OF ORKAMBI® (LUMACAFTOR/IVACAFTOR) AND KALYDECO® (IVACAFTOR)

17A: CURRENT PRIOR AUTHORIZATION CRITERIA

17B: UTILIZATION OF ORKAMBI® AND KALYDECO®

17C: PRIOR AUTHORIZATION OF ORKAMBI® AND KALYDECO®

17D: MARKET NEWS AND UPDATES

17E: COLLEGE OF PHARMACY RECOMMENDATIONS

17F: UTILIZATION DETAILS OF ORKAMBI® AND KALYDECO®

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 18: ANNUAL REVIEW OF IRON CHELATING AGENTS AND VOTE TO PRIOR AUTHORIZE JADENU® SPRINKLE (DEFERASIROX ORAL GRANULES)

18A: CURRENT PRIOR AUTHORIZATION CRITERIA

18B: UTILIZATION OF IRON CHELATING AGENTS

18C: PRIOR AUTHORIZATION OF IRON CHELATING AGENTS

18D: MARKET NEWS AND UPDATES

18E: COLLEGE OF PHARMACY RECOMMENDATIONS

18F: UTILIZATION DETAILS OF IRON CHELATING AGENTS

Materials included in agenda packet; presented by Dr. Adams
Dr. Harrell moved to approve with changes; seconded by Dr. Munoz

ACTION: MOTION CARRIED

AGENDA ITEM NO. 19: ANNUAL REVIEW OF HEPATITIS C MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE MAVYRET™ (GLECAPREVIR/PIBRENTASVIR) AND VOSEVI® (SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR)

- 19A: INTRODUCTION**
- 19B: CURRENT PRIOR AUTHORIZATION CRITERIA**
- 19C: UTILIZATION OF HEPATITIS C MEDICATIONS**
- 19D: PRIOR AUTHORIZATION OF HEPATITIS C MEDICATIONS**
- 19E: MARKET NEWS AND UPDATES**
- 19F: REGIMEN COMPARISON**
- 19G: MAVYRET™ (GLECAPREVIR/PIBRENTASVIR) PRODUCT SUMMARY**
- 19H: VOSEVI® (SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR) PRODUCT SUMMARY**
- 19I: COLLEGE OF PHARMACY RECOMMENDATIONS**
- 19J: UTILIZATION DETAILS OF HEPATITIS C MEDICATIONS**

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NONE REQUIRED

AGENDA ITEM NO. 20: ANNUAL REVIEW OF VARIOUS SYSTEMIC ANTIBIOTIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BAXDELA™ (DELAFLORACIN INJECTION AND TABLETS), OFLOXACIN 300MG TABLETS, MINOLIRA™ (MINOCYCLINE EXTENDED-RELEASE TABLETS), SOLOSEC™ (SECNIDAZOLE ORAL GRANULES), AND VABOMERE™ (MEROPENEM/VABORBACTAM INJECTION)

- 20A: CURRENT PRIOR AUTHORIZATION CRITERIA**
- 20B: UTILIZATION OF VARIOUS SYSTEMIC ANTIBIOTIC MEDICATIONS**
- 20C: PRIOR AUTHORIZATION OF VARIOUS SYSTEMIC ANTIBIOTIC MEDICATIONS**
- 20D: MARKET NEWS AND UPDATES**
- 20E: BAXDELA™ (DELAFLORACIN) PRODUCT SUMMARY**
- 20F: MINOLIRA™ (MINOCYCLINE EXTENDED-RELEASE TABLETS) PRODUCT SUMMARY**
- 20G: SOLOSEC™ (SECNIDAZOLE ORAL GRANULES) PRODUCT SUMMARY**
- 20H: VABOMERE™ (MEROPENEM/VABORBACTAM INJECTION) PRODUCT SUMMARY**
- 20I: COST COMPARISON**
- 20J: COLLEGE OF PHARMACY RECOMMENDATIONS**
- 20K: UTILIZATION DETAILS OF VARIOUS SYSTEMIC ANTIBIOTIC MEDICATIONS**

Materials included in agenda packet; presented by Dr. Nichols

ACTION: NONE REQUIRED

AGENDA ITEM NO. 21: ANNUAL REVIEW OF GOUT MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE DUZALLO® (LESINURAD/ALLOPURINOL)

- 21A: CURRENT PRIOR AUTHORIZATION CRITERIA**
- 21B: UTILIZATION OF GOUT MEDICATIONS**
- 21C: PRIOR AUTHORIZATION OF GOUT MEDICATIONS**
- 21D: MARKET NEWS AND UPDATES**
- 21E: DUZALLO® (LESINURAD/ALLOPURINOL) PRODUCT SUMMARY**
- 21F: COLLEGE OF PHARMACY RECOMMENDATIONS**
- 21G: UTILIZATION DETAILS OF GOUT MEDICATIONS**

Materials included in agenda packet; presented by Dr. Chandler

ACTION: NONE REQUIRED

AGENDA ITEM NO. 22: ANNUAL REVIEW OF PANCREATIC ENZYMES

- 22A: CURRENT PRIOR AUTHORIZATION CRITERIA**
- 22B: UTILIZATION OF PANCREATIC ENZYMES**
- 22C: PRIOR AUTHORIZATION OF PANCREATIC ENZYMES**

22D: MARKET NEWS AND UPDATES

22E: COLLEGE OF PHARMACY RECOMMENDATIONS

22F: UTILIZATION DETAILS OF PANCREATIC ENZYMES

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 23: INDUSTRY NEWS AND UPDATES

23A: INTRODUCTION

23B: NEWS AND UPDATES

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 24: 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. 25: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)

25A: MAINTENANCE ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MEDICATIONS

25B: PHOSPHATE BINDING MEDICATIONS

25C: DUCHENNE MUSCULAR DYSTROPHY MEDICATIONS

25D: OCULAR ALLERGY MEDICATIONS

25E: ANTI-EMETIC MEDICATIONS

****FUTURE BUSINESS SUBJECT TO CHANGE***

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NONE REQUIRED

AGENDA ITEM NO. 26: ADJOURNMENT

The meeting was adjourned at 5:32 pm.



The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: November 9, 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 November 8, 2017

Recommendation 1: Fall Pipeline Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Kevzara® (Sarilumab), Siliq™ (brodalumab), Tremfya™ (Guselkumab), Cyltezo™ (Adalimumab-adbm), and Renflexis™ (Infliximab-abda)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Kevzara® (sarilumab), Siliq™ (brodalumab), Tremfya™ (guselkumab), Cyltezo™ (adalimumab-adbm), and Renflexis™ (infliximab-abda) to Tier-3 of the Targeted Immunomodulator Agents Product Based Prior Authorization (PBPA) category. Current Tier-3 approval criteria for this category will apply.

- If the net cost of Cyltezo™ (adalimumab-adbm) and Renflexis™ (infliximab-abda) is determined to be greater than the net cost of the reference product formulations of Cyltezo™ and Renflexis™, authorization would also require a patient-specific, clinically significant reason why the member could not use the reference product formulations of Cyltezo™ and Renflexis™.
- The following criteria will also apply for authorization of Siliq™ (brodalumab):

- Initial authorizations of Siliq™ (brodalumab) will be for the duration of 12 weeks at which time the prescriber must verify the member is responding to treatment. If an adequate response has not been achieved after 12 to 16 weeks of treatment with brodalumab, consideration should be given to discontinuing therapy.
- Members must also be enrolled in the Siliq™ REMS Program for approval.
- Members with a concomitant diagnosis of Crohn's disease will not be approved.

Additionally, the College of Pharmacy recommends the following criteria for Actemra® (tocilizumab) for a diagnosis of giant cell arteritis:

Actemra® (Tocilizumab) Approval Criteria [Giant Cell Arteritis (GCA) Diagnosis]:

1. An FDA approved diagnosis of GCA; and
2. Member must be 50 years of age or older; and
3. A history of erythrocyte sedimentation rate (ESR) ≥ 30 mm/hr or a history of C-reactive protein (CRP) ≥ 1 mg/dL; and
4. Member should have a trial of glucocorticoids for a minimum of four weeks or a reason why this is not appropriate; and
5. Actemra® will be taken in combination with tapering course of a glucocorticoid upon initiation; and
6. Member must have baseline liver enzymes, absolute neutrophil count (ANC), lipid panel, and platelet count and verification that they are acceptable to prescriber; and
7. Member must not have severe hepatic impairment; and
8. Actemra® should not be initiated in patients with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
9. Approval quantity will be based on Actemra® prescribing information and FDA approved dosing regimen(s).

Lastly, the College of Pharmacy recommends the following criteria for Actemra® (tocilizumab) for a diagnosis of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS):

Actemra® (Tocilizumab) Approval Criteria [Chimeric Antigen Receptor (CAR) T Cell-Induced Cytokine Release Syndrome (CRS) Diagnosis]:

1. An FDA approved diagnosis of CAR T cell-induced CRS.

Targeted Immunomodulator Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. A trial of at least one Tier-1 medication in the last 90 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. For a diagnosis of Crohn's disease (CD) or ulcerative colitis (UC) authorization of a Tier-2 product requires history of failure of a mesalamine product (does not have to be within the last 90 days) and a trial of one Tier-1 in the last 90 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
4. Prior stabilization on the Tier-2 medication documented within the last 100 days.

Targeted Immunomodulator Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and

2. Recent trials of one Tier-1 medication and all available Tier-2 medications that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. Prior stabilization on the Tier-3 medication documented within the last 100 days; or
4. A unique FDA-approved indication not covered by Tier-2 products.

Targeted Immunomodulator Agents*‡		
Tier-1 (DMARDs appropriate to disease state)	Tier-2*	Tier-3+
6-mercaptopurine	adalimumab (Humira®)€	abatacept (Orencia®)
azathioprine	etanercept (Enbrel®)	adalimumab-adbm (Cyltezo™)
hydroxychloroquine		adalimumab-atto (Amjevita™)
leflunomide		alefacept (Amevive®)
mesalamine		anakinra (Kineret®)
methotrexate		apremilast (Otezla®)
minocycline		brodalumab (Siliq™)
NSAIDs		canakinumab (Ilaris®)‡
oral corticosteroids		certolizumab pegol (Cimzia®)
		etanercept-szss (Erelzi™)
		golimumab (Simponi® & Simponi® Aria™)
		guselkumab (Tremfya™)
		infliximab (Remicade®)
		infliximab-abda (Renflexis™)
		infliximab-dyyb (Inflectra™)
		ixekizumab (Taltz®)
		rituximab (Rituxan®)
		sarilumab (Kevzara®)
		secukinumab (Cosentyx®)Ω
		tocilizumab (Actemra®)π
		tofacitinib (Xeljanz® & Xeljanz® XR)
		ustekinumab (Stelara®)
		vedolizumab (Entyvio™)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC) if NADAC unavailable. Tier-2 drugs subject to move to Tier-3.

Appropriate laboratory monitoring must be verified by the prescriber prior to approval.

DMARDs = Disease modifying anti-rheumatic drugs, NSAIDs = Nonsteroidal anti-inflammatory drugs

‡Biosimilars or reference products preferred based on lowest net cost product. Authorization of higher net cost biosimilars or reference products requires a patient-specific, clinically significant reason why the member could not use the preferred formulation.

€Unique criteria applies for a diagnosis of hidradenitis suppurativa (HS) or noninfectious intermediate and posterior uveitis or panuveitis.

*May be rebated to Tier-2 status only.

‡Unique criteria applies for a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), or Familial Mediterranean Fever (FMF).

ΩFor Cosentyx™ (secukinumab), only a trial of Humira® from the available Tier-2 medications will be required (based on supplemental rebate participation).

πUnique criteria applies for a diagnosis of giant cell arteritis (GCA) or chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS).

Recommendation 3: Vote to Prior Authorize Blincyto® (Blinatumomab), Besponsa® (Inotuzumab Ozogamicin), Bosulif® (Bosutinib), Gleevec® (Imatinib), Iclusig® (Ponatinib), Kymriah™ (Tisagenlecleucel), Synribo® (Omacetaxine), Sprycel® (Dasatinib), and Tasigna® (Nilotinib)

MOTION CARRIED by unanimous approval.

Blincyto® (Blinatumomab) Approval Criteria:

1. Blincyto® should be used as a single-agent only; and
2. For **one** of the following diseases:
 - a. Relapsed/refractory Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL); or
 - b. Relapsed/refractory Philadelphia chromosome positive (Ph+) ALL after failure of two Tyrosine Kinase Inhibitors (TKIs); or
 - c. Ph- ALL as consolidation in adult/young adolescent or patients younger than 65 years without substantial comorbidity with persistent or late clearance minimal residual disease positive (MRD+) following a complete response to induction.

Besponsa® (Inotuzumab Ozogamicin) Approval Criteria:

1. Besponsa® must be used as a single-agent only; and
2. Member must have **one** of the following:
 - a. Relapsed/refractory Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL); or
 - b. Relapsed/refractory Philadelphia chromosome positive (Ph+) ALL who are intolerant/refractory to two or more Tyrosine Kinase Inhibitors (TKIs).

Bosulif® (Bosutinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Bosulif® may be authorized for relapsed/refractory ALL either as:
 - a. Single-agent; or
 - b. In combination with an induction regimen not previously given; and
2. Bosulif® must be only used in patients with E255K/V, F317L/VI/C, F359V/C/I, T315A, or Y253H mutations.

Bosulif® (Bosutinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Patients with chronic, accelerated, or blast phase CML with resistance or intolerance after primary treatment with either: dasatinib, imatinib, or nilotinib with the following BCR-ABL1 transcript levels:
 - a. 0.01% to 1% at >12 months; or
 - b. >1% to 10% at ≥12 months; or
 - c. >10% at any milestone.

Gleevec® (Imatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Gleevec® may be approved for **one** of the following indications:
 - a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single-agent; or

- b. Maintenance therapy including:
 - i. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
 - ii. Post-hematopoietic stem cell transplant; or
- c. In relapsed/refractory ALL and as a single-agent or in combination with multi-agent chemotherapy.

Gleevec® (Imatinib) Approval Criteria [Bone Cancer – Chordoma Diagnosis]:

- 1. Single-agent therapy or in combination with cisplatin or sirolimus for the treatment of recurrent disease.

Gleevec® (Imatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

- 1. Member must have one of the following:
 - a. Newly diagnosed chronic, accelerated, or blast phase CML; or
 - b. Post-hematopoietic stem cell transplant.

Gleevec® (Imatinib) Approval Criteria [Melanoma Diagnosis]:

- 1. Member must meet all of the following criteria:
 - a. Gleevec® must be used as a single-agent; and
 - b. Second-line or subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapy; and
 - c. Metastatic or unresectable tumors; and
 - d. Activating mutations of C-KIT; and
 - e. Member must have an ECOG performance status of 0 to 2.

Gleevec® (Imatinib) Approval Criteria [Myelodysplastic Syndrome (MDS) Diagnosis]:

- 1. Chronic myelomonocytic leukemia (CMML) for 5q31-33 translocations and/or PDGFRβ gene rearrangements.

Gleevec® (Imatinib) Approval Criteria [Non-Melanoma Skin Cancers – Dermatofibrosarcoma Protuberans (DFSP) Diagnosis]:

- 1. Tumors with t(17;22) translocation; and
- 2. Member must have one of the following:
 - a. Adjuvant therapy for positive surgical margins following excision; or
 - b. Recurrent disease if disease is unresectable or if additional resection would lead to unacceptable functional or cosmetic outcomes; or
 - c. For metastatic disease.

Gleevec® (Imatinib) Approval Criteria [Soft Tissue Sarcoma – Desmoid Tumors (Aggressive Fibromatosis) Diagnosis]:

- 1. Primary, recurrent, or progressive disease with one of the following:
 - a. Initial treatment for resectable disease; or
 - b. Adjuvant treatment for gross residual disease; or
 - c. Initial treatment for unresectable disease or for disease for which surgery would be unacceptably morbid.

Gleevec® (Imatinib) Approval Criteria [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:

1. Primary/preoperative treatment for patients with documented GIST with one of the following:
 - a. Resectable with risk of significant morbidity; or
 - b. Unresectable; or
 - c. Recurrent; or
 - d. Metastatic; or
2. Postoperative treatment with one of the following:
 - a. Complete resection of primary GIST; or
 - b. Persistent gross residual disease; or
3. Continued treatment for one of the following:
 - a. Limited progression; or
 - b. Generalized progression.

Gleevec® (Imatinib) Approval Criteria [Soft Tissue Sarcoma – Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor Diagnosis]:

1. Gleevec® must be used as a single-agent only.

Iclusig® (Ponatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Member must have one of the following:
 - a. Induction/consolidation with HyperCVAD; or
 - b. Maintenance therapy in combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
 - c. Maintenance therapy post-hematopoietic stem cell transplant; or
 - d. Relapsed/refractory disease either as a single-agent, in combination with chemotherapy not previously given, or in patients with T315I mutations.

Iclusig® (Ponatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Member must have one of the following:
 - a. In patients with a T315I mutation; or
 - b. Intolerant or resistant to all other Tyrosine Kinase Inhibitors (TKIs); or
 - c. Post-hematopoietic stem cell transplantation in patients with prior accelerated or blast phase prior to transplant or who have relapsed.

Kymriah™ (Tisagenlecleucel) Approval Criteria:

1. All of the following must be met for approval:
 - a. B-Cell precursor acute lymphoblastic leukemia (ALL); and
 - b. Member must be 25 years of age or younger; and
 - c. Refractory or in second or later relapse:
 - i. Philadelphia chromosome negative (Ph-) ALL: must be refractory or with ≥ 2 relapses; or
 - ii. Philadelphia chromosome positive (Ph+) ALL: must have failed ≥ 2 Tyrosine Kinase Inhibitors (TKIs); and
 - d. Therapies to consider prior to tisagenlecleucel if appropriate: clinical trial, multi-agent chemotherapy with or without hematopoietic cell transplantation (HCT),

- blinatumomab (category 1 recommendation), and inotuzumab (category 1 recommendation).
2. Healthcare facilities must be on the certified list to administer CAR T cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the REMS requirements.

Synribo® (Omacetaxine) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Synribo® must be used as a single-agent only; and
2. Member must have one of the following:
 - a. Primary treatment of advanced phase CML with disease progression to accelerated phase; or
 - b. Post-hematopoietic stem cell transplant in patients who have relapsed; or
 - c. Patients with T315I mutation; or
 - d. Patients who are intolerant or resistant to two or more Tyrosine Kinase Inhibitors (TKIs).

Sprycel® (Dasatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Member must have one of the following:
 - a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single-agent; or
 - b. Maintenance therapy including:
 - i. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
 - ii. Post-hematopoietic stem cell transplant; or
 - c. Relapsed/refractory as a single-agent or in combination with multi-agent chemotherapy.

Sprycel® (Dasatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Member must have one of the following:
 - a. Newly diagnosed chronic, accelerated, or blast phase CML; or
 - b. Post-hematopoietic stem cell transplant.

Sprycel® (Dasatinib) Approval Criteria [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:

1. Member must have all of the following:
 - a. Progressive disease and failed imatinib, sunitinib, or regorafenib; and
 - b. PDGFRA D842V mutation.

Tasigna® (Nilotinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Member must have one of the following:
 - a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single-agent; or
 - b. Maintenance therapy including:
 - i. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or

- ii. Post-hematopoietic stem cell transplant; or
- c. Relapsed/refractory as a single-agent or in combination with multi-agent chemotherapy.

Tasigna® (Nilotinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Member must have **one** of the following:
 - a. Newly diagnosed chronic, accelerated, or blast phase CML; or
 - b. Post-hematopoietic stem cell transplant.

Tasigna® (Nilotinib) Approval Criteria [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:

1. Member must have progressive disease and failed imatinib, sunitinib, or regorafenib.

Recommendation 4: Vote to Prior Authorize Bavencio® (Avelumab) and Update Skin Cancer Medications Prior Authorization Criteria

MOTION CARRIED by unanimous approval.

- Update the prior authorization criteria to reflect new FDA approved indications and guideline recommendations. Changes can be seen in the following criteria listed in red (only criteria with updates listed).
- The prior authorization of Bavencio® (avelumab) with the following criteria listed in red:

Bavencio® (Avelumab) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. A diagnosis of metastatic MCC; and
2. Member must be 12 years of age or older.

Bavencio® (Avelumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. A diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Disease has progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

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

1. A diagnosis of metastatic NSCLC; and
2. The member has not previously failed other PD-1 inhibitors [e.g., Opdivo® (nivolumab)]; and
3. Tumor proportion scores for PD-L1 expression as follows:
 - a. Single-agent, first-line: $\geq 50\%$; or
 - b. First-line in combination with carboplatin and pemetrexed: no expression required; or
 - c. Single-agent, second-line: $\geq 1\%$; and
4. Member meets **one** of the following:
 - a. Previously untreated metastatic non-squamous NSCLC in combination with pemetrexed and carboplatin; or
 - b. New diagnosis as first-line therapy (patient has not received chemotherapy to treat disease) if:

- i. Tumor does not express sensitizing Epidermal Growth Factor Receptor (EGFR) mutations or Anaplastic Lymphoma Kinase (ALK) translocations; and
 - ii. Member has an ECOG performance status of 0 to 1; or
 - c. Single-agent for disease progression on or after platinum-containing chemotherapy (e.g., cisplatin or carboplatin):
 - i. Patients with EGFR-mutation-positive disease should have disease progression on an FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations; and*
 - 1. *Examples of drugs for EGFR-mutation-positive tumors: osimertinib, erlotinib, afatinib, or gefitinib*
 - ii. Patients with ALK genomic tumor aberrations should have disease progression on an FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations; and*
 - 1. *Examples of drugs for ALK-mutation-positive tumors: crizotinib, ceritinib, or alectinib*
 - iii. Member has an ECOG performance status of 0 to 2.

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

- 1. Locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy; or
- 2. Within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or
- 3. Frontline pembrolizumab for patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.
 - a. Cisplatin ineligibility is defined as:
 - i. Baseline creatinine clearance of <60mL/min, or an ECOG performance status of 2, or Class III heart failure, or grade 2 or greater peripheral neuropathy, or grade 2 or greater hearing loss.

Keytruda® (Pembrolizumab) Approval Criteria [Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumor (Tissue/Site-Agnostic) or Metastatic Colorectal Cancer Diagnosis]:

- 1. MSI-H or dMMR solid tumors that have progressed following prior treatment with no satisfactory alternative treatment options; or
- 2. MSI-H or dMMR colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Keytruda® (Pembrolizumab) Approval Criteria [Gastric or Gastroesophageal Junction Tumor Diagnosis]:

- 1. Recurrent, locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma; and
- 2. Tumors must express PD-L1; and
- 3. Disease progression on or after two or more prior systemic therapies (including fluoropyrimidine- and platinum-containing chemotherapy, and if appropriate, HER2/neu-targeted therapy).

Opdivo® (Nivolumab) Approval Criteria [Head and Neck Cancer]:

1. A diagnosis of recurrent or metastatic head and neck cancer; and
2. Squamous cell histology; and
3. Patient has received prior platinum containing regimen (cisplatin or carboplatin); and
4. Member has an ECOG performance status of 0 to 1; and
5. Dose as follows:
 - a. 3mg/kg every two weeks.

Opdivo® (Nivolumab) Approval Criteria [Urothelial Bladder Cancer Diagnosis]:

1. A diagnosis of metastatic or unresectable locally advanced cancer; and
2. Used as second-line or greater therapy; and
3. Patient has failed a platinum containing regimen; and
4. Member has an ECOG performance status of 0 to 1.

Opdivo® (Nivolumab) Approval Criteria [Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer Diagnosis]:

1. Diagnosis of MSI-H or dMMR metastatic colorectal cancer; and
2. Progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Opdivo® (Nivolumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Relapsed or progressive disease; and
2. Member must have been previously treated with sorafenib.

Opdivo® (Nivolumab) Approval Criteria [Renal Cell Cancer Diagnosis]:

1. A diagnosis of relapsed or surgically unresectable stage IV disease; and
- ~~2. Tumor histology: predominantly clear cell; and~~
3. Failed prior therapy with one of the following medications:
 - a. Sunitinib; or
 - b. Sorafenib; or
 - c. Pazopanib; or
 - d. Axitinib; and
4. Nivolumab must be used as a single-agent; and
5. Member has an ECOG performance status of 0 to 2; and
6. The patient has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)]; and
7. Dose as follows:
 - a. Single-agent: 240mg every two weeks.

Recommendation 5: Vote to Prior Authorize Haegarda® [C1 Esterase Inhibitor (Human)]

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Haegarda® [C1 esterase inhibitor (human)] similar to the other prior authorized hereditary angioedema (HAE) prophylaxis medications with the following criteria:

Cinryze® (C1 Esterase Inhibitor) and Haegarda® (C1 Esterase Inhibitor) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Must be used for *prophylaxis* of HAE; and
3. History of at least one or more abdominal or respiratory HAE attacks per month, or history of laryngeal attacks, or three or more emergency medical treatments per year; and
4. Not currently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
5. Member meets the following:
 - a. Documented intolerance, insufficient response, or contraindication to attenuated androgens (e.g., danazol, stanozolol, oxandrolone, methyltestosterone); and
 - b. Documented intolerance, insufficient response, or contraindication to antifibrinolytic agents (e.g., ε – aminocaproic acid, tranexamic acid); or
 - c. Recent hospitalization for severe episode of angioedema; and
6. **Cinryze® Dosing:**
 - a. The recommended dose of Cinryze® is 1,000 units IV every 3 to 4 days, approximately two times per week, to be infused at a rate of 1mL/min; and
 - b. Initial doses should be administered in an outpatient setting by a healthcare provider. Patients can be taught by their healthcare provider to self-administer Cinryze® intravenously; and
 - c. A quantity limit of 8,000 units per month will apply (i.e., two treatments per week or eight treatments per month); or
7. **Haegarda® Dosing:**
 - a. **The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and**
 - b. **A quantity limit of two treatments per week or eight treatments per month will apply.**

Recommendation 6: Vote to Prior Authorize Axid® (Nizatidine Capsules and Solution), Tagamet® (Cimetidine Tablets), and Yosprala™ (Aspirin/Omeprazole Delayed-Release Tablets)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Anti-Ulcer Medication Product Based Prior Authorization (PBPA) category:

1. Place Yosprala™ (aspirin/omeprazole delayed-release tablets) into the Special Prior Authorization (PA) Tier of the Anti-Ulcer PBPA category. The following criteria will apply:
 - a. A patient-specific, clinically significant reason why the separate products (aspirin and omeprazole) cannot be used in place of this combination product.
2. Place nizatidine solution (Axid®) into the Special PA Tier of the Anti-Ulcer PBPA category based on net cost. The following criteria will apply:
 - a. A previous trial of ranitidine syrup or a patient-specific, clinically significant reason why ranitidine syrup is not appropriate for the member.

3. Place cimetidine tablets (Tagamet®) and nizatidine capsules (Axid®) into the Special PA Tier of the Anti-Ulcer PBPA category based on net costs. The following criteria will apply:
 - a. A previous trial of ranitidine and famotidine or a patient-specific, clinically significant reason why ranitidine and famotidine are not appropriate for the member.
4. Move esomeprazole (Nexium® packets) and pantoprazole (Protonix® I.V.) to Tier-2 based on net costs. Current Tier-2 criteria and special formulation criteria will apply.
5. For famotidine suspension (Pepcid®), add a previous trial of ranitidine syrup or a patient-specific, clinically significant reason why ranitidine syrup is not appropriate for the member.

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

Anti-Ulcer Medications*			
Tier-1	Tier-2	Tier-3	Special PA
omeprazole (Prilosec® caps)	dexlansoprazole (Dexilant® caps)	esomeprazole (Nexium® caps, packets , I.V.)	aspirin/omeprazole DR tabs (Yosprala™)
pantoprazole (Protonix® tabs)	esomeprazole (Nexium® packets)	esomeprazole strontium caps	cimetidine tabs (Tagamet®)
	lansoprazole (Prevacid® caps, ODT)	dexlansoprazole (Dexilant® SoluTab)	famotidine (Pepcid® susp)
	pantoprazole (Protonix® I.V.)	omeprazole (Prilosec® susp, powder)	nizatidine caps & sol (Axid®)
	rabeprazole sodium (Aciphex® tabs)	pantoprazole (Protonix® susp, I.V.)	omeprazole/sodium bicarbonate (Zegerid®)
		rabeprazole sodium (Aciphex® Sprinkles)	ranitidine (caps, Zantac® Effervescent Tabs)
			sucralfate susp UD cups

ODT = orally disintegrating tablets; caps = capsules; tabs = tablets; I.V. = intravenous; susp = suspension; sol = solution; DR = delayed-release; UD = unit dose

*Special formulations including ODTs, granules, suspension, sprinkle capsules, and solution for I.V. require special reason for use.

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

Tagamet® (Cimetidine Tablets) Approval Criteria:

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

Pepcid® (Famotidine Suspension) Approval Criteria:

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

Axid® (Nizatidine Capsules) Approval Criteria:

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

Axid® (Nizatidine Solution) Approval Criteria:

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

Yosprala™ (Aspirin/Omeprazole Delayed-Release Tablets) Approval Criteria:

1. A patient-specific, clinically significant why the separate products (aspirin and omeprazole) cannot be used in place of this combination product.

Recommendation 7: Vote to Prior Authorize Trulance™ (Plecanatide), Xermelo™ (Telotristat Ethyl), Symproic® (Naldemedine), and Motofen® (Difenoxin/Atropine)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Trulance™ (plecanatide), Xermelo™ (telotristat ethyl), Symproic® (naldemedine), and Motofen® (difenoxin/atropine) with the following criteria:

Trulance™ (Plecanatide) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least three different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. One of the three trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment.
6. A quantity limit of 30 tablets for a 30-day supply will apply.

Xermelo™ (Telotristat Ethyl) Approval Criteria:

1. An FDA approved diagnosis of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy; and
2. Member must be 18 years of age or older; and
3. Member must have been taking a stable dose of SSA therapy for the last three months and be inadequately controlled (four or more bowel movements per day); and
4. Prescriber must verify member will continue taking SSA therapy in combination with Xermelo™; and

5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment.
6. A quantity limit of 90 tablets for a 30-day supply will apply.

Criteria number six for Symproic® was removed (see below in red) due to cost information recently becoming available; the cost of Symproic® is comparable to Amitiza® and Movantik®.

Symproic® (Naldemedine) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least three different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. One of the three trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
- ~~6. A patient-specific, clinically significant reason why member cannot use Amitiza® (lubiprostone) or Movantik® (naloxegol) must be provided; and~~
7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment.
8. Symproic® must be discontinued if treatment with the opioid pain medication is also discontinued.
9. A quantity limit of 30 tablets for a 30-day supply will apply.

Motofen® (Difenoxin/Atropine) Approval Criteria:

1. An FDA approved diagnosis of acute nonspecific diarrhea or acute exacerbations of chronic functional diarrhea; and
2. Member must not be 2 years of age or younger; and
3. Member must not have diarrhea associated with organisms that penetrate the intestinal mucosa (e.g., toxigenic *Escherichia coli*, *Salmonella species*, *Shigella*) or pseudomembranous colitis associated with broad spectrum antibiotics; and
4. A patient-specific, clinically significant reason why the member cannot use Lomotil® (diphenoxylate/atropine) and loperamide must be provided; and
5. A quantity limit of 16 tablets per 2 days will apply.

Additionally, the College of Pharmacy recommends updating the current approval criteria for Xifaxan® (rifaximin) 200mg to remove from the approval criteria the required reason why the member cannot use a fluoroquinolone antibiotic, which addresses the FDA Drug Safety Communication that updated the warnings for fluoroquinolone antibiotics. The College of Pharmacy also recommends updating the current approval criteria for Viberzi® (eluxadoline) to

exclude members with any contraindications to taking Viberzi®, which addresses the recent FDA Drug Safety Communication regarding use of Viberzi® in patients without a gallbladder. The proposed changes can be seen in red in the following criteria:

Xifaxan® (Rifaximin) 200mg Approval Criteria:

1. An FDA approved diagnosis of traveler's diarrhea (TD); and
2. Member must be 12 years of age or older; and
3. TD must be due to noninvasive strains of *Escherichia coli*; and
4. ~~A patient specific, clinically significant reason why the member cannot use a fluoroquinolone antibiotic (e.g., ciprofloxacin, levofloxacin) must be provided.~~
5. A quantity limit of 9 tablets for a 3-day supply will apply.

Viberzi® (Eluxadoline) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
2. Member must be 18 years of age or older; and
3. ~~Member must not have any of the contraindications for use of Viberzi® (e.g., removed gallbladder; biliary duct obstruction or sphincter of Oddi disease or dysfunction; alcoholism, alcohol abuse, or alcohol addiction; history of pancreatitis or structural diseases of the pancreas; severe hepatic impairment; history of chronic or severe constipation; mechanical gastrointestinal obstruction); and~~
4. Documentation of trials of two of the following three medications that failed to relieve diarrhea: loperamide, dicyclomine, or diphenoxylate/atropine (each trial should be for at least 10 to 14 consecutive days at the recommended dosing). Trials must be within the past 90 days. Documentation should be provided including dates, dosing, and reason for trial failure.
5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment.
6. A quantity limit of 60 tablets for a 30-day supply will apply.

Recommendation 8: Vote to Prior Authorize MiCort™ HC (Hydrocortisone Acetate 2.5% Cream) and Update the Topical Corticosteroids Product Based Prior Authorization Tier Chart and Criteria

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of MiCort™ HC (hydrocortisone acetate 2.5% cream) with the criteria noted in red:

MiCort™ HC (Hydrocortisone Acetate 2.5% Cream) Approval Criteria:

1. ~~A patient-specific, clinically significant reason why the member cannot use Proctosol-HC® (hydrocortisone 2.5% cream).~~

Additionally the College of Pharmacy recommends following changes to the Topical Corticosteroid Product Based Prior Authorization (PBPA) category:

Topical Corticosteroid PBPA Tier Chart and Criteria Recommendations:

1. The creation of a third Tier to account for very high net cost products.

2. Move Aclovate® (alclometasone dipropionate cream and ointment) from Tier-1 to Tier-2 under Low Potency of the Topical Corticosteroid PBPA Tier Chart based on cost.
3. Move Derma-Smoothe® and Derma-Smoothe FS® (fluocinolone acetonide 0.01% oil) from Tier-2 to Tier-3 under Low Potency of the Topical Corticosteroid PBPA Tier Chart based on cost.
4. Move Desonate® (desonide 0.05% gel) and Capex® (fluocinolone acetonide 0.01% shampoo) from Tier-2 to Tier-1 under Low Potency of the Topical Corticosteroid PBPA Tier Chart based on cost.
5. Move Sernivo™ (betamethasone dipropionate 0.05% spray) and Westcort® (hydrocortisone valerate 0.2% cream and ointment) from Tier-2 to Tier-3 under Medium/High to Medium Potency of the Topical Corticosteroid PBPA Tier Chart based on cost.
6. Move Temovate® (clobetasol propionate 0.05% cream and solution) from Tier-2 to Tier-1 under the Ultra-high to High Potency of the Topical Corticosteroid PBPA Tier Chart based on cost.
7. Move Clobex® (clobetasol propionate 0.05% shampoo and spray), Olux-E® and Olux® (clobetasol propionate 0.05% foam), Temovate® (clobetasol propionate 0.05% ointment), and Topicort® (desoximetasone 0.25% cream, ointment, and spray) from Tier-2 to Tier-3 under the Ultra-high to High Potency of the Topical Corticosteroid PBPA Tier Chart based on cost.

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

Tier-2 Topical Corticosteroid Approval Criteria:

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

Tier-3 Topical Corticosteroid Approval Criteria:

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

Topical Corticosteroids					
Tier-1		Tier-2		Tier-3	
Ultra-High to High Potency					
augmented betamethasone dipropionate (Diprolene AF®)	C	amcinonide	C,O,L	clobetasol propionate 0.05% (Clobex®)	Sh,Spr
augmented betamethasone dipropionate (Diprolene®)	G	augmented betamethasone dipropionate (Diprolene®)	O,L	clobetasol propionate 0.05% (Olux®, Olux-E®)	F
betamethasone dipropionate (Diprosone®)	O	betamethasone dipropionate (Diprosone®)	C	clobetasol propionate 0.05% (Temovate®)	O
clobetasol propionate 0.05% (Temovate®)	C,So	clobetasol propionate 0.05% (Clobex®)	L	desoximetasone 0.25% (Topicort®)	C,O,Spr
fluocinonide 0.05%	C,O,So	clobetasol propionate 0.05% (Temovate®)	G		
halobetasol propionate (Ultravate®)	C	desoximetasone 0.05% (Topicort®)	G		
		diflorasone diacetate 0.05% (Apexicon®)	C		
		diflorasone diacetate 0.05% (Apexicon E®)	C,O		
		fluocinonide 0.05%	G		
		fluocinonide 0.1% (Vanos®)	C		
		flurandrenolide tape (Cordran®)	Tape		
		halcinonide (Halog®)	C,O		
		halobetasol propionate 0.05% (Ultravate®)	L,O		
		halobetasol propionate/lactic acid (Ultravate X®)	C		
Medium/High to Medium Potency					
betamethasone dipropionate	L	betamethasone dipropionate/calcipotriene (Taclonex®)	O,Sus,Spr	betamethasone dipropionate 0.05% (Sernivo™)	Spr
betamethasone valerate 0.1% (Beta-Val®)	C,O,L	betamethasone valerate 0.12% (Luxiq®)	F	hydrocortisone valerate 0.2% (Westcort®)	C,O
fluticasone propionate (Cutivate®)	C,O	calcipotriene/betamethasone dipropionate (Enstilar®)	F		
mometasone furoate (Elocon®)	C,L	desoximetasone 0.05% (Topicort LP®)	C,O		
triamcinolone acetonide	C,O,L	fluocinolone acetonide 0.025% (Synalar®)	C,O		
		fluocinonide emollient (Lidex E®)	C		
		flurandrenolide 0.05%	C,L,O		
		fluticasone propionate (Cutivate®)	L		
		hydrocortisone butyrate 0.1%	C,O,So		
		hydrocortisone probutate (Pandel®)	C		
		mometasone furoate 0.1%	O		
		prednicarbate (Dermatop®)	O,C		

Topical Corticosteroids					
Tier-1		Tier-2		Tier-3	
		triamcinolone acetonide (Kenalog®)	Spr		
Low Potency					
desonide 0.05% (Desonate®)	G	alclometasone dipropionate (Acloivate®)	C,O	fluocinolone acetonide 0.01% (Derma- Smoothe®; Derma- Smoothe FS®)	Oil
fluocinolone acetonide 0.01% (Capex®)*	Sh	clo cortolone pivalate (Cloderm®)	C		
fluocinolone acetonide 0.01% (Synalar®)	C	desonide 0.05% (Verdeso®)	F		
hydrocortisone acetate 2.5%	C,O,L	desonide emollient	C,O		
hydrocortisone/urea (U-Cort®)	C	fluocinolone acetonide 0.01% (Synalar®)	So		
		hydrocortisone 2.5% (Texacort®)	So		
		hydrocortisone/pramoxine (Pramosone®)	C,L		

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

*Capex® (fluocinolone acetonide 0.1% shampoo) is not a required trial for non-scalp conditions.

Recommendation 9: Vote to Prior Authorize Noctiva™ (Desmopressin Acetate Nasal Spray)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends placement of Noctiva™ (desmopressin acetate) into the Special Prior Authorization (PA) Tier of the Bladder Control Medications Product Based Prior Authorization (PBPA) category with the following criteria:

Noctiva™ (Desmopressin Acetate) Approval Criteria:

1. An FDA approved diagnosis of nocturia due to nocturnal polyuria in adults 50 years of age and older; and
2. All other causes of nocturia have been ruled out or adequately treated [e.g., benign prostatic hyperplasia (BPH), overactive bladder (OAB), obstructive sleep apnea (OSA)]; and
3. The prescriber must confirm the member has a 6-month history of at least two nocturic episodes per night; and
4. Member has failed behavior modifications including reducing caffeine intake, alcohol intake, and nighttime fluid intake; and
5. Member must have failed a trial of DDAVP® (desmopressin) tablets or have a patient-specific, clinically significant reason why the tablet formulation cannot be used; and
6. The prescriber must be willing to measure serum sodium levels within seven days of anticipated start of treatment and document levels are acceptable; and

7. The prescriber must agree to monitor serum sodium levels within one month of starting treatment or increasing the dose; and
8. The prescriber must confirm the member is not taking any of the following:
 - a. Other medications via the nasal route; or
 - b. Loop diuretics; ~~or~~
 - c. ~~Inhaled or systemic glucocorticoids; and~~
9. The prescriber must confirm the member does not have renal impairment with estimated glomerular filtration rate (eGFR) below 50mL/min/1.73m²; and
10. Initial approvals will be for the duration of 3 months, and for continued authorization the prescriber must provide the following:
 - a. Documentation that serum sodium levels are acceptable to the prescriber; and
 - b. Documentation that the member is responding to treatment.

Bladder Control Medications			
Tier-1	Tier-2	Tier-3	Special PA
fesoterodine (Toviaz®)	tolterodine (Detrol®)	darifenacin (Enblex®)	desmopressin acetate nasal spray (Noctiva™)⁺
oxybutynin (Ditropan®)	tropium (Sanctura®)	mirabegron (Myrbetriq®)	oxybutynin patch (Oxytrol®) ⁺
oxybutynin ER (Ditropan XL®)		oxybutynin gel (Gelnique®)	
		solifenacin (VESicare®)	
		tolterodine ER (Detrol LA®)	
		tropium ER (Sanctura XR®)	

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

ER = extended release

⁺Unique criteria specific to Oxytrol® (oxybutynin patch) and Noctiva™ (desmopressin acetate nasal spray) applies.

Recommendation 10: Vote to Prior Authorize Sprix® (Ketorolac Tromethamine Nasal Spray) and Cataflam® (Diclofenac Potassium Tablets)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following:

1. The placement of Cataflam® (diclofenac potassium tablets) into Tier-2 of the NSAID Product Based Prior Authorization (PBPA) category based on national average drug acquisition cost (NADAC).
2. The placement of Sprix® (ketorolac tromethamine nasal spray), Nalfon® (fenoprofen), Meclomen® (meclofenamate), and Celebrex® (celecoxib 400mg capsules) into the Special Prior Authorization (PA) Tier of the NSAID PBPA category based on wholesale acquisition cost (WAC) and NADAC. Current Special PA Tier criteria will apply. Additionally, for Celebrex® (celecoxib 400mg capsules) the following criteria will apply:
 - a. **Celebrex® (Celecoxib 400mg Capsules) Approval Criteria:**
 - i. A diagnosis of Familial Adenomatous Polyposis (FAP); and

- ii. A patient-specific, clinically significant reason why the member cannot use two celecoxib 200mg capsules to achieve a 400mg dose.
3. Move Celebrex® (celecoxib 50mg, 100mg, and 200mg capsules) from Tier-2 to Tier-1 based on NADAC.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	Tier-2	Special PA
celecoxib (Celebrex®) 50mg, 100mg, & 200mg caps	diclofenac potassium (Cataflam®)	celecoxib (Celebrex®) 400mg caps
diclofenac ER (Voltaren® XR)	diclofenac sodium/ misoprostol (Arthrotec®)	diclofenac (Zorvolex®)
diclofenac sodium (Voltaren®) 50mg & 75mg tabs	diclofenac sodium (Voltaren®) 25mg tabs	diclofenac epolamine (Flector®) patch
etodolac (Lodine®) 400mg & 500mg tabs	etodolac (Lodine®) 200mg & 300mg caps	diclofenac potassium (Cambia®) powder pack
flurbiprofen (Ansaid®)	etodolac ER (Lodine® XL)	diclofenac potassium (Zipsor®) caps
ibuprofen (Motrin®)	naproxen sodium (Anaprox®) 275mg & 550mg tabs	diclofenac sodium (Dyloject™)
ketoprofen (Orudis®)	oxaprozin (Daypro®)	diclofenac sodium (Pennsaid®) topical drops
meloxicam (Mobic®)	piroxicam (Feldene®)	diclofenac sodium (Voltaren®) gel
nabumetone (Relafen®)	tolmetin (Tolectin®)	fenoprofen (Nalfon®)
naproxen (Naprosyn®)		ibuprofen/famotidine (Duexis®)
naproxen EC (Naprosyn®)		Indomethacin (Indocin®) susp & ER caps
sulindac (Clinoril®)		indomethacin (Tivorbex®)
		ketoprofen ER (Oruvail®)
		ketorolac tromethamine (Sprix®) nasal spray
		meclofenamate (Meclomen®)
		mefenamic acid (Ponstel®)
		meloxicam (Vivlodex®) caps
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)

ER = extended-release, EC = enteric coated, caps = capsules, tabs = tablets, susp = suspension

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

NSAIDs Tier-2 Approval Criteria:

1. Previous use of at least two Tier-1 NSAID products (from different product lines) plus a proton pump inhibitor (PPI) within the last 120 days.

NSAIDs Special Prior Authorization (PA) Approval Criteria:

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

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

Recommendation 11: Vote to Prior Authorize Promacta® (Eltrombopag) and Update Prior Authorization Criteria for Nplate® (Romiplostim)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Promacta® (eltrombopag) with the following criteria:

Promacta® (Eltrombopag) Approval Criteria:

1. An FDA approved indication of chronic immune (idiopathic) thrombocytopenia (ITP); and
 - a. Previous insufficient response to at least one of the following:
 - i. Corticosteroids; or
 - ii. Immunoglobulins; or
 - iii. Splenectomy; and
 - b. Degree of thrombocytopenia and clinical condition increase the risk for bleeding; and
 - c. Must be prescribed by, or in consultation with, a hematologist or oncologist; or
2. An FDA approved indication of thrombocytopenia in patients with chronic hepatitis C (CHC) to allow initiation and maintenance of interferon (IFN)-based therapy; and
 - a. Promacta® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist for hepatitis C therapy within the last three months; and
 - b. Patient must be prescribed IFN for treatment of CHC infection; or
3. An FDA approved indication of severe aplastic anemia (SAA); and
 - a. Previous insufficient response or documented contraindication or intolerance to immunosuppressive therapy; and
 - b. Must be prescribed by, or in consultation with, a hematologist or oncologist; and
4. For the diagnoses of chronic ITP and CHC associated thrombocytopenia, initial approvals will be for the duration of 1 month. For the diagnosis of SAA, initial approvals will be for the duration of 4 months. Subsequent approvals may be authorized if the prescriber documents the member is responding well to therapy and the following criteria is met, based upon member's diagnoses:
 - a. For All Diagnoses:
 - i. Must not have excessive platelet count responses. Promacta® should be discontinued if platelets exceed $400 \times 10^9/L$ after two weeks of therapy at the lowest dose; and
 - ii. Prescriber documents liver function tests are being monitored and levels are acceptable to the prescriber.

- b. Chronic ITP:
 - i. Documentation that platelet count has increased to a level sufficient to avoid clinically important bleeding or that a dose increase is planned, if not already on maximum dose. Promacta® should be discontinued if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after four weeks of therapy at the maximum daily dose of 75mg.
- c. CHC-Associated Thrombocytopenia:
 - i. Documentation that member continues to be on antiviral therapy. Promacta® should be discontinued when antiviral therapy is discontinued.
- d. SAA:
 - i. Documentation that member has had a hematologic response (e.g., increase in platelet count, increase in hemoglobin, increase in absolute neutrophil count, reduction in frequency of platelet or red blood cell transfusions). Promacta® should be discontinued if no hematologic response has occurred after 16 weeks of therapy.

Additionally, the College of Pharmacy recommends updating the Nplate® (romiplostim) prior authorization criteria with the following changes noted in red:

Nplate® (Romiplostim) Approval Criteria:

1. An FDA approved indication of chronic immune (idiopathic) thrombocytopenia purpura (ITP); and
2. Previous insufficient response with at least ~~two~~ **one** of the following treatments:
 - a. Corticosteroids; or
 - b. Immunoglobulins; or
 - c. Splenectomy; and
- ~~3. Recent platelet count of $< 50 \times 10^9/L$; and~~
- 4. Degree of thrombocytopenia and clinical condition increase the risk for bleeding; and**
- 5. Nplate® (romiplostim) is not being used in an attempt to normalize platelet counts; and**
- 6. Must be prescribed by, or in consultation with, a hematologist or oncologist; and**
7. Initial dosing of 1mcg/kg once weekly as a subcutaneous injection with recent patient weight in kilograms provided; and
8. Continuation criteria:
 - a. Weekly CBCs with platelet count and peripheral blood smears until stable platelet count ($\geq 50 \times 10^9/L$ for at least four weeks without dose adjustment) has been achieved, then obtain monthly thereafter; and
 - b. Dosing adjustments:
 - i. Platelets $< 50 \times 10^9/L$, increase dose by 1mcg/kg; or
 - ii. Platelets $> 200 \times 10^9/L$ for two consecutive weeks, reduce dose by 1mcg/kg; or
 - iii. Platelets $> 400 \times 10^9/L$, do not dose. Continue to assess platelet count weekly. When platelets $< 200 \times 10^9/L$, resume at a dose reduced by 1mcg/kg; and
9. Discontinuation criteria:
 - a. Platelet count does not increase to a level sufficient to avoid clinically important bleeding after four weeks of therapy at the maximum weekly dose of 10mcg/kg; and
10. Approval period will be for four weeks initially, and then quarterly.

Recommendation 12: Vote to Prior Authorize Odactra™ (House Dust Mite Allergen Extract) and Update the Allergen Immunotherapy Prior Authorization Criteria

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Odactra™ (house dust mite allergen extract) with the following criteria:

Odactra™ (House Dust Mite Allergen Extract) Approval Criteria:

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

The College of Pharmacy also recommends updating the existing prior authorization criteria for Grastek® (Timothy grass pollen allergen extract), Ragwitek® (short ragweed pollen allergen extract), and Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens allergen extract) to include an upper limit age restriction of 65 years of age based on FDA approved indication.

Recommendation 13: Annual Review of Nuedexta® (Dextromethorphan/Quinidine)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Nuedexta® (dextromethorphan/quinidine) prior authorization criteria with the following changes noted in red:

Nuedexta® (Dextromethorphan/Quinidine) Approval Criteria:

1. An FDA approved diagnosis of Pseudobulbar Affect (PBA) **secondary to a neurological condition (e.g., ALS, MS, Parkinson's disease, stroke, traumatic brain injury); and**
2. **Documentation of the secondary neurological condition must be submitted; and**
3. Member must be 18 years of age or older; and
4. **Nuedexta® must be prescribed by, or in consultation with, a neurologist or psychiatrist (or be an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and**
5. **Member must not have a contraindication to therapy [e.g., concomitant use with quinidine, quinine, or mefloquine; history of quinidine, quinine, or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions; known hypersensitivity to dextromethorphan; use with a monoamine oxidase inhibitor (MAOI) or within 14 days of stopping an MAOI; prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure; complete atrioventricular (AV) block without implanted pacemaker, or at high risk of complete AV block; currently taking other drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimozide)]; and**
6. **Prescriber must document baseline number of PBA laughing or crying episodes per day; and**
7. A quantity limit of 60 capsules per 30 days will apply; and
8. Initial approvals will be for the duration of ~~one year~~ **12 weeks**. Reauthorizations may be granted if the prescriber documents the member is responding well to treatment as indicated by a reduction in the number of PBA episodes of laughing or crying per day compared to baseline. Current users must meet the revised approval criteria when reapplying for prior authorization continuation.

Recommendation 14: Annual Review of Orkambi® (Lumacaftor/Ivacaftor) and Kalydeco® (Ivacaftor)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Kalydeco® (ivacaftor) approval criteria to reflect the new FDA approved indications:

Kalydeco® (Ivacaftor) Approval Criteria:

1. **An FDA approved indication of cystic fibrosis (CF) with a mutation in the *CFTR* gene detected by genetic testing that is responsive to ivacaftor based on clinical and/or in vitro assay data; and**
2. **Documentation must be submitted with results of *CFTR* genetic testing; and**
3. Member must be 2 years of age or older; and
4. A quantity limit of two tablets or two granule packets per day (56 per 28 days) will apply.

5. Initial approval will be for the duration of six months, after which time compliance and information regarding efficacy, such as improvement in FEV₁, will be required for continued approval.

Recommendation 15: Annual Review of Iron Chelating Agents and Vote to Prior Authorize Jadenu® Sprinkle (Deferasirox Oral Granules)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Jadenu® Sprinkle (deferasirox oral granules) with the following criteria:

Jadenu® (Deferasirox), Jadenu® Sprinkle (Deferasirox), and Ferriprox® (Deferiprone) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use Exjade® (deferasirox) must be provided; and
3. For Jadenu® Sprinkle (deferasirox oral granules), an age restriction of six years and younger will apply. Members older than six years of age will require a patient-specific, clinically significant reason why Jadenu® oral tablets cannot be used even when the tablets are crushed; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Recommendation 16: Annual Review of Hepatitis C Medications and 30-Day Notice to Prior Authorize Mavyret™ (Glecaprevir/Pibrentasvir) and Vosevi® (Sofosbuvir/Velpatasvir/Voxilaprevir)

NO ACTION REQUIRED.

Recommendation 17: Annual Review of Various Systemic Antibiotic Medications and 30-Day Notice 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)

NO ACTION REQUIRED.

Recommendation 18: Annual Review of Gout Medications and 30-Day Notice to Prior Authorize Duzallo® (Lesinurad/Allopurinol)

NO ACTION REQUIRED.

Recommendation 19: Annual Review of Pancreatic Enzymes

NO ACTION REQUIRED.

Recommendation 20: Industry News and Updates

NO ACTION REQUIRED.

Recommendation 21: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

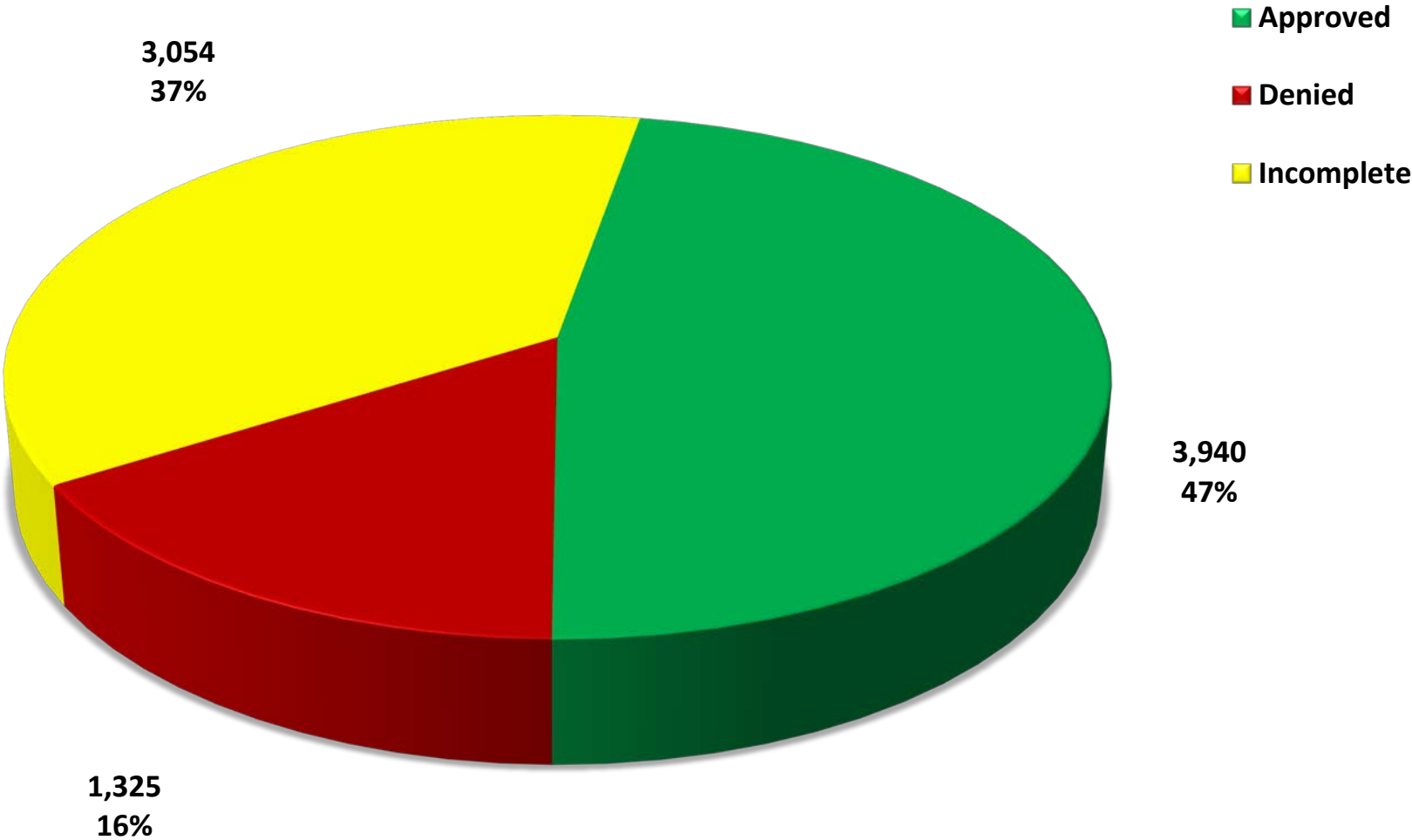
NO ACTION REQUIRED.



Appendix B

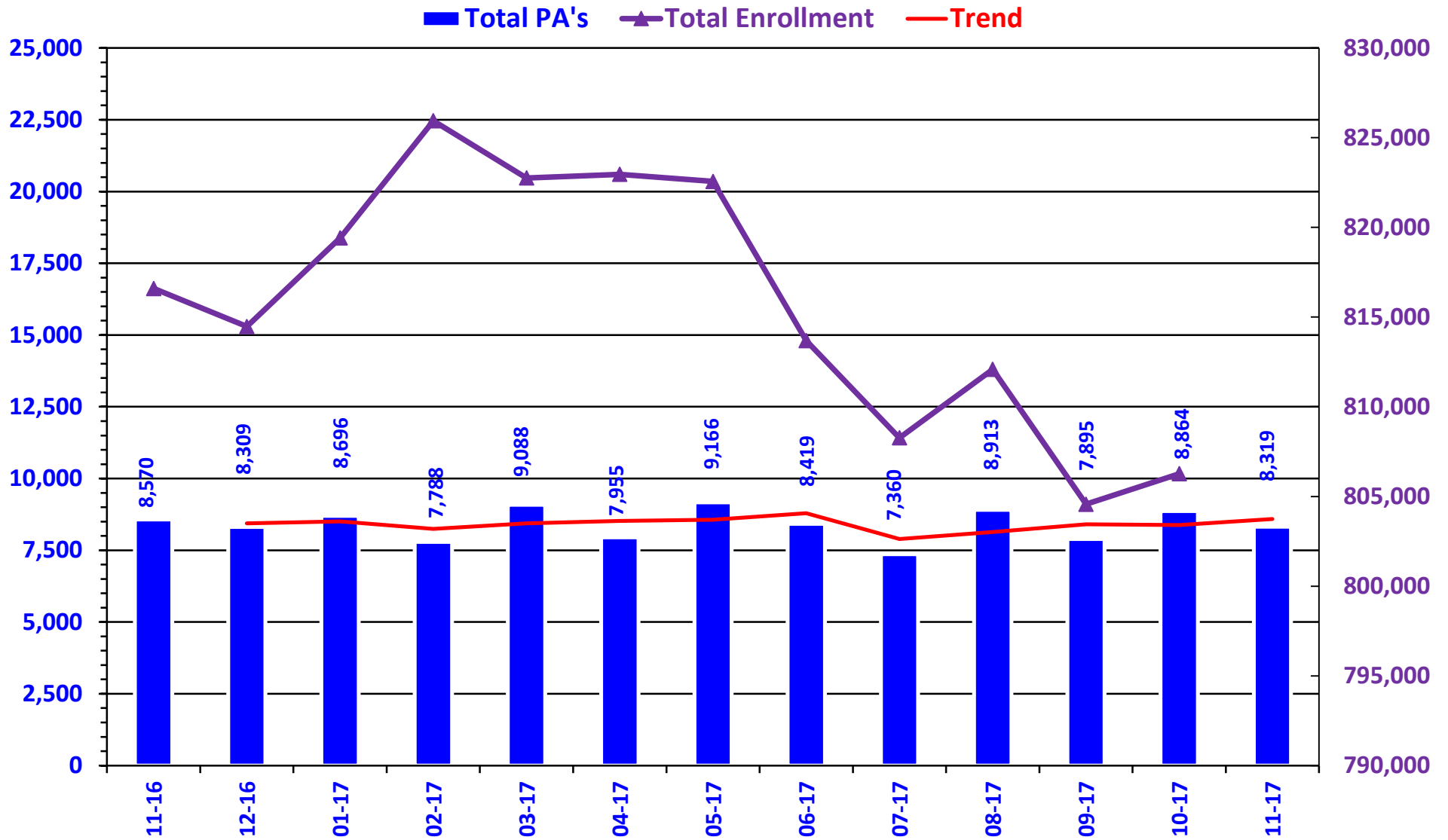


PRIOR AUTHORIZATION ACTIVITY REPORT: NOVEMBER 2017



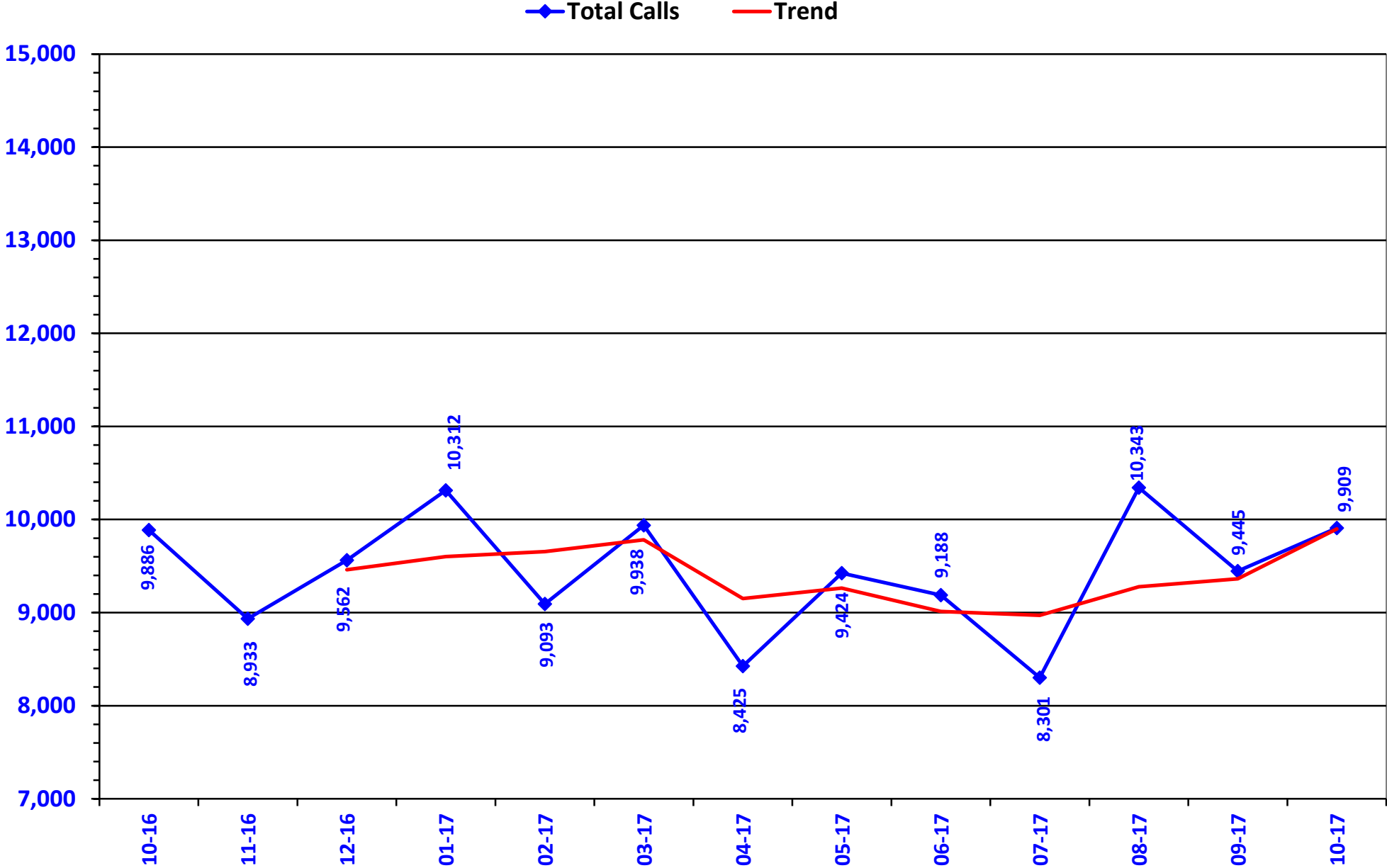
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: NOVEMBER 2016 – NOVEMBER 2017



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: NOVEMBER 2016 – NOVEMBER 2017



Prior Authorization Activity 11/1/2017 Through 11/30/2017

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	114	13	27	74	315
Analgesic - NonNarcotic	30	0	11	19	0
Analgesic, Narcotic	453	226	64	163	161
Antiasthma	62	12	18	32	274
Antibiotic	28	18	5	5	283
Anticonvulsant	112	39	10	63	331
Antidepressant	266	89	33	144	331
Antidiabetic	156	63	17	76	355
Antihistamine	42	12	13	17	306
Antimigraine	42	5	17	20	154
Antineoplastic	56	33	7	16	145
Antiulcers	132	22	39	71	146
Anxiolytic	70	36	3	31	285
Atypical Antipsychotics	226	145	13	68	331
Biologics	112	57	15	40	300
Bladder Control	48	7	15	26	357
Blood Thinners	178	110	7	61	319
Botox	27	19	7	1	357
Buprenorphine Medications	350	252	18	80	78
Cardiovascular	95	42	24	29	327
Chronic Obstructive Pulmonary Disease	167	32	44	91	332
Constipation/Diarrhea Medications	150	31	57	62	214
Contraceptive	22	16	2	4	358
Dermatological	161	36	57	68	156
Diabetic Supplies	478	291	11	176	183
Endocrine & Metabolic Drugs	131	82	9	40	196
Erythropoietin Stimulating Agents	28	15	3	10	112
Fibric Acid Derivatives	11	1	2	8	358
Fibromyalgia	196	38	94	64	267
Fish Oils	15	3	4	8	358
Gastrointestinal Agents	110	26	32	52	164
Glaucoma	14	4	4	6	108
Growth Hormones	66	58	0	8	158
Hepatitis C	191	148	20	23	9
HFA Rescue Inhalers	62	16	8	38	165
Insomnia	28	4	7	17	256
Insulin	90	32	6	52	308
Miscellaneous Antibiotics	14	0	3	11	0
Multiple Sclerosis	72	34	12	26	171
Muscle Relaxant	46	5	15	26	41
Nasal Allergy	58	14	12	32	190
Neurological Agents	90	31	16	43	288
NSAIDs	202	38	53	111	205
Ocular Allergy	44	7	13	24	86
Ophthalmic Anti-infectives	13	0	7	6	0
Osteoporosis	17	4	6	7	357
Other*	327	76	78	173	239
Otic Antibiotic	17	0	1	16	0
Statins	21	6	2	13	303
Stimulant	821	375	118	328	346
Synagis	309	112	95	102	136

* 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	21	1	4	16	20
Topical Corticosteroids	108	8	51	49	55
Vitamin	55	10	30	15	210
Pharmacotherapy	60	55	0	5	273
Emergency PAs	0	0	0	0	
Total	6,864	2,820	1,257	2,787	

Overrides

Brand	37	20	6	11	325
Compound	12	11	0	1	43
Cumulative Early Refill	2	2	0	0	168
Diabetic Supplies	1	0	0	1	0
Dosage Change	358	332	1	25	14
High Dose	6	5	0	1	282
Ingredient Duplication	27	22	0	5	9
Lost/Broken Rx	66	60	2	4	12
NDC vs Age	278	200	19	59	249
Nursing Home Issue	62	55	0	7	9
Opioid Quantity	26	26	0	0	153
Other*	29	24	0	5	13
Quantity vs. Days Supply	521	353	35	133	247
STBS/STBSM	13	8	1	4	44
Stolen	18	13	0	5	36
Temporary Unlock	1	1	0	0	26
Third Brand Request	39	27	4	8	18
Overrides Total	1,455	1,120	68	267	
Total Regular PAs + Overrides	8,319	3,940	1,325	3,054	

Denial Reasons

Unable to verify required trials.	2,318
Does not meet established criteria.	1,347
Lack required information to process request.	703

Other PA Activity

Duplicate Requests	617
Letters	9,542
No Process	8
Changes to existing PAs	656
Helpdesk Initiated Prior Authorizations	643
PAs Missing Information	32

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

SoonerPsych Program Update

Oklahoma Health Care Authority
December 2017

Prescriber Mailing Summary

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

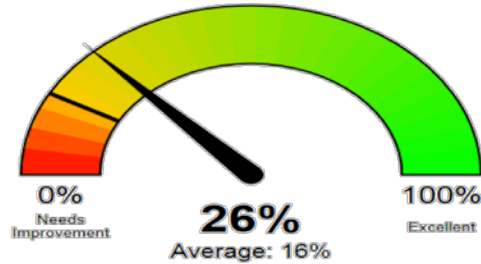
The SoonerPsych program has been using a “report card” format since April 2014. Beginning in April 2016, educational letters were sent to the same group of prescribers with all modules included in each mailing. Included prescribers receive four letters per year, to better inform them of their SoonerCare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

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

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

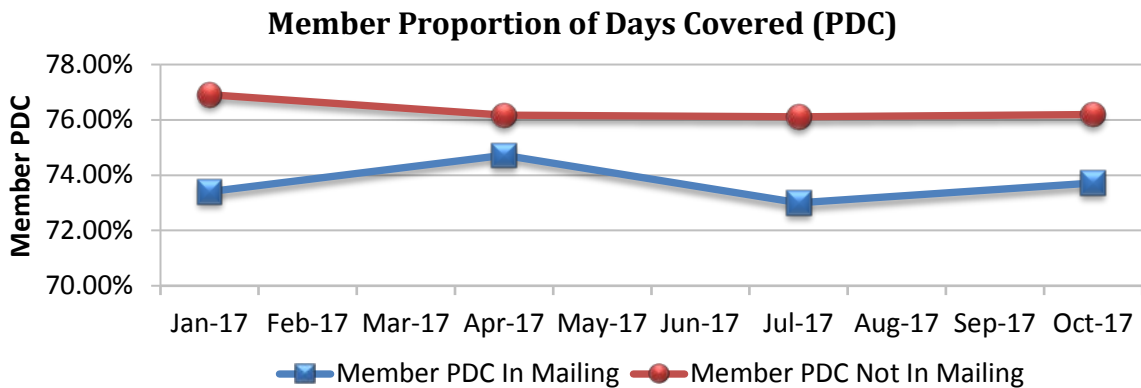
Example Gauge

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

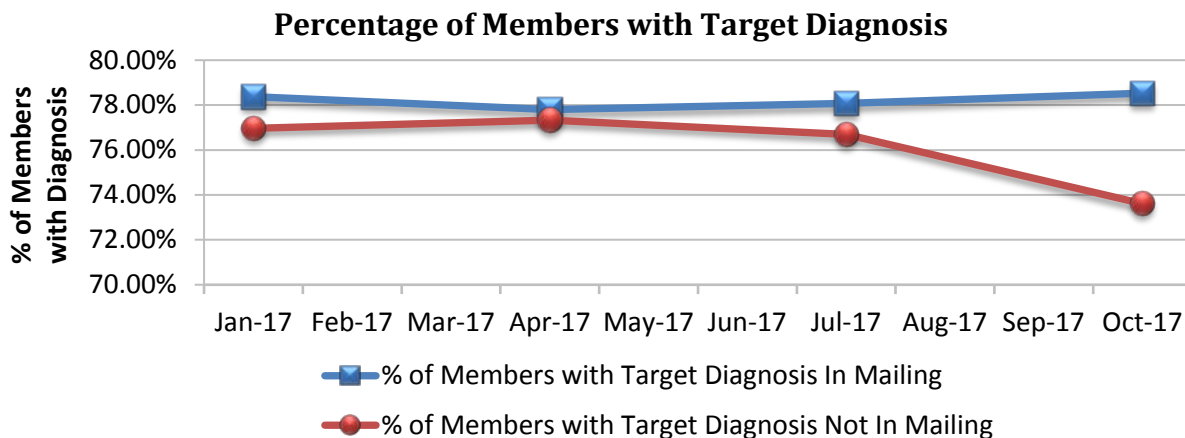


SoonerPsych Trends

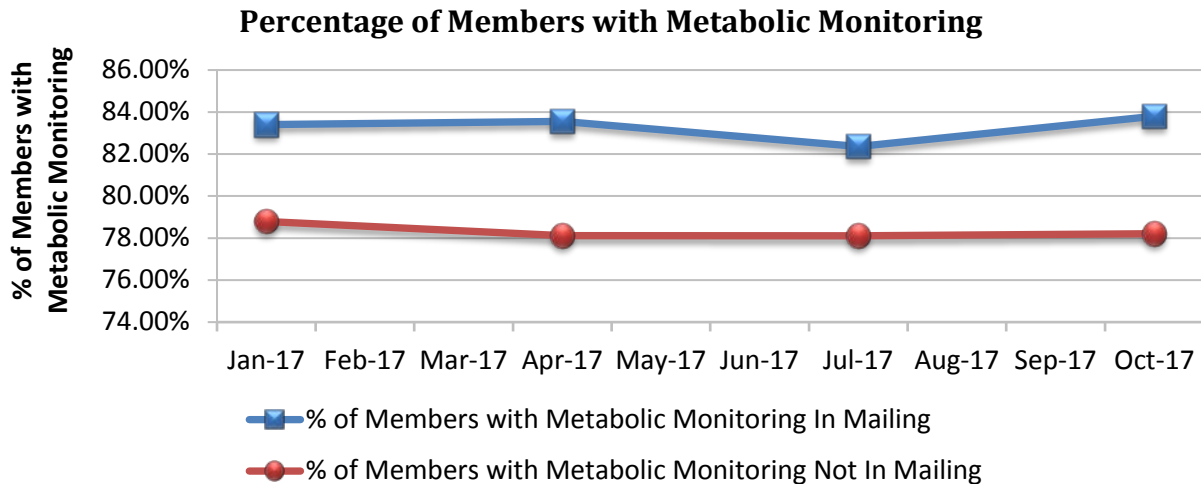
The following graph shows the 2017 trends for member PDC. Those prescribers who received a mailing are designated separately from those who did not. Please note, the vertical axis starts at 70% PDC in order to reflect small changes.



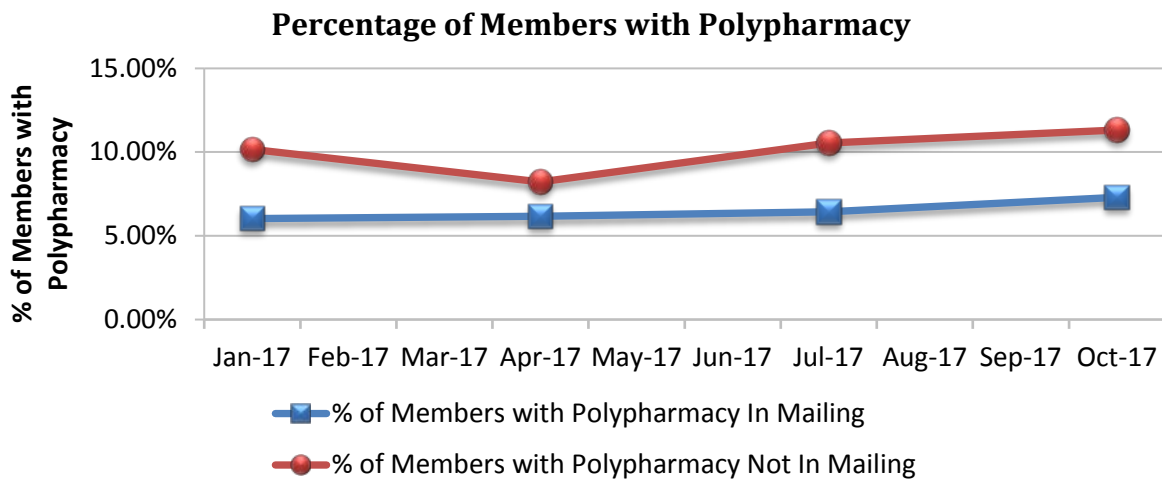
The following graph shows the 2017 trends for the percentage of members with a strong indication for prescribing an atypical antipsychotic medication. Those prescribers who received a mailing are designated separately from those who did not. Please note, the vertical axis starts at 70% of members in order to reflect small changes.



The following graph shows the 2017 trends for the percentage of members with appropriate metabolic monitoring while on an antipsychotic medication. Those prescribers who received a mailing are designated separately from those who did not. Please note, the vertical axis starts at 74% of members in order to reflect small changes.



The following graph shows the 2017 trends for the percentage of members with polypharmacy (concurrent use of two or more atypical antipsychotic medications for more than 90 days). Those prescribers who received a mailing are designated separately from those who did not. Please note, unlike the previous graphs, the vertical axis starts at 0% of members, and that a lower percentage is a better outcome (indicates less prescribing of concomitant atypical antipsychotic medications).



Conclusions

In every parameter except adherence, the members whose prescriber was included in the mailings had better outcomes compared to the members whose prescriber was not included in the mailings. These results indicate that consistently receiving evidence-based educational mailings reminds providers of evidence-based practices, and averts some potentially inappropriate prescribing. Recent changes to the mailing format (including all modules in each

mailing and mailing to consistent prescribers), as well as expanding the data collection process, are intended to sustain improvements and reduce waning interventions. The College of Pharmacy will continue to work with the Oklahoma Health Care Authority to improve educational mailings with the goal of improving the quality of care for SoonerCare members utilizing atypical antipsychotic medications. Future results of the combined mailing and the expanded data collection will be reviewed with the Drug Utilization Review (DUR) board as they become available.



Appendix C



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

Oklahoma Health Care Authority
December 2017

Introduction^{1,2}

- **Mavyret™ [glecaprevir (GLEC)/pibrentasvir (PIB)]** is a fixed-dose combination of GLEC, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and PIB, an HCV NS5A inhibitor, and is indicated for the treatment of patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). GLEC/PIB is also indicated for the treatment of adult patients with HCV genotype 1 infection, who have been previously treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. GLEC/PIB is not recommended in patients with moderate hepatic impairment (Child-Pugh B) and is contraindicated in severe hepatic impairment (Child-Pugh C). Mavyret™ is supplied as oral tablets containing 100mg GLEC and 40mg PIB to be dispensed in a carton for a total of 28 days or 56 days of therapy. The recommended dosing is three tablets taken orally once daily with food. The length of therapy of GLEC/PIB is dependent upon patient cirrhosis status, prior treatment experience, and viral genotype. Recommended regimen durations can be seen in the following table:

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

- **Vosevi® [sofosbuvir (SOF)/velpatasvir (VEL)/voxilaprevir (VOX)]** is a fixed-dose combination of SOF, an HCV nucleotide analog NS5B polymerase inhibitor, VEL, an HCV NS5A inhibitor, and VOX, an HCV NS3/4A protease inhibitor indicated for the treatment of adult patients with chronic HCV infection with or without compensated cirrhosis who have:
 - Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor; or
 - Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing SOF without an NS5A inhibitor

Additional benefit of SOF/VEL/VOX over SOF/VEL was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with SOF without an NS5A

inhibitor. No dosage recommendation for SOF/VEL/VOX can be given for patients with severe renal impairment [estimated Glomerular Filtration Rate (eGFR) less than 30 mL/min/1.73m²] or with end-stage renal disease (ESRD). SOF/VEL/VOX is not recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C) due to higher exposures of VOX in these patients. Vosevi[®] is available as a fixed-dose oral tablet containing 400mg of SOF, 100mg of VEL, and 100mg of VOX. It is dispensed in a bottle for a total of 28 days of therapy. The recommended dosage of SOF/VEL/VOX is one tablet by mouth once daily with food. The recommended treatment regimens and duration can be found in the following table:

Genotype	Prior Treatment Experience	Treatment Regimen and Duration
1, 2, 3, 4, 5, or 6	NS5A inhibitor	SOF/VEL/VOX for 12 weeks
1a or 3	SOF w/o NS5A inhibitor	SOF/VEL/VOX for 12 weeks

w/o = without; SOF = sofosbuvir; VEL = velpatasvir; VOX = voxilaprevir

Examples of NS5A inhibitors include: daclatasvir, elbasvir, ledipasvir, ombitasvir, pibrentasvir, velpatasvir

Recommendations

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 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 Sovaldi [®] + RBV + PEG IFN for 12 weeks 1a: Viekira Pak [™] or Viekira XR [™] + RBV for 12 weeks 1b: Viekira Pak [™] or Viekira XR [™] for 12 weeks 1a: Zepatier [®] for 12 weeks (without baseline RAVs) 1a: Zepatier [®] + RBV for 16 weeks (with baseline RAVs) 1b: Zepatier [®] for 12 weeks

Genotype	Patient Factors	Preferred Regimen(s)
1	Treatment-naïve, cirrhotic	Epclusa® for 12 weeks (with RBV if decompensated) Harvoni® for 12 weeks (with RBV if decompensated) Mavyret™ for 12 weeks Sovaldi® + RBV + PEG IFN for 12 weeks 1a: Viekira Pak™ or Viekira XR™ + RBV for 24 weeks 1b: Viekira Pak™ or Viekira XR™ for 12 weeks 1a: Zepatier® for 12 weeks (without baseline RAVs) 1a: Zepatier® + RBV for 16 weeks (with baseline RAVs) 1b: Zepatier® for 12 weeks
Genotype 2		
2	Treatment-naïve, non-cirrhotic	Epclusa® for 12 weeks Mavyret™ for 8 weeks Sovaldi® + RBV for 12 weeks
2	Treatment-naïve, cirrhotic	Epclusa® for 12 weeks (with RBV if decompensated) Mavyret™ for 12 weeks Sovaldi® + RBV for 12 weeks
Genotype 3		
3	Treatment-naïve, non-cirrhotic	Epclusa® for 12 weeks Mavyret™ for 8 weeks Sovaldi® + RBV for 24 weeks (only if can't use Epclusa® or Mavyret™)
3	Treatment-naïve, cirrhotic	Epclusa® for 12 weeks (with RBV if decompensated) Mavyret™ for 12 weeks Sovaldi® + RBV for 24 weeks (only if can't use Epclusa® or Mavyret™)
Genotype 4		
4	Treatment-naïve, non-cirrhotic	Epclusa® for 12 weeks Harvoni® for 12 weeks Mavyret™ for 8 weeks Sovaldi® + RBV + PEG IFN for 12 weeks Technivie™ + RBV for 12 weeks Zepatier® for 12 weeks
4	Treatment-naïve, cirrhotic	Epclusa® for 12 weeks (with RBV if decompensated) Harvoni® for 12 weeks (with RBV if decompensated) Mavyret™ for 12 weeks Sovaldi® + RBV + PEG IFN 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 (with RBV if decompensated)
5 or 6	Treatment-naïve, cirrhotic	Epclusa® for 12 weeks (with RBV if decompensated) Mavyret™ for 12 weeks Harvoni® for 12 weeks (with RBV if decompensated)

If not specified, regimen applies to all genotypic subtypes.

RBV = ribavirin; PEG IFN = peginterferon alfa; 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.

Viekira Pak™ (ombitasvir/paritaprevir/ritonavir/dasabuvir), Viekira XR™ (ombitasvir/paritaprevir/ritonavir/dasabuvir ER), Harvoni® (sofosbuvir/ledipasvir), Sovaldi® (sofosbuvir), 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 HCV genotype 1. Use of an alternative regimen including 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. Member must have a METAVIR fibrosis score of F1 or greater or equivalent scoring with an alternative test. Fibrosis testing type and scoring must be indicated on prior authorization request (members with a fibrosis score of F0 will be eligible for approval January 1, 2018); 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. Member must have a METAVIR fibrosis score of F1 or greater or equivalent scoring with an alternative test. Fibrosis testing type and scoring must be indicated on prior authorization request (members with a fibrosis score of F0 will be eligible for approval January 1, 2018); 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/1.73m²]; 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: H₂-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.

¹ Mavyret™ Product Information. AbbVie Inc. Available online at: http://www.rxabbvie.com/pdf/mavyret_pi.pdf. Last revised 08/2017. Last accessed 11/09/2017.

² Vosevi[®] Product Information. Gilead Sciences, Inc. Available online at: http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/vosevi/vosevi_pi.pdf. Last revised 07/2017. Last accessed 11/09/2017.



Appendix D



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

Oklahoma Health Care Authority
December 2017

Introduction^{1,2,3,4}

- **Baxdela™ (delafloxacin)** is a fluoroquinolone (FQ) antibiotic indicated for treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. Delafloxacin is dosed twice daily for 5 to 14 days using either intravenous (IV) or tablet formulation. Delafloxacin, like other FQ products, has a boxed warning for serious adverse reactions including tendinitis, tendon rupture, peripheral neuropathy, central nervous system (CNS) effects, and exacerbation of myasthenia gravis. The wholesale acquisition cost (WAC) for Baxdela™ is \$132.50 per 300mg vial and \$67.50 per 450mg tablet.
- **Minolira™ [minocycline hydrochloride extended-release (ER) tablet]** is a tetracycline-class drug indicated to treat inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 12 years of age and older. Minolira™ is available as 105mg and 135mg functionally scored ER tablets, which should not be crushed or chewed. Minolira™ should be dosed as approximately 1g/kg once daily, with or without food. There is no launch or pricing information available at this time, however the national average drug acquisition cost (NADAC) of minocycline immediate-release capsules is approximately \$0.22 to \$0.48 per capsule, resulting in a 30-day course costing approximately \$13.20 to \$28.80.
- **Solosec™ (secnidazole oral granules)** is a nitroimidazole antimicrobial indicated for the treatment of bacterial vaginosis in adult women. Secnidazole is available in a unit-of-use foil packet containing 2 grams of oral granules. Secnidazole should be dosed as 2 grams (one packet), as a single-dose, without regard to timing of meals. It is recommended that the entire contents of one packet be sprinkled onto applesauce, yogurt, or pudding and be consumed within 30 minutes, without chewing or crunching the granules. It should not be dissolved in any liquid. There is no launch or pricing information available at this time, however the NADAC for a 7-day course of metronidazole 500mg tablets is \$4.20 and the NADAC for a 2-day course of tinidazole 500mg tablets is \$26.80.
- **Vabomere™ (meropenem/vaborbactam injection)** is a carbapenem and beta-lactamase inhibitor combination indicated for the treatment of patients 18 years of age and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter cloacae* species complex. Vabomere™ is available as a 2 gram

(meropenem 1 gram/vaborbactam 1 gram) vial. The recommended dosing for Vabomere™ is 4 grams via IV every 8 hours, infused over 3 hours, for up to 14 days. The dose of Vabomere™ should be adjusted for patients with renal impairment based on prescribing information recommendations. The WAC for a 10-day course of Vabomere™ is \$13,860.00, compared to the WAC for a 10-day course of piperacillin/tazobactam at approximately \$378.00.

Recommendations

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 ofloxacin 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 antibiotic 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 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).

¹ Baxdela™ Prescribing Information. Melinta Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208610s000,208611s000lbl.pdf. Last revised 06/2017. Last accessed 11/10/2017.

² Minolira™ Prescribing Information. Promius Pharma, LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209269s000lbl.pdf. Last revised 05/2017. Last accessed 11/10/2017.

³ Solosec™ Prescribing Information. Symbiomix Therapeutics, LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209363s000lbl.pdf. Last revised 09/2017. Last accessed 11/20/2017.

⁴ Vabomere™ Prescribing Information. The Medicines Company. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209776lbl.pdf. Last revised 08/2017. Last accessed 11/10/2017.



Appendix E

Vote to Prior Authorize Duzallo® (Lesinurad/Allopurinol)

Oklahoma Health Care Authority
December 2017

Introduction¹

Duzallo® (lesinurad/allopurinol) is a combination of lesinurad, a URAT1 inhibitor, and allopurinol, a xanthine oxidase inhibitor, indicated for the treatment of 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. Lesinurad/allopurinol lowers sUA levels by increasing excretion and inhibiting production of uric acid. Lesinurad/allopurinol has a boxed warning for risk of acute renal failure. It is supplied as film-coated tablets containing 200mg of lesinurad and 200mg of allopurinol or 200mg of lesinurad and 300mg of allopurinol. The recommended dose is one 200mg lesinurad/300mg allopurinol tablet per day [or one 200mg lesinurad/200mg allopurinol tablet per day for patients with a creatinine clearance (CrCl) 45mL/min to less than 60mL/min on a medically appropriate dose of 200mg allopurinol]. Lesinurad/allopurinol is not recommended for patients taking daily doses of allopurinol less than 300mg (or less than 200mg in patients with CrCl less than 60mL/min). One tablet contains the maximum daily lesinurad dose (200mg). Patients should not take more than one tablet of lesinurad/allopurinol per day. Contraindications for lesinurad/allopurinol include: severe renal impairment (CrCl less than 30mL/min), end-stage renal disease, kidney transplant recipients, patients on dialysis, tumor lysis syndrome, or Lesch-Nyhan syndrome.

Cost Comparison:

Medication	Cost Per Tablet	Cost Per 30 Days
Duzallo® (lesinurad/allopurinol) 200mg/200mg tablet	\$12.37	\$371.10
Duzallo® (lesinurad/allopurinol) 200mg/300mg tablet	\$12.37	\$371.10
Zurampic® (lesinurad) 200mg tablet	\$12.37	\$371.10
allopurinol 100mg tablet	\$0.13	\$17.10*
allopurinol 300mg tablet	\$0.21	\$6.30*

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

*Cost for 30 days of allopurinol based on equivalent maximum dosing of Duzallo® (allopurinol 300mg/day).

Recommendations

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.

¹ Duzallo[®] Prescribing Information. Ironwood Pharmaceuticals, Inc. Available online at: <https://www.irwdpi.com/duzallo/DuzalloPIandMedguide2017.pdf#page=1>. Last revised 09/2017. Last accessed 11/08/2017.



Appendix F



Fiscal Year 2017 Annual Review of Phosphate Binders

Oklahoma Health Care Authority
December 2017

Current Prior Authorization Criteria

Generic calcium acetate containing products, Fosrenol® (lanthanum carbonate 500mg and 750mg chewable tablets), PhosLo® (calcium acetate gelcaps), Phoslyra® (calcium acetate oral solution), Renagel® (sevelamer hydrochloride tablets), and Renvela® (sevelamer carbonate tablets and packets for suspension) are currently available without prior authorization.

Velphoro® (Sucroferric Oxyhydroxide) and Auryxia® (Ferric Citrate) Approval Criteria:

1. A diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis; and
2. 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.
3. For Auryxia®, a quantity limit of 12 tablets per day will apply.

Fosrenol® (Lanthanum Carbonate) 1,000mg Chewable Tablets, 750mg Oral Powder, and 1,000mg Oral Powder Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in patients with end-stage renal disease (ESRD); and
2. 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; and
3. For the approval of Fosrenol® oral powder, a patient-specific, clinically significant reason why a special formulation is needed over a phosphate binder available without a prior authorization, such as Fosrenol® 500mg or 750mg chewable tablets which can be crushed, must be provided; and
4. For the approval of Fosrenol® 1,000mg chewable tablets, a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without a prior authorization, such as Fosrenol® 500mg or 750mg chewable tablets, must be provided.

Utilization of Phosphate Binders: Fiscal Year 2017

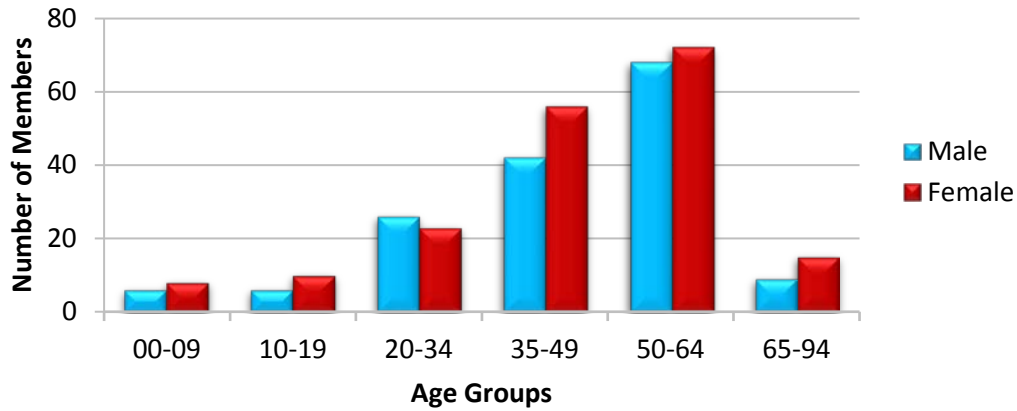
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2016	341	1,385	\$1,306,157.77	\$943.07	\$32.59	374,321	40,073
2017	341	1,470	\$1,239,441.01	\$843.16	\$29.43	350,973	42,116
% Change	0.00%	6.10%	-5.10%	-10.60%	-9.70%	-6.20%	5.10%
Change	0	85	-\$66,716.76	-\$99.91	-\$3.16	-23,348	2,043

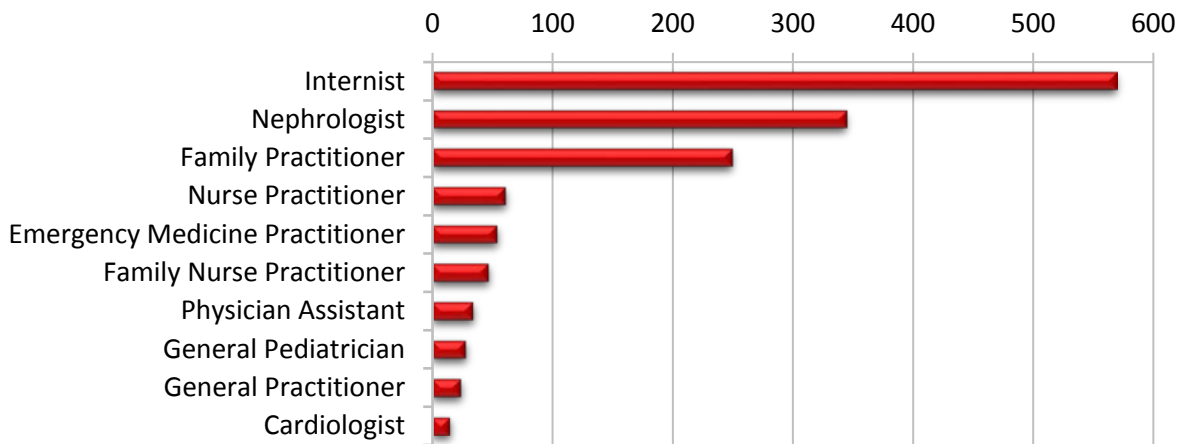
*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Phosphate Binders



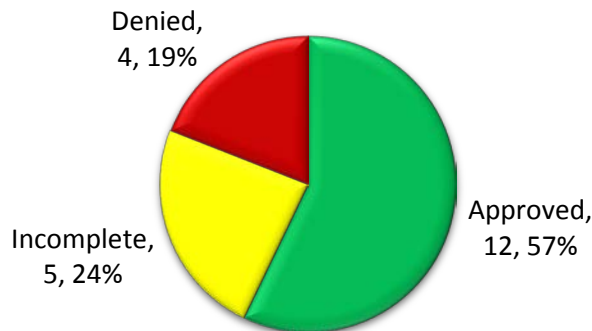
Top Prescriber Specialties of Phosphate Binders by Number of Claims



Prior Authorization of Phosphate Binders

There were 21 prior authorization requests submitted for phosphate binders during fiscal year 2017. The prior authorization for phosphate binders was implemented on May 8, 2017. The following chart shows the status of the submitted petitions during fiscal year 2017.

Status of Petitions



Market News and Updates^{1,2,3,4}

Generic Availability:

- **August 2017:** Natco Pharmaceuticals announced the approval of the Abbreviated New Drug Application (ANDA) from the U.S. Food and Drug Administration (FDA) for 500mg, 750mg, and 1,000mg lanthanum carbonate chewable tablets. This is the first generic product available for Fosrenol® chewable tablets.
- **September 2017:** Dr. Reddy's Laboratories launched a generic version of Renvela® (sevelamer carbonate) 800mg tablets.

New Indication(s):

- **November 2017:** The FDA has expanded the use of Auryxia® (ferric citrate) to patients with iron deficiency anemia and chronic kidney disease (CKD) who are not on dialysis. Auryxia® was originally approved by the FDA in September 2014 for the control of serum phosphorus levels in patients with CKD who are undergoing dialysis.

Recommendations

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.

Utilization Details of Phosphate Binders: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
CALCIUM ACETATE PRODUCTS						
CALC ACETATE CAP 667MG	692	179	\$53,007.35	3.87	\$76.60	4.28%
CALC ACETATE TAB 667MG	18	10	\$1,982.93	1.80	\$110.16	0.16%
PHOSLYRA SOL 667MG/5ML	4	2	\$802.08	2.00	\$200.52	0.06%
SUBTOTAL	714	191	\$55,792.36	3.74	\$78.14	4.50%
SEVELAMER CARBONATE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/MEMBER	COST/CLAIM	% COST
REVELA TAB 800MG	537	148	\$847,141.67	3.63	\$1,577.55	68.35%
REVELA PAK 2.4GM	74	14	\$103,928.70	5.29	\$1,404.44	8.39%
REVELA PAK 0.8GM	23	10	\$43,597.54	2.30	\$1,895.55	3.52%
SEVELAMER POW 0.8GM	1	1	\$1,381.95	1.00	\$1,381.95	0.11%
SUBTOTAL	635	173	\$996,049.86	3.67	\$1,568.58	80.37%
SEVELAMER HYDROCHLORIDE PRODUCTS						
RENAGEL TAB 800MG	17	7	\$21,968.14	2.43	\$1,292.24	1.77%
RENAGEL TAB 400MG	4	2	\$1,330.35	2.00	\$332.59	0.11%
SUBTOTAL	21	9	\$23,298.49	2.33	\$1,109.45	1.88%
LANTHANUM CARBONATE PRODUCTS						
FOSRENOL CHW 1000MG	12	5	\$18,706.02	2.40	\$1,558.84	1.51%
FOSRENOL CHW 500MG	9	3	\$8,775.72	3.00	\$975.08	0.71%
SUBTOTAL	21	8	\$27,481.74	2.63	\$1,308.65	2.22%
SUCROFERRIC OXYHYDROXIDE PRODUCTS						
VELPHORO CHW 500MG	57	15	\$117,910.62	3.80	\$2,068.61	9.51%
SUBTOTAL	57	15	\$117,910.62	3.80	\$2,068.61	9.51%
FERRIC CITRATE PRODUCTS						
AURYXIA TAB 210MG	22	7	\$18,907.94	3.14	\$859.45	1.53%
SUBTOTAL	22	7	\$18,907.94	3.14	\$859.45	1.53%
TOTAL	1,470	341*	\$1,239,441.01	4.31	\$843.16	100%

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

¹ Dr. Reddy's Laboratories Ltd. Dr. Reddy's Laboratories Announces the Launch of Sevelamer Carbonate Tablets in the U.S. Market. *Business Wire*. Available online at: <http://www.businesswire.com/news/home/20170929005632/en/Dr.-Reddys-Laboratories-Announces-Launch-Sevelamer-Carbonate>. Issued 09/29/2017. Last accessed 10/02/2017.

² Natco: News and Announcements. Natco & Its Alliance Partner Lupin Receive FDA Approval for Generic Lanthanum Carbonate Chewable Tablets. Available online at: <http://www.natcopharma.co.in/about/news/>. Issued 08/14/2017. Last accessed 10/02/2017.

³ NN&I Staff. FDA to Review Application for New Indication for Keryx's Auryxia. *Nephrology News and Issues*. Available online at: <https://www.nephrologynews.com/fda-review-application-new-indication-keryxs-auryxia/>. Issued 03/08/2017. Last accessed 10/02/2017.

⁴ Brooks M. FDA Expands Auryxia Indication to CKD Patients Not on Dialysis. *Medscape*. Available online at: https://www.medscape.com/viewarticle/888143?nlid=118941_3901&src=wnl_newsart_171107_MSCPEDIT&impID=1476464&faf=1. Issued 11/07/2017. Last accessed 11/07/2017.



Appendix G



Fiscal Year 2017 Annual Review of Soliris® (Eculizumab)

Oklahoma Health Care Authority
December 2017

Current Prior Authorization Criteria

Soliris® (Eculizumab) Approval Criteria:

1. Member must have an established diagnosis of paroxysmal nocturnal hemoglobinuria or atypical hemolytic uremic syndrome via international classification of disease (ICD) coding in the member's medical claims history; and
2. An age restriction of 18 years and older will apply; and
3. For members younger than 18 years of age, approval can be granted with a documented diagnosis of atypical hemolytic uremic syndrome.

Utilization of Soliris® (Eculizumab): Fiscal Year 2017

Soliris® (Eculizumab) Utilization: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
2017	7	40	\$1,449,643.80	\$36,241.10	5,927

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Soliris® (Eculizumab) Fiscal Year Comparison: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2016	4	80	\$1,729,571.78	\$21,619.65	\$1,525.20	10,640	1,134
2017	4	79	\$1,711,063.67	\$21,659.03	\$1,565.47	17,990	1,093
% Change	0.00%	-1.30%	-1.10%	0.20%	2.60%	69.10%	-3.60%
Change	0	-1	-\$18,508.11	\$39.38	\$40.27	7,350	-41

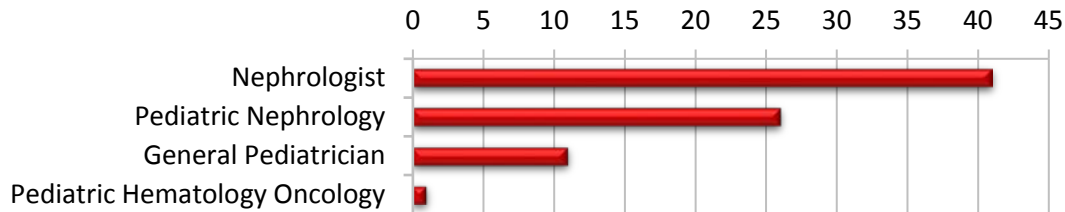
*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Soliris® (Eculizumab)

- Due to the small number of members utilizing Soliris® (eculizumab), detailed demographic information cannot be provided.

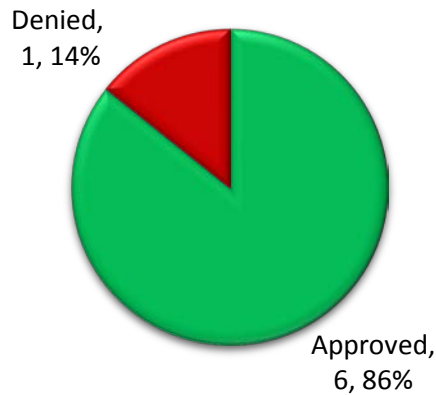
Top Prescriber Specialties of Soliris® (Eculizumab) by Number of Claims: Pharmacy Claims



Prior Authorization of Soliris® (Eculizumab)

There were 7 prior authorization requests submitted for Soliris® (eculizumab) 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}

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

- **October 2017:** Alexion Pharmaceuticals announced that the FDA approved Soliris® (eculizumab) for adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive. Approval was based on the Phase 3 REGAIN study, which demonstrated treatment benefits for patients with anti-AChR antibody-positive gMG who had previously failed immunosuppressive treatment and continued to suffer from unresolved disease symptoms. Alexion Pharmaceuticals anticipates approximately 5% to 10% of all patients with myasthenia gravis (MG) will be candidates for eculizumab.

News:

- **October 2017:** Soliris® (eculizumab) was approved for the treatment of gMG despite missing statistical significance on the primary efficacy endpoint of change from baseline in MG-Activities of Daily Living (MG-ADL) total score after 26 weeks of treatment ($p=0.0698$). Eculizumab did meet statistical significance with p-values less than 0.05 in 18 out of 22 pre-specified endpoints.

Soliris® (Eculizumab) for Myasthenia Gravis (MG) Summary^{2,3,4,5}

MG Summary:

MG is a progressive autoimmune disorder characterized by fluctuating and variable weakness in ocular, bulbar, limb, and respiratory muscles. The weakness is a result of an antibody-mediated, T-cell dependent, immunological attack directed at proteins in the postsynaptic membrane of the neuromuscular junction (AChR and/or receptor-associated proteins). Patients who have detectable antibodies to AChR or to the muscle-specific receptor tyrosine kinase (MuSK) are considered to have seropositive MG; approximately 90% of patients with gMG are seropositive.

The prevalence of MG is estimated to range from 70 to 320 per million lives with bimodal age of onset (early peak in second and third decade of life; late peak in sixth to eighth decade of life). There are two clinical forms of MG: ocular and generalized. In ocular MG, the weakness is limited to the ocular muscles. In gMG, the weakness can affect ocular muscles, but it also involves bulbar, limb, and respiratory muscles. About 50% of patients who present with ocular manifestations will develop gMG by two years. Weakness progresses as the disease progresses with fewer symptom free periods later in the disease.

Current therapies to treat MG include: symptomatic treatments (e.g., anticholinesterase agents); chronic immunomodulating treatments (e.g., glucocorticoids and other immunosuppressive drugs); rapid immunomodulating treatments [e.g., plasmapheresis and intravenous immune globulin (IVIG)]; and surgical treatment (e.g., thymectomy). Symptoms can be treated with acetylcholinesterase inhibitors (e.g., pyridostigmine bromide). However, most patients will require some form of immunotherapy. Commonly used immunomodulating drugs are prednisone, azathioprine, cyclosporine, and mycophenolate mofetil. Patients with refractory MG may use other agents such as rituximab, periodic IVIG, monthly pulse cyclophosphamide, and tacrolimus. Plasmapheresis and IVIG are rapid immunotherapies that work quickly but have a short duration of action. These are usually reserved for certain situations, such as myasthenic crisis, preoperatively before thymectomy, as a "bridge" while initiating slower acting immunotherapies, or as an adjuvant to other immunotherapeutic medications in patients with refractory MG.

Phase 3 REGAIN Study:

The efficacy of eculizumab for the treatment of gMG was established in a 26-week randomized, double-blind, parallel-group, placebo-controlled trial. The study enrolled patients who met the following criteria at screening: 1) positive serologic test for anti-AChR antibodies; 2) Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV; 3) MG-ADL total score ≥ 6 ; and 4) failed treatment over one year or more with two or more immunosuppressive therapies (ISTs) either in combination or as monotherapy, or failed at least one IST and required chronic plasmapheresis or plasma exchange (PE) or IVIG. A total of 62 patients were randomized to receive eculizumab treatment and 63 were randomized to receive placebo. Over 95% of patients in each group were receiving acetylcholinesterase inhibitors, and 98% were receiving ISTs. Approximately 50% of each group had been previously treated with at least three ISTs. The primary efficacy endpoint was a comparison of the change from baseline between treatment groups in the MG-ADL total score at week 26. The MG-ADL is a categorical

scale that assesses the impact on daily function of eight signs or symptoms that are typically affected in gMG. Each item is assessed on a 4-point scale where a score of 0 represents normal function and a score of 3 represents loss of ability to perform that function (total score 0 to 24). A statistically significant difference favoring eculizumab was observed in the mean change from baseline to week 26 in MG-ADL total scores [-4.2 points in the eculizumab-treated group compared with -2.3 points in the placebo-treated group (p=0.006)]. A key secondary endpoint in gMG Study 1 was the change from baseline in the Quantitative Myasthenia Gravis (QMG) total score at week 26. The QMG is a 13-item categorical scale assessing muscle weakness. Each item is assessed on a 4-point scale where a score of 0 represents no weakness and a score of 3 represents severe weakness (total score 0 to 39). A statistically significant difference favoring eculizumab was observed in the mean change from baseline to week 26 in QMG total scores [-4.6 points in the eculizumab-treated group compared with -1.6 points in the placebo-treated group (p=0.001)]. The results of the analysis of the MG-ADL and QMG are shown in the following table:

Efficacy Endpoints	Soliris-LS Mean (n=62) (SEM)	Placebo-LS Mean (n=63) (SEM)	Change Relative to Placebo-LS Mean Difference	p-values
MG-ADL	-4.2 (0.49)	-2.3 (0.48)	-1.9 (-3.3, -0.6)	(0.006 ^a ; 0.014 ^b)
QMG	-4.6 (0.60)	-1.6 (0.59)	-3.0 (-4.6, -1.3)	(0.001 ^a ; 0.005 ^b)

SEM = Standard Error of the Mean; Soliris-LS Mean = least square mean for the treatment group; Placebo-LS Mean = least square mean for the placebo group; LS Mean-Difference (95% CI) = Difference in least square mean with 95% confidence interval; MG-ADL = myasthenia gravis activities of daily living; QMG = quantitative myasthenia gravis
p-values (testing the null hypothesis that there is no difference between the two treatment arms; a: in least square means at week 26 using a repeated measure analysis; b: in ranks at week 26 using a worst rank analysis).

Dosing:

- Soliris® (eculizumab) is supplied as a single-dose 300mg/10mL vial intended for intravenous (IV) infusion.
- The recommended dosing of eculizumab for a diagnosis of gMG includes the following: 900mg weekly for the first four weeks, followed by 1,200mg for the fifth dose one week later, then 1,200mg every two weeks thereafter.

Cost:

Medication	Cost per Month*	Cost per Year*
Soliris® (eculizumab) 300mg/10mL	\$54,391.20	\$652,694.40

*Costs based on maintenance dosing after loading dosing is complete.

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

Recommendations

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.

¹ Alexion Pharmaceuticals, Inc. FDA Approves Soliris® (Eculizumab) for the Treatment of Patients with Generalized Myasthenia Gravis (gMG). *Business Wire*. Available online at: <http://news.alexionpharma.com/press-release/product-news/fda-approves-soliris-eculizumab-treatment-patients-generalized-myasthenia>. Issued 10/23/2017. Last accessed 11/14/2017.

² Alexion Pharmaceuticals, Inc. Interim Analysis from Phase 3 Open-Label Extension Study Shows Sustained Benefits of Soliris® (Eculizumab) Treatment for Patients with Refractory Generalized Myasthenia Gravis. *Business Wire*. Available online at: <http://www.businesswire.com/news/home/20170913006366/en/Interim-Analysis-Phase-3-Open-Label-Extension-Study>. Issued 09/13/2017. Last accessed 11/14/2017.

³ Bird SJ. Clinical manifestations of myasthenia gravis. *Up-to-Date*. Available online at: https://www.uptodate.com/contents/clinical-manifestations-of-myasthenia-gravis?source=search_result&search=myasthenia+gravis&selectedTitle=3%7E150. Last revised 08/24/2017. Last accessed 11/14/2017.

⁴ Bird SJ. Treatment of myasthenia gravis. *Up-to-Date*. Available online at: https://www.uptodate.com/contents/treatment-of-myasthenia-gravis?source=search_result&search=myasthenia+gravis&selectedTitle=4%7E150. Last revised 06/15/2017. Last accessed 11/14/2017.

⁵ Soliris® Prescribing Information. Alexion Pharmaceuticals, Inc. Available online at: http://www.alexion.com/Documents/Soliris_USPI.aspx. Last revised 10/2017. Last accessed 11/14/2017.



Appendix H



Fiscal Year 2017 Annual Review of Duchenne Muscular Dystrophy (DMD) Medications and 30-Day Notice to Prior Authorize Emflaza® (Deflazacort)

Oklahoma Health Care Authority
December 2017

Current Prior Authorization Criteria

Exondys 51™ (Eteplirsen) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping; and
2. 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 DMD Medications [Exondys 51™ (Eteplirsen)]: Fiscal Year 2017

There was no utilization of DMD medications during fiscal year 2017.

Prior Authorization of DMD Medications [Exondys 51™ (Eteplirsen)]

There were no prior authorization requests submitted for DMD medications during fiscal year 2017.

Market News and Updates^{1,2,3,4,5,6,7,8,9,10,11,12,13}

Anticipated Patent Expiration(s):

- Exondys 51™ (eteplirsen): March 2034

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

- Emflaza® (deflazacort): February 2017

News:

- **February 2017:** Senator Bernie Sanders and Representative Elijah E. Cummings sent a letter to the chief executive of Marathon Pharmaceuticals, arguing that the Illinois company is “abusing” government policies that encourage the development of treatments for orphan diseases. The letter urged the pharmaceutical company to lower the price before launching their drug Emflaza® (deflazacort) and stated that the planned list price of \$89,000 per year is “unconscionable.” In response to concerns about pricing, Marathon chief executive Jeffrey Aronin announced that the company would delay its launch.
- **March 2017:** PTC Therapeutics, Inc. announced it entered into an asset purchase agreement with Marathon Pharmaceuticals, LLC to acquire all rights to Emflaza® (deflazacort). Emflaza®, a corticosteroid, is the first treatment approved in the United States for all DMD patients five years of age and older, regardless of their genetic mutation. Under the terms of the asset purchase agreement, Marathon will receive

total upfront consideration of \$140 million upon closing of the transaction, and is also entitled to receive payments from PTC based on annual net sales of Emflaza® beginning in 2018. In addition, Marathon has the opportunity to receive a single \$50 million sales-based milestone.

- **March 2017:** Akashi Therapeutics reported that the FDA completed its review and concluded that Akashi may resume clinical development of HT-100 (delayed-release halofuginone) in patients with any of the genetic mutations that cause DMD. This comes after Akashi suspended the HALO study in January 2016, when one of the patients in the trial experienced serious, life-threatening health issues. At that time, the company began working with the FDA and launched a comprehensive investigation. HT-100 is an oral drug candidate being developed to reduce fibrosis and inflammation and to promote healthy muscle fiber regeneration in DMD patients.
- **April 2017:** Bristol-Myers Squibb announced that it entered into an agreement to license BMS-986089, an anti-myostatin adnectin, to Roche. Under the agreement, Roche will pay Bristol-Myers Squibb an upfront payment of \$170 million with potential milestone payments of up to \$205 million. Bristol-Myers Squibb will receive tiered double-digit royalties if it is approved and commercialized. BMS-986089 is a novel fusion protein designed to suppress myostatin, a negative regulator of muscle growth. It is currently being investigated as a treatment option for patients with DMD.
- **May 2017:** PTC Therapeutics, Inc. announced it is planning a \$35,000 annual net price for Emflaza® (deflazacort), its newly acquired and FDA-approved DMD drug. The previous owner, Marathon Pharmaceuticals, created significant controversy with the original price of \$89,000 per year. While the current planned price is considerably lower, deflazacort is sold in other countries for as low as \$1,000 per year.
- **September 2017:** Sarepta Therapeutics, Inc., the makers of Exondys 51™ (eteplirsen), announced muscle biopsy results from its 4053-101 study, a Phase 1/2 first-in-human study conducted in Europe to assess the safety, tolerability, pharmacokinetics, and efficacy of golodirsen (SRP-4053) in 25 boys with confirmed deletions of the DMD gene amenable to exon 53 skipping. The analysis included biopsies of the bicep muscle at baseline and on-treatment at week 48. All participants displayed an increase in skipping exon 53 ($p < 0.001$) over baseline levels, demonstrating proof of mechanism. Mean dystrophin protein increased to 1.019% of normal compared to a mean baseline of 0.095% of normal ($p < 0.001$), the primary biological endpoint in the study, representing a 10.7 fold increase from baseline.
- **October 2017:** PTC Therapeutics, Inc. announced that the FDA issued a complete response letter (CRL) for the New Drug Application (NDA) of the investigational medicine ataluren. Ataluren is an oral, first-in-class, protein restoration therapy designed to enable the formation of a functioning protein in patients with genetic disorders caused by a nonsense mutation, including some forms of DMD. The CRL stated that the FDA is unable to approve the application in its current form. Specifically, that evidence of effectiveness from additional adequate and well-controlled clinical trial(s) will be necessary at a minimum to provide substantial evidence of effectiveness.

Pipeline:

- **AT-300 and DT-200:** In addition to HT-100, Akashi Therapeutics is developing AT-300 and DT-200 for the treatment of DMD. AT-300 is a modified form of a peptide discovered in the venom of the Chilean Rose Tarantula that addresses calcium level

imbalances in muscle, an early trigger of critical pathologies in DMD muscle that leads to loss of function. It has been shown to positively affect cellular calcium homeostasis in preclinical DMD model studies. It has been granted Orphan Drug designation by the FDA. DT-200 is an oral selective androgen receptor modulator (SARM) with positive Phase 1 clinical data. If DT-200 is found to increase muscle mass, strength, and motor function in healthy volunteers, it may lead to further development as a DMD treatment.

- **Edasalonexent (CAT-1004):** The FDA has granted Catabasis Pharmaceutical's drug, edasalonexent, Orphan Drug, Fast Track, and Rare Pediatric Disease designations for the treatment of DMD. It is a novel drug designed to potentially benefit patients regardless of DMD mutation type. Edasalonexent inhibits nuclear factor kappa-light-chain-enhancer of activated B cells (NF- κ B) which plays a key role in skeletal muscle health. Activated NF- κ B is seen in patients affected with DMD prior to the clinical manifestations of the disease. Favorable safety, tolerability, pharmacokinetics, and positive biological marker results were observed in Phase 1 trials. Edasalonexent is currently being studied in Phase 2 trials.
- **MNK-1411:** Mallinckrodt has filed an Investigational New Drug (IND) application with the FDA to assess MNK-1411's potential in the treatment of patients with DMD. The company completed a Phase 1 study for MNK-1411 in healthy volunteers, and is using the information that was derived to determine optimal dosing for patients in the Phase 2 trial, which should begin late 2017. MNK-1411 (cosyntropin injection) is a depot formulation of tetracosactide, a synthetic 24 amino acid melanocortin receptor agonist. It is approved and marketed outside of the United States as Synacthen[®] Depot.
- **Resolaris™ (ATYR1940):** aTyr Pharma is developing Resolaris™ for the treatment of early-onset facioscapulohumeral muscular dystrophy (FSHD). FSHD is the most prevalent of the nine primary types of muscular dystrophy. According to results from the Phase 1/2 trials, Resolaris™ improved the muscle strength of nearly two-thirds of the studied patients with early-onset FSHD. Resolaris™ is derived from a naturally occurring protein, the histidine aminoacyl tRNA synthetase (HARS). It is thought to reset the immune system in diseased tissue to a more normal state without interfering with overall immunity. The FDA has granted Resolaris™ Orphan Drug and Fast Track designation for the treatment of limb girdle muscular dystrophy (LGMD) as well. Resolaris™ is not currently being studied for DMD.
- **SRP-4045 and SRP-4053:** Sarepta Therapeutics is evaluating the safety and effectiveness of SRP-4045 and SRP-4053 (golodirsen) in ESSENCE, a randomized, placebo-controlled Phase 3 study. SRP-4045 and SRP-4053 are being studied for DMD patients who have a deletion in the dystrophin gene that is amenable to exon 45 or exon 53 skipping, respectively. By promoting the synthesis of a shorter dystrophin protein, these medications are intended to slow the decline of ambulation and mobility seen in DMD patients.

Emflaza[®] (Deflazacort) Product Summary^{14,15}

Indication(s): Emflaza[®] (deflazacort) is a corticosteroid indicated for the treatment of DMD in patients 5 years of age and older.

Dosing:

- Deflazacort is available as 6mg, 18mg, 30mg, and 36mg oral tablets. It is also available as a 22.75mg/mL oral suspension in a 13mL bottle with two 1mL dosing syringes.
- The recommended dose is approximately 0.9mg/kg by mouth once daily. It is recommended to round up to the nearest possible dose when using tablets, and to the nearest tenth of a milliliter (mL) when using suspension.
- Deflazacort tablets can be administered whole or crushed. If crushed, the tablets should be taken immediately after mixing with applesauce.
- It is recommended that the appropriate dose of deflazacort suspension be added to 3 to 4 ounces of juice or milk and mixed well. The dose should then be administered immediately.

Contraindication(s):

- Known hypersensitivity to deflazacort or to any of the inactive ingredients

Adverse Reactions: Common adverse reactions in $\geq 5\%$ of deflazacort-treated patients that occurred over 52 weeks of exposure to deflazacort 0.9mg/kg/day in Study 1 include the following:

- | | | |
|-------------------------|---------------------|-----------------------------|
| ▪ Cushingoid appearance | ▪ Pollakiuria | ▪ Contusion |
| ▪ Hirsutism | ▪ Constipation | ▪ Nausea |
| ▪ Weight increase | ▪ Irritability | ▪ Psychomotor hyperactivity |
| ▪ Erythema | ▪ Abnormal behavior | ▪ Epistaxis |
| ▪ Central obesity | ▪ Pyrexia | ▪ Skin striae |
| ▪ Abdominal pain | ▪ Back pain | |
| | ▪ Rash | |

Use in Specific Population(s):

- Pediatric Use: The safety and effectiveness of deflazacort for the treatment of DMD have been established in patients 5 years of age and older. Deflazacort suspension contains benzyl alcohol and is not approved for use in pediatric patients 5 years of age or younger. Serious adverse reactions including fatal reactions and “gasping syndrome” occurred in premature neonates and low birth weight infants in the neonatal intensive care unit who received drugs containing benzyl alcohol as a preservative. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known (deflazacort suspension contains 10.45mg of benzyl alcohol per mL).

Efficacy: The effectiveness of deflazacort for the treatment of DMD was established in a multi-center, randomized, double-blind, placebo-controlled, 52-week study.

- **Study 1:** The study included 196 male pediatric patients 5 to 15 years of age with documented mutation(s) of the dystrophin gene, onset of weakness before 5 years of age, and serum creatinine kinase activity at least ten times the upper limit of normal (ULN) at some stage in their illness. Patients were randomized to therapy with deflazacort (0.9 or 1.2mg/kg/day), an active comparator (prednisone 0.75mg/kg/day), or placebo. A comparison to placebo was made after 12 weeks of treatment. After 12 weeks, placebo patients were re-randomized to receive either deflazacort or prednisone; all patients continued treatment for an additional 40 weeks. The efficacy was evaluated by assessing the change between baseline and week 12 in average

strength of 18 muscle groups. Individual muscle strength was graded using a modified Medical Research Council (MRC) 11-point scale, with higher scores representing greater strength. All treatment groups demonstrated significant improvement in muscle strength compared with placebo at 12 weeks. The change in average muscle strength score between baseline and week 12 was significantly greater for deflazacort 0.9mg/kg/day ($p=0.017$), deflazacort 1.2mg/kg/day ($p=0.0003$), and prednisone 0.75mg/kg/day ($p=0.0002$) than for the placebo group. Compared with the deflazacort 0.9mg/kg/day group, the deflazacort 1.2mg/kg/day group demonstrated a small additional benefit compared to placebo at week 12, but had a greater incidence of adverse reactions. Therefore, use of deflazacort 1.2mg/kg/day is not recommended. Deflazacort was associated with less weight gain than prednisone.

- **Study 2:** An additional randomized, double-blind, placebo-controlled, 104-week clinical trial evaluated deflazacort in comparison to placebo. The study population consisted of 29 male pediatric patients 6 to 12 years of age with a confirmed diagnosis of DMD. The results of the analysis of the primary endpoint of average muscle strength scores (graded on a 0 to 5 scale) at 2 years were not statistically significant.

Cost Comparison:

Medication	Cost Per 30 Days*	Cost Per Year*
Emflaza® (deflazacort) tablet 6mg, 18mg, 30mg, & 36mg	\$5,233.20 - \$14,580.00	\$62,798.40 - \$174,960.00
Emflaza® (deflazacort) suspension 22.75mg/mL	\$5,967.00 - \$21,216.00	\$71,604.00 - \$254,592.00
prednisone tablet 20mg	\$4.50 - \$13.50	\$54.00 - \$162.00

Cost does not reflect rebated price or net cost. Costs based on National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

*Cost given as a range based on average weight for males 5 to 19 years of age at recommended dosing.

Guideline Recommendations¹⁶

The American Academy of Neurology (AAN) published a practice guideline update on corticosteroid treatment of DMD in 2016 in the journal *Neurology*. The recommendations are as follows with AAN classifications of evidence noted[‡]:

- Level B evidence: Prednisone to improve strength and pulmonary function.
- Level C evidence: Prednisone may be used for improving timed motor function, reducing the need for scoliosis surgery, and delaying cardiomyopathy onset by 18 years of age.
- Level C evidence: Deflazacort may be used for improving strength and timed motor function, as well as delaying age at loss of ambulation by 1.4 to 2.5 years. Additionally, deflazacort may be used for improving pulmonary function, reducing the need for scoliosis surgery, delaying cardiomyopathy onset, and increasing survival at 5 to 15 years of follow-up.
- Level C evidence: Prednisone may be associated with greater weight gain in the first years of treatment than deflazacort.

The AAN found that prednisone may be associated with increased weight gain in the first years of treatment compared with deflazacort. Deflazacort may be associated with increased risk of cataracts compared with prednisone (Level C evidence). The guidelines do not recommend one corticosteroid over the other.

‡ Level A = Established as effective, ineffective, or harmful; Level B = Probably effective, ineffective, or harmful; Level C = Possibly effective, ineffective, or harmful; Level U = Data inadequate or conflicting

Recommendations

The College of Pharmacy recommends the prior authorization of Emflaza® (deflazacort) with the following criteria:

Emflaza® (Deflazacort) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD); and
2. Member must be 5 years of age or older; and
3. Emflaza® must be prescribed by or in consultation with a prescriber who specializes in the treatment of DMD; and
4. A patient-specific, clinically significant reason why the member cannot use prednisone even when the tablets are crushed must be provided; and
5. Patients already established on deflazacort via the ACCESS DMD Program must also document a patient-specific, clinically significant reason why the member cannot use prednisone even when the tablets are crushed; and
6. For Emflaza® suspension, a patient-specific, clinically significant reason why the member cannot use the tablet formulation in the place of oral suspension even when the tablets are crushed must be provided; and
7. For continued authorization, the member's recent weight must be provided in order to authorize the appropriate amount of drug required according to package labeling.
8. For the tablets, a quantity limit of 30 tablets per 30 days will apply and for the suspension, a quantity limit of 39mL (3 bottles) per 30 days will apply. Quantity limit requests will be based on the member's recent weight taken within the last 30 days.

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- ¹ U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Last revised 09/2017. Last accessed 10/17/2017.
- ² Johnson CY. Lawmakers slam new \$89,000 price tag on rare disease treatment: 'Unconscionable.' *The Washington Post*. Available online at: https://www.washingtonpost.com/news/wonk/wp/2017/02/13/outrage-over-a-drug-price-controversy-is-building-in-congress-again/?utm_term=.9f66dae0bd8d. Issued 02/13/2017. Last accessed 11/02/2017.
- ³ PTC Therapeutics, Inc. PTC Therapeutics Announces Agreement to Acquire Emflaza™ for the Treatment of Duchenne Muscular Dystrophy in U.S. *PR Newswire*. Available online at: <https://www.prnewswire.com/news-releases/ptc-therapeutics-announces-agreement-to-acquire-emflaza-for-the-treatment-of-duchenne-muscular-dystrophy-in-us-300424705.html>. Issued 03/16/2017. Last accessed 11/02/2017.
- ⁴ Akashi Therapeutics. Akashi Therapeutics Receives FDA Clearance to Resume HT-100 Clinical Development. Available online at: <https://akashirx.com/news/akashi-therapeutics-receives-fda-clearance-resume-ht-100-clinical-development/>. Issued 03/22/2017. Last accessed 10/26/2017.
- ⁵ Bristol-Myers Squibb: Press Release. Bristol-Myers Squibb Enters into Separate Agreements with Biogen and Roche to License Anti-eTau and Anti-Myostatin Compounds, Respectively. Available online at: <https://news.bms.com/press-release/partnering-news/bristol-myers-squibb-enters-separate-agreements-biogen-and-roche-licen>. Issued 04/13/2017. Last accessed 10/26/2017.
- ⁶ Sagonowsky E. How low does DMD med Emflaza's price need to go? PTC hopes \$35,000 is low enough. *FiercePharma*. Available online at: <http://www.fiercepharma.com/pharma/ptc-therapeutics-set-for-emflaza-launch-35-000-price-tag>. Issued 05/08/2017. Last accessed 11/02/2017.
- ⁷ Sarepta Therapeutics. Sarepta Therapeutics Announces Positive Results in Its Study Evaluating Gene Expression, Dystrophin Production, and Dystrophin Localization in Patients with Duchenne Muscular Dystrophy (DMD) Amenable to Skipping Exon 53 Treated with Golodirsen (SRP-4053). *Globe Newswire*. Available online at: <https://globenewswire.com/news-release/2017/09/06/1108211/0/en/Sarepta-Therapeutics-Announces-Positive-Results-in-Its-Study-Evaluating-Gene-Expression-Dystrophin-Production-and-Dystrophin-Localization-in-Patients-with-Duchenne-Muscular-Dystrop.html>. Issued 09/06/2017. Last accessed 10/26/2017.
- ⁸ PTC Therapeutics, Inc. PTC Therapeutics Receives Complete Response Letter for Ataluren's NDA. *PR Newswire*. Available online at: <https://www.prnewswire.com/news-releases/ptc-therapeutics-receives-complete-response-letter-for-atalurens-nda-300543195.html>. Issued 10/25/2017. Last accessed 11/02/2017.
- ⁹ Akashi Therapeutics. Pipeline. Available online at: <https://akashirx.com/pipeline/>. Last accessed 10/26/2017.
- ¹⁰ Catabasis Pharmaceuticals. Our Pipeline. Available online at: <http://www.catabasis.com/technology-pipeline/our-pipeline.php>. Last accessed 10/26/2017.
- ¹¹ Mallinckrodt Pharmaceuticals. News Releases. Mallinckrodt Confirms License Transfer of Synacthen® Depot; Continues Development Efforts for MNK-1411 in Treatment of DMD. Available online at: <https://www.mallinckrodt.com/about/news-and-media/2286626>. Issued 07/16/2017. Last accessed 10/26/2017.
- ¹² Henriques C. Resolaris Improved Muscle Strength of Nearly Two-thirds of FSHD Patients, Phase 1/2 Trial Shows. *Muscular Dystrophy News Today*. Available online at: <https://muscular dystrophynews.com/tag/resolaris/>. Issued 10/10/2017. Last accessed 10/26/2017.
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Appendix I



Fiscal Year 2017 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)

Oklahoma Health Care Authority
December 2017

Current Prior Authorization Criteria

Inhaled Corticosteroids (ICS) and ICS/Long-Acting Beta ₂ Agonists (LABA) Combination Products	
Tier-1	Tier-2
beclomethasone dipropionate (QVAR®)	budesonide/formoterol (Symbicort®)
budesonide (Pulmicort®)	fluticasone furoate (Arnuity® Ellipta®)
ciclesonide (Alvesco®)	fluticasone furoate/vilanterol (Breo® Ellipta®)
flunisolide (Aerospan®)	
fluticasone propionate (Flovent®)	
fluticasone/salmeterol (Advair®)	
mometasone/formoterol (Dulera® HFA)	
mometasone furoate (Asmanex®)	

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

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

Symbicort® (Budesonide/Formoterol) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD) or asthma; and
2. For a diagnosis of COPD, failure of Advair® (fluticasone/salmeterol) or a reason why Advair® is not appropriate for the member; and
3. For a diagnosis of asthma the following must be met:
 - a. Member must be at or above the minimum age indicated; and
 - b. Failure of both Advair® and Dulera® or a reason why Advair® and Dulera® are not appropriate for the member; and
 - c. Member must have used an inhaled corticosteroid for at least one month immediately prior; and
 - d. Member must be considered uncontrolled by provider [required rescue medication >2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids]; or

- e. A clinical situation warranting initiation with combination therapy due to severity of asthma.

Arnuity® Ellipta® (Fluticasone Furoate) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 12 years of age or older; and
3. A patient-specific, clinically significant reason why Flovent® (fluticasone propionate) is not appropriate for the member.

Breo® Ellipta® (Fluticasone Furoate/Vilanterol) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD) or chronic bronchitis and/or emphysema associated with COPD; and
 - a. For a diagnosis of COPD or chronic bronchitis and/or emphysema associated with COPD, trials of Advair® and Symbicort®, consisting of at least 30 days each within the last 90 days that did not adequately control COPD symptoms; or
2. An FDA approved diagnosis of asthma in patients 18 years of age and older; and
 - a. For a diagnosis of asthma, trials of Advair® and Dulera®, consisting of at least 30 days each within the last 90 days that did not adequately control asthma symptoms.

Long-Acting Beta ₂ Agonists (LABA) and Long-Acting Muscarinic Antagonists (LAMA)	
Tier-1	Tier-2
LABA Products*	
salmeterol inhalation powder (Serevent®)	arformoterol nebulizer solution (Brovana®)
	formoterol nebulizer solution (Perforomist®)
	indacaterol inhalation powder (Arcapta® Neohaler®)
	olodaterol inhalation spray (Striverdi® Respimat®)
LAMA Products	
tiotropium inhalation powder (Spiriva®)	aclidinium inhalation powder (Tudorza® PressAir®)
	glycopyrrloate inhalation powder (Seebri™ Neohaler®)
	tiotropium soft mist inhaler (Spiriva® Respimat®) [†]
	umeclidinium inhalation powder (Incruse® Ellipta®)

*Combination products that contain a Tier-1 ingredient qualify as Tier-1 agents (e.g., Advair®)

[†]Unique criteria applies for a diagnosis of asthma.

Tier-1 medications do not require prior authorization.

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

Long-Acting Beta₂ Agonists (LABA) and Long-Acting Muscarinic Antagonist (LAMA) Tier-2 Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD), chronic bronchitis, or emphysema; and
3. A four week trial of at least one LABA and a four week trial of one LAMA within the past 90 days; or

4. A documented adverse effect, drug interaction, or contraindication to all available Tier-1 products; or
5. A clinical exception may apply for members who are unable to effectively use hand-actuated devices, such as Spiriva® Handihaler®, or who are stable on nebulized therapy.

Spiriva® RespiMat® (Tiotropium Bromide Soft Mist Inhaler) Approval Criteria [Asthma Diagnosis]:

1. Member must have an FDA approved diagnosis of asthma; and
2. Member must be 6 years of age or older; and
3. Member must have used a high-dose inhaled corticosteroid and long-acting beta₂ agonist (ICS/LABA) product for at least one month immediately prior to request for authorization; and
4. Member must have had a trial of a leukotriene receptor antagonist for at least one month in the last 90 days; and
5. Member must have a history of exacerbations despite required trials; and
6. Member must remain on an ICS or ICS/LABA while on tiotropium therapy; and
7. Member meets one of the following:
 - a. Member's asthma must be considered uncontrolled by prescriber:
 - i. Member requires rescue inhaler more than two days per week for reasons other than prevention of exercise induced bronchospasms; or
 - ii. Member requires oral systemic corticosteroids; or
 - b. A clinical situation warranting initiation of tiotropium therapy in addition to an ICS/LABA due to severity of asthma; and
8. A patient-specific, clinically significant reason the member is unable to use Spiriva® Handihaler® (tiotropium) which does not require prior authorization.

Anoro® Ellipta® (Umeclidinium/Vilanterol), Bevespi Aerosphere® (Glycopyrrolate/Formoterol Fumarate), Stiolto® RespiMat® (Tiotropium/Olodaterol), and Utibron™ Neohaler® (Indacaterol/Glycopyrrolate) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
3. A patient-specific, clinically significant reason why the member cannot use Tier-1 long-acting beta₂ agonist (LABA) and long-acting muscarinic antagonist (LAMA) individual components.

Daliresp® (Roflumilast) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD) with history of chronic bronchitis; and
2. Forced expiratory volume (FEV) less than or equal to 50% of predicted; and
3. Member is inadequately controlled on long-acting bronchodilator therapy (must have three or more claims for long-acting bronchodilators in the previous six months).

Nucala® (Mepolizumab Injection) Approval Criteria:

1. An FDA approved indication for add-on maintenance treatment of patients with severe eosinophilic phenotype asthma; and
2. Member must be age 12 years or older; and

3. Member must have a baseline blood eosinophil count of 150 cell/mcL or greater within the last six weeks of initiation of dosing; and
4. Member must have had at least two asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of high-dose inhaled corticosteroid (ICS) plus at least one additional controller medication; and
5. Member must have failed a high-dose ICS (≥ 880 mcg/day fluticasone propionate or equivalent daily dose or ≥ 440 mcg/day in ages 12 to 17 years) used compliantly for at least the past 12 months (for ICS/LABA combination products, the highest approved dose meets this criteria); and
6. Member must have failed at least one other asthma controller medication used in addition to the high-dose ICS compliantly for at least the past three months; and
7. Nucala[®] must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last twelve months (or be an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
8. Initial approvals will be for the duration of six months after which time compliance will be evaluated for continued approval; and
9. A quantity limit of 1 vial per 28 days will apply.

Cinqair[®] (Reslizumab) Approval Criteria:

1. An FDA approved indication of add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype; and
2. Member must be 18 years of age or older; and
3. Member must have a blood eosinophil count of at least 400cell/mcL (within three to four weeks of dosing); and
4. Member must have had at least two asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of high-dose inhaled corticosteroid (ICS) plus at least one additional controller medication; and
5. Member must have failed a high-dose ICS (≥ 880 mcg/day fluticasone propionate or equivalent daily dose or ≥ 440 mcg/day in ages 12 to 17 years) used compliantly for at least the past 12 months (for ICS/LABA combination medications, the highest approved dose meets this criteria); and
6. Member must have failed at least one other asthma controller medication used in addition to the high-dose ICS compliantly for at least the past three months; and
7. Cinqair[®] must be administered in a healthcare setting by a healthcare professional prepared to manage anaphylaxis; and
8. Cinqair[®] must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last twelve months (or be an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
9. Initial approvals will be for the duration of six months after which time compliance will be evaluated for continued approval; and

10. Member's weight should be provided on prior authorization requests. Weights should have been taken within the last four weeks to provide accurate weight-based dosing.

Xolair® (Omalizumab) Approval Criteria [Asthma Diagnosis]:

1. Member must have a diagnosis of severe persistent asthma [as per National Asthma Education and Prevention Program (NAEPP) guidelines]; and
2. Member must be between 6 and 75 years of age; and
3. Member must have a positive skin test to at least one perennial aeroallergen. Positive perennial aeroallergens must be listed on the prior authorization request; and
4. Member must have a pretreatment serum IgE level between 30 and 1,300 IU/mL (depending on member age); and
5. Member's weight must be between 20kg and 150kg; and
6. Member must have been on high-dose inhaled corticosteroids (ICS) (≥ 880 mcg/day fluticasone propionate or equivalent daily dose or ≥ 440 mcg/day in ages 12 to 17 years) for at minimum the past three months; and
7. Prescribed Xolair® dose must be an FDA approved regimen per Xolair® prescribing information; and
8. Xolair® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last twelve months (or be an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
9. Member must have been in the emergency room (ER) or hospitalized, due to an asthma exacerbation, twice in the past 12 months (date of visits must be listed on the prior authorization request), or member must have been determined to be dependent on systemic corticosteroids to prevent serious exacerbations; and
10. Both the prior authorization request form and statement of medical necessity form must be submitted for processing; and
11. Initial approvals will be for the duration of six months after which time compliance will be evaluated for continued approval.

Xolair® (Omalizumab) Approval Criteria [Chronic Idiopathic Urticaria Diagnosis]:

1. An FDA approved diagnosis of chronic idiopathic urticaria; and
2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Other potential causes of urticaria must be ruled out; and
5. Member must have an Urticaria Activity Score (UAS) greater than or equal to 16; and
6. Prescriber must be an allergist, immunologist, dermatologist, or be an advanced care practitioner with a supervising physician that is an allergist, immunologist, or dermatologist; and
7. Member must have tried and failed to obtain relief from other treatments including the following trials within the last six months (member must fail all classes unless contraindicated):
 - a. At least two different H₁-antihistamine trials for a minimum duration of two weeks each:

- i. One trial must be a second generation antihistamine dosed four times the maximum FDA dose; and
- ii. One trial must be tried in combination with an H₂-antihistamine; and
- b. A 4-week trial of a leukotriene receptor antagonist in combination with a 4-week trial of doxepin 10mg to 50mg daily; and
8. Initial dosing will only be approved for 150mg every four weeks. If the member has inadequate results at this dose, then the dose may be increased to 300mg every four weeks.
9. Initial approvals will be for the duration of 3 months.

Utilization of Maintenance Asthma and COPD Medications: Fiscal Year 2017

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2016	6,348	30,441	\$10,002,333.36	\$328.58	\$10.75	990,741	930,717
2017	7,348	32,349	\$11,073,368.79	\$342.31	\$11.20	1,041,548	988,899
% Change	15.80%	6.30%	10.70%	4.20%	4.20%	5.10%	6.30%
Change	1,000	1,908	\$1,071,035.43	\$13.73	\$0.45	50,807	58,182

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Data excludes monoclonal antibodies and monotherapy inhaled corticosteroids (see end of report for details).

Comparison of Fiscal Years: Monoclonal Antibodies[¥]

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2016	17	82	\$293,332.51	\$3,577.23	\$127.65	318	2,298
2017	25	99	\$410,260.58	\$4,144.05	\$148.00	418	2,772
% Change	47.10%	20.70%	39.90%	15.80%	15.90%	31.40%	20.60%
Change	8	17	\$116,928.07	\$566.82	\$20.35	100	474

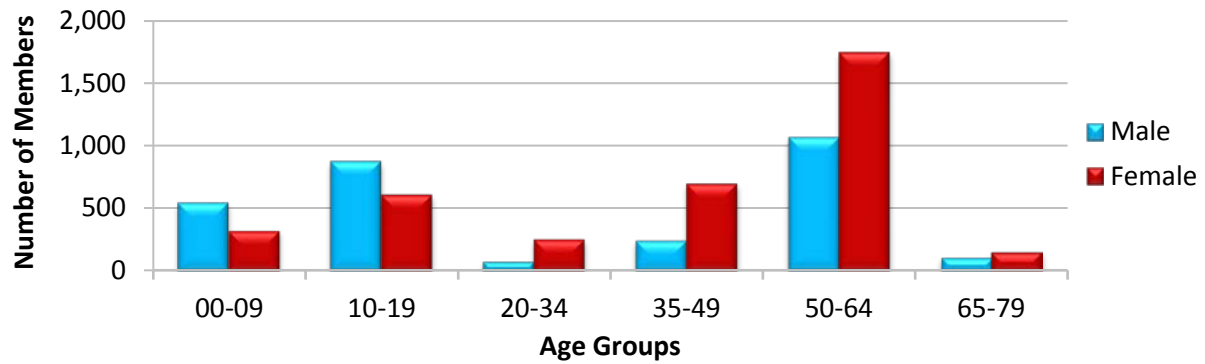
[¥]Pharmacy claims data only.

*Total number of unduplicated members.

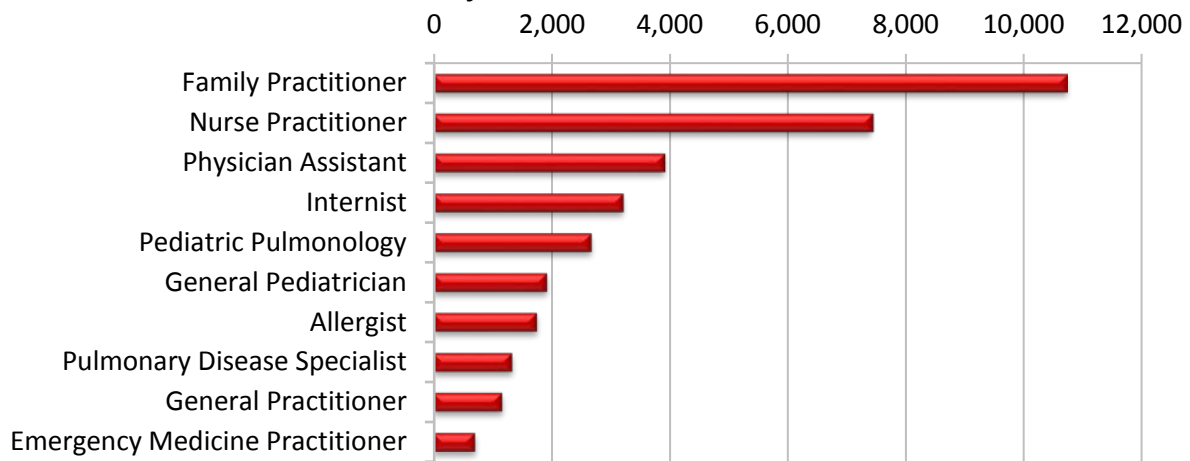
Costs do not reflect rebated prices or net costs.

- Please note Cinqair[®] (reslizumab) is billed by medical claims only and not reflected in the above pharmacy claims data; however, there were no paid medical claims for Cinqair[®] (reslizumab) or Nucala[®] (mepolizumab) during fiscal year 2017. Xolair[®] (omalizumab) medical claims utilization details can be found at the end of this report.

Demographics of Members Utilizing Maintenance Asthma and COPD Medications



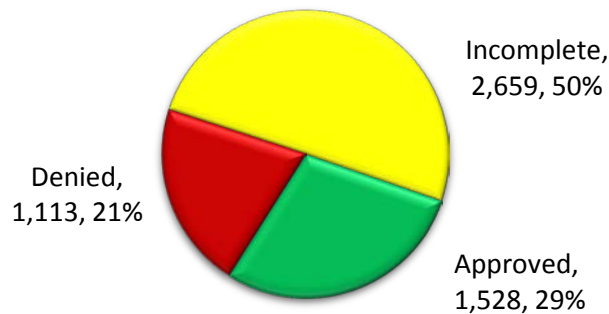
Top Prescriber Specialties of Maintenance Asthma and COPD Medications by Number of Claims



Prior Authorization of Maintenance Asthma and COPD Medications

There were 5,300 prior authorization requests submitted for maintenance asthma and COPD medications during fiscal year 2017. Of those prior authorization requests, 148 were submitted for monoclonal antibody medications. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions



Anticipated Patent Expiration(s):

- Dulera[®] (mometasone/formoterol inhalation aerosol): May 2020
- Foradil[®] (formoterol aerosolized powder): November 2020; discontinued from market
- Perforomist[®] (formoterol nebulizer solution): June 2021
- Brovana[®] (arformoterol nebulizer solution): November 2021
- Daliresp[®] (roflumilast oral tablet): March 2024
- Tudorza[®] PressAir[®] (aclidinium inhalation powder): April 2027
- Arcapta[®] Neohaler[®] (indacaterol inhalation powder): October 2028
- Seebri[™] Neohaler[®] (glycopyrrolate inhalation powder): October 2028
- Utibron[™] Neohaler[®] (indacaterol/glycopyrrolate inhalation powder): October 2028
- Symbicort[®] (budesonide/formoterol inhalation aerosol): October 2029
- Spiriva[®] HandiHaler[®] (tiotropium inhalation powder): April 2030
- Striverdi[®] Respimat[®] (olodaterol inhalation spray): October 2030
- Stiolto[®] Respimat[®] (tiotropium bromide/olodaterol inhalation spray): October 2030
- Breo[®] Ellipta[®] (fluticasone furoate/vilanterol inhalation powder): October 2030
- Incruse[®] Ellipta[®] (umeclidinium inhalation powder): October 2030
- Arnuity[®] Ellipta[®] (fluticasone furoate inhalation powder): October 2030
- Anoro[®] Ellipta[®] (umeclidinium/vilanterol inhalation powder): November 2030
- Bevespi Aerosphere[®] (glycopyrrolate/formoterol fumarate inhalation aerosol): March 2031
- Spiriva[®] Respimat[®] (tiotropium soft mist inhaler): April 2031

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

- **January 2017:** AirDuo[™] RespiClick[®] (fluticasone propionate/salmeterol inhalation powder)
- **January 2017:** ArmonAir[™] RespiClick[®] (fluticasone propionate inhalation powder)
- **August 2017:** Qvar[®] RediHaler[™] (beclomethasone dipropionate HFA inhalational aerosol)
- **September 2017:** Trelegy[™] Ellipta[®] (fluticasone furoate/umeclidinium/vilanterol inhalation powder)
- **November 2017:** Fasentra[™] (benralizumab injection)

New Indication(s):

- **January 2017:** The FDA approved Symbicort[®] (budesonide/formoterol fumarate dehydrate inhalation aerosol 80/4.5mcg) for the treatment of asthma in pediatric patients 6 years of age and older. Symbicort[®] 80/4.5mcg and 160/4.5mcg were previously approved to treat asthma in patients 12 years of age and older. Symbicort[®] 160/4.5mcg is also approved for the maintenance treatment of airflow obstruction in COPD in adults.
- **February 2017:** The FDA expanded approval of Spiriva[®] Respimat[®] (tiotropium bromide inhalation spray) for the maintenance treatment of asthma in patients 6 years of age and older. Spiriva[®] Respimat[®] was approved in September 2015 for the long-term, once-daily, prescription maintenance treatment of asthma in patients 12 years of age

and older. The FDA approved the supplemental New Drug Application (sNDA) under a priority review designation, and the FDA also granted pediatric exclusivity to Spiriva® Respimat® in light of the clinical trials conducted by Boehringer Ingelheim.

Pipeline:

- **March 2017:** Mylan received a Complete Response Letter (CRL) rejection from the FDA in response to its Abbreviated New Drug Application (ANDA) for a generic version of Advair Diskus® (fluticasone propionate/salmeterol) and has since removed the product from its 2017 guidance.
- **May 2017:** Sunovion Pharmaceuticals received a CRL from the FDA in response to its New Drug Application (NDA) for its COPD treatment candidate SUN-101/eFlow (glycopyrrolate), a LAMA bronchodilator, delivered via the proprietary investigational eFlow closed system nebulizer. Sunovion notes the CRL does not require any additional clinical studies and will work with the FDA to determine the appropriate path forward.
- **May 2017:** Hikma Pharmaceuticals and Vectura received a CRL rejection from the FDA in response to its ANDA for a generic version of Advair® Diskus® (fluticasone propionate/salmeterol) including issues with the clinical endpoint study.
- **June 2017:** The FDA accepted an ANDA for a generic version of Advair® Diskus® (fluticasone propionate/salmeterol) from Novartis' Sandoz.
- **July 2017:** Theravance Biopharma and Mylan announced revefenacin (TD-4208) has shown promise in a Phase 3 clinical trial enrolling 1,055 COPD patients to investigate the safety and tolerability of two revefenacin doses (88mcg or 175mcg once daily via a nebulizer) for 12 months compared to the standard of care with tiotropium. About half of the enrollees in the study were concurrently receiving treatment with other COPD therapies, including LABA or LABA/ICS. Revefenacin, an investigational LAMA and the first once-daily nebulized bronchodilator in development to treat COPD, will be compatible with a range of jet nebulizers. The companies plan to reveal the detailed results of the study at future scientific meetings, but stated both treatment doses caused fewer adverse side effects in comparison with tiotropium, the standard of care. Previous studies have shown that treatment with revefenacin once daily (either 88mcg or 175mcg) provided improved lung function, assessed by forced expiratory volume in one second (FEV₁), compared to placebo. An NDA was submitted to the FDA in November 2017 for revefenacin for the treatment of COPD.
- **September 2017:** Amgen and AstraZeneca announced results from the PATHWAY Phase 2b trial of tezepelumab, a novel anti-thymic stromal lymphopoietin (TSLP) monoclonal antibody that showed a significant reduction in the annual asthma exacerbation rate compared with placebo in patients with severe, uncontrolled asthma. The PATHWAY trial achieved its primary efficacy endpoint, showing annual asthma exacerbation rate reductions of 61%, 71%, and 66% in the tezepelumab arms receiving either 70mg or 210mg every four weeks or 280mg every two weeks, respectively (p<0.001 for all comparisons to placebo). In the trial, tezepelumab was given as an add-on therapy to patients with a history of asthma exacerbations and uncontrolled asthma despite receiving ICS/LABA with or without oral corticosteroids and additional asthma controllers. Significant and clinically meaningful reductions in the exacerbation rate

were observed independent of baseline blood eosinophil count or other type two inflammatory biomarkers.

- **September 2017:** AstraZeneca announced positive top-line results from the Phase 3 AMPLIFY trial for Duaklir® (aclidinium bromide/formoterol 400mcg/12mcg) twice daily. Duaklir® met its primary endpoints, demonstrating a statistically-significant improvement in lung function in patients with moderate-to-very-severe stable COPD compared to each individual component. Additionally, aclidinium bromide achieved its primary bronchodilation endpoint of demonstrating non-inferiority to tiotropium bromide 18mcg once-daily. A full evaluation of the AMPLIFY data is ongoing and AstraZeneca is expected to submit an NDA during the first half of 2018 to the FDA based on the AMPLIFY data.
- **September 2017:** Dupixent® (dupilumab) injection, which was FDA approved in March 2017 to treat adults with moderate-to-severe eczema (atopic dermatitis), met its two primary endpoints in a late-stage, Phase 3 trial in patients with uncontrolled, persistent asthma. The trial, involving 1,902 patients, reduced the frequency of severe asthma attacks by 46% in the group overall and by 60% to 67% in patients with high levels of eosinophilic cells. Sanofi announced they expect to submit an application into the FDA by the end of 2017.

Guideline Update(s):

- **January 2017:** The Global Initiative for Obstructive Lung Disease (GOLD) released the 2017 report, which refined the ABCD severity grading system that separates spirometric grades and is derived exclusively from patient symptoms and history of exacerbations. The 2017 GOLD guidelines advise pharmacotherapy recommendations for COPD patients according to the ABCD assessment tool. The updated guidelines also generally advise against the routine use of supplemental oxygen to stable COPD patients without severe resting hypoxemia, however; individual patient factors may be considered when evaluating a patient's need for supplemental oxygen.

ArmonAir™ RespiClick® (Fluticasone Propionate Inhalation Powder) Product Summary^{22,23}

Indication(s): ArmonAir™ RespiClick® (fluticasone propionate inhalation powder) is an ICS indicated for maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older.

- Limitation of Use: ArmonAir™ RespiClick® is not indicated for the relief of acute bronchospasm.

Dosing:

- ArmonAir™ RespiClick® is supplied as an inhalation powder aerosol containing 55mcg, 113mcg, or 232mcg of fluticasone propionate per actuation.
- ArmonAir™ RespiClick® is for oral inhalation only. The starting dose is based on prior asthma therapy and disease severity.
- The recommended dose is one inhalation twice daily.
- The ArmonAir™ RespiClick® inhaler should not be used with a spacer or volume holding chamber.

Contraindication(s):

- Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required
- Hypersensitivity to any of the ingredients of ArmonAir™ RespiClick®

Adverse Reactions: The most common adverse reactions (reported in ≥3% of subjects) are nasopharyngitis, upper respiratory tract infection, oral candidiasis, headache, and cough.

Efficacy: The safety and efficacy of ArmonAir™ RespiClick® were evaluated in 2,130 patients with asthma. The development program included two confirmatory trials of 12 weeks duration (Trial 1 and Trial 2), a 26-week safety trial, and two dose-ranging trials. Compared to placebo, ArmonAir™ RespiClick® showed clinically relevant and greater benefit in the improvement of lung function, as measured by FEV₁, demonstrating efficacy.

- In Trial 1, patients receiving ArmonAir™ RespiClick® 55mcg and ArmonAir™ RespiClick® 113mcg had significantly greater improvements in trough FEV₁ [ArmonAir™ RespiClick® 55mcg, least square (LS) mean change of 0.172 L at 12 weeks and ArmonAir™ RespiClick® 113mcg, LS mean change of 0.204 L at 12 weeks] compared with placebo (LS mean change of 0.053 L at 12 weeks). The estimated mean differences in trough FEV₁ between ArmonAir™ RespiClick® 55mcg and ArmonAir™ RespiClick® 113mcg compared to placebo are 0.119 L (95% CI: 0.025, 0.212) and 0.151 L (95% CI: 0.057, 0.244), respectively.
- In Trial 2, the efficacy results were similar to those observed in Trial 1. Patients receiving ArmonAir™ RespiClick® 113mcg and ArmonAir™ RespiClick® 232mcg had significantly greater improvements in trough FEV₁ (ArmonAir™ RespiClick® 113mcg, LS mean change of 0.119 L at 12 weeks and ArmonAir™ RespiClick® 232mcg, LS mean change of 0.179 L at 12 weeks) compared with placebo (LS mean change of -0.004 L at 12 weeks). The estimated mean differences in trough FEV₁ between ArmonAir™ RespiClick® 113mcg and ArmonAir™ RespiClick® 232mcg compared to placebo are 0.123 L (95% CI: 0.038, 0.208) and 0.183 L (95% CI: 0.098, 0.268), respectively.

Cost Comparison:

Medication	Cost Per Inhaler	Cost Per Year
ArmonAir™ RespiClick® (fluticasone propionate) 55mcg	\$156.74	\$1,880.88
ArmonAir™ RespiClick® (fluticasone propionate) 113mcg & 232mcg	\$209.87	\$2,518.44
Flovent® Diskus® (fluticasone propionate) 50mcg	\$156.60	\$1,879.20
Flovent® Diskus® (fluticasone propionate) 100mcg	\$164.40	\$1,972.80
Flovent® Diskus® (fluticasone propionate) 250mcg	\$220.20	\$2,642.40

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

Trelegy™ Ellipta® (Fluticasone Furoate/Umeclidinium/Vilanterol Inhalation Powder) Product Summary^{24,25}

Indication(s): Trelegy™ Ellipta® (fluticasone furoate/umeclidinium/vilanterol inhalation powder) is a combination of fluticasone furoate, an ICS, umeclidinium, a LAMA, and vilanterol, a

LABA, indicated for the long-term, once-daily, maintenance treatment of patients with COPD, including chronic bronchitis and/or emphysema, who are on a fixed-dose combination of fluticasone furoate and vilanterol for airflow obstruction and reducing exacerbations in whom additional treatment of airflow obstruction is desired or for patients who are already receiving umeclidinium and a fixed-dose combination of fluticasone furoate and vilanterol.

- **Limitation of Use:** Trelegy™ Ellipta® is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

Dosing:

- Trelegy™ Ellipta® is supplied as an inhalation powder containing two foil blister strips of powder formulation for oral inhalation. One strip contains fluticasone furoate 100mcg per blister and the other contains umeclidinium/vilanterol 62.5mcg/25mcg per blister.
- The recommended regimen for the maintenance treatment of COPD is one oral inhalation once daily.

Contraindication(s):

- Severe hypersensitivity to milk proteins or any ingredients of Trelegy™ Ellipta®

Adverse Reactions: The most common adverse reactions (incidence ≥1%) are headache, back pain, dysgeusia, diarrhea, cough, oropharyngeal pain, and gastroenteritis.

Efficacy: The efficacy of Trelegy™ Ellipta® is based primarily on the co-administration of umeclidinium 62.5mcg and fluticasone furoate/vilanterol 100mcg/25mcg in two 12-week treatment studies. Comparative *in vitro* data provide support for reliance on co-administration studies with umeclidinium and fluticasone furoate/vilanterol. The primary endpoint was the change from baseline in trough FEV₁ at day 85.

- For both studies, umeclidinium and fluticasone furoate/vilanterol demonstrated a statistically significant increase in FEV₁ vs. placebo and fluticasone furoate/vilanterol.
- The confirmatory trials did not evaluate the effect of umeclidinium and fluticasone furoate/vilanterol on the rate of COPD exacerbations. However, the contribution of fluticasone furoate to fluticasone furoate/vilanterol 100mcg/25mcg on COPD exacerbations was evaluated in two 52-week trials that evaluated fluticasone furoate/vilanterol 100mcg/25mcg vs. vilanterol 25mcg monotherapy. Fluticasone furoate/vilanterol was associated with a reduction in the mean annual rate of moderate and severe COPD exacerbations: ratio vs. vilanterol in the first trial = 0.79 (95% CI: 0.64, 0.97), ratio vs. vilanterol 25mcg in the second trial = 0.66 (95% CI: 0.54, 0.81).

Cost Comparison:

Medication	Cost Per Inhaler	Cost Per Year
Trelegy™ Ellipta® (fluticasone furoate/umeclidinium/vilanterol) 100mcg/62.5mcg/25mcg	\$529.80	\$6,357.60
Breo® Ellipta® (fluticasone furoate/vilanterol) 100mcg/25mcg	\$309.60	\$3,715.20
Incruse® Ellipta® (umeclidinium) 62.5mcg	\$311.10	\$3,733.20
Flovent® Diskus® (fluticasone propionate powder) 100mcg	\$164.40	\$1,972.80

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.

Qvar[®] RediHaler[™] (Beclomethasone Dipropionate HFA) Product Summary^{26,27,28}

Indication(s): Qvar[®] RediHaler[™] (beclomethasone dipropionate HFA) is an ICS indicated for maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older.

- **Limitation of Use:** Qvar[®] RediHaler[™] is not indicated for the relief of acute bronchospasm.

Dosing:

- Qvar[®] RediHaler[™] is supplied as a breath-actuated inhalation aerosol containing either 40mcg or 80mcg per actuation.
- Qvar[®] RediHaler[™] is for oral inhalation only. The starting dose is based on prior asthma therapy and disease severity.
- The recommended dose for patients 4 to 11 years of age is 40mcg or 80mcg twice daily. The recommended dose in patients 12 years of age and older is 40mcg, 80mcg, 160mcg, or 320mcg twice daily.
- Qvar[®] RediHaler[™] inhaler should be discarded when the dose counter displays zero or after the expiration date on the product, whichever comes first.
- A spacer or volume holding chamber should not be used with Qvar[®] RediHaler[™].

Contraindication(s):

- Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required
- Hypersensitivity to any of the ingredients of Qvar[®] RediHaler[™]

Adverse Reactions: The most common adverse reactions (incidence $\geq 3\%$ and greater than placebo) include oral candidiasis, upper respiratory tract infection, nasopharyngitis, allergic rhinitis, oropharyngeal pain, and sinusitis.

Efficacy: The efficacy and safety of Qvar[®] RediHaler[™] were evaluated in two placebo-controlled studies in 695 patients 12 years of age and older and one placebo-controlled study in 568 patients 4 to 11 years of age. The primary endpoint for all three studies was the standardized baseline-adjusted trough morning FEV₁ area under the effect curve.

- In Trial 1, patients in both treatment groups had significantly greater improvements in trough FEV₁ vs. placebo [80mcg/day, LS mean change of 0.124 L (95% CI: 0.054, 0.193), 160mcg/day, LS mean change of 0.116 L (95% CI: 0.048, 0.185)].
- In Trial 2, patients in both treatment groups had significantly greater improvements in trough FEV₁ vs. placebo [320mcg/day, LS mean change of 0.144 L (95% CI: 0.0807, 0.2066), 640mcg/day, LS mean change of 0.150 L [95% CI: 0.0868, 0.2132]]. Treatment with Qvar[®] inhalation aerosol was similar to Qvar[®] RediHaler[™] [LS mean change of 0.148 L (95% CI: 0.0847, 0.2114)].
- In the pediatric study evaluating patients 4 to 11 years of age, the primary endpoint was not statistically significant. However, change in weekly average of daily morning peak expiratory flow (L/min) was 11.3 (95% CI: 5.58, 17.06) and 8.5 (95% CI: 2.71, 14.24) for the 80mcg/day and 160mcg/day doses, respectively, at nominal significance.

Availability: Qvar® RediHaler™ (beclomethasone dipropionate HFA) is currently unavailable with an anticipated launch date during the first quarter of 2018. Qvar® MDI (beclomethasone dipropionate HFA) with dose counter, the currently available form of Qvar® approved by the FDA in 2014, will be discontinued upon the launch of Qvar® RediHaler™.

Cost Comparison:

Medication	Cost Per Inhaler	Cost Per Year
Qvar® RediHaler™ (beclomethasone dipropionate HFA) 80mcg	\$209.87	\$2,518.44 - \$5,036.88
Qvar® RediHaler™ (beclomethasone dipropionate HFA) 40mcg	\$156.74	\$1,880.88
Qvar® MDI (beclomethasone dipropionate HFA) 40mcg and 80mcg	\$201.49	\$2,417.90

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.

**AirDuo™ RespiClick® (Fluticasone Propionate/Salmeterol Inhalation Powder)
Product Summary^{29,30}**

Indication(s): AirDuo™ RespiClick® (fluticasone propionate/salmeterol inhalation powder) is a fixed dose combination product containing an ICS and a LABA indicated for the treatment of asthma in patients 12 years of age and older.

- Limitation of Use: AirDuo™ RespiClick® is not indicated for the relief of acute bronchospasm.

Dosing:

- AirDuo™ RespiClick® is supplied as an inhalation powder containing fluticasone propionate 55mcg, 113mcg, or 232mcg and salmeterol 14mcg per actuation.
- AirDuo™ RespiClick® is for oral inhalation only. The starting dose is based on prior asthma therapy and disease severity.
- The recommended dose is one inhalation twice daily.
- The AirDuo™ RespiClick® inhaler should not be used with a spacer or volume holding chamber.

Contraindication(s):

- Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required
- Severe hypersensitivity to any of the ingredients of AirDuo™ RespiClick®

Adverse Reactions: The most common adverse reactions (reported in ≥3% of patients) include nasopharyngitis, oral candidiasis, back pain, headache, and cough.

Launch Information: Teva simultaneously launched AirDuo™ RespiClick® and an authorized generic fluticasone propionate/salmeterol inhalation powder and expects that sales of the authorized generic will represent most of the sales of the two products.

Efficacy: The safety and efficacy of AirDuo™ RespiClick® were evaluated in 3,004 asthmatic patients. The development program included two confirmatory trials of 12 weeks duration, a 26-week safety trial, and three dose-ranging trials. Compared to placebo, AirDuo™ RespiClick®

showed clinically relevant and greater benefit in the improvement of lung function, as measured by FEV₁, demonstrating efficacy of AirDuo™ RespiClick® in the dose-ranging trials and confirmatory trials. AirDuo™ RespiClick® compared to ArmonAir™ RespiClick® (fluticasone propionate inhalation powder) had significantly greater improvements in FEV₁ at 12 weeks in two trials. The estimated mean difference between AirDuo™ RespiClick® 113mcg/14mcg and ArmonAir™ RespiClick® 113mcg was 0.111 L (95% CI: 0.017, 0.206) and the estimated mean difference between AirDuo™ RespiClick® 55mcg/14mcg and ArmonAir™ RespiClick® 55mcg was 0.147 L (95% CI: 0.053, 0.242) in Trial 1. The efficacy results in Trial 2 were similar to those observed in Trial 1.

Cost Comparison:

Medication	Cost Per Month	Cost Per Year
AirDuo™ RespiClick® (fluticasone propionate/salmeterol) 55mcg/14mcg, 113mcg/14mcg, 232mcg/14mcg	\$285.00	\$3,420.00
fluticasone propionate/salmeterol 55mcg/14mcg, 113mcg/14mcg, 232mcg/14mcg	\$90.00	\$1,080.00
Advair Diskus® (fluticasone propionate/salmeterol) 100mcg/50mcg	\$279.60	\$3,355.20
Advair Diskus® (fluticasone propionate/salmeterol) 250mcg/50mcg	\$347.40	\$4,168.80
Advair Diskus® (fluticasone propionate/salmeterol) 500mcg/50mcg	\$457.20	\$5,486.40

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

Fasenra™ (Benralizumab Injection) Product Summary^{20,31}

Indication(s): Fasenra™ (benralizumab injection) is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa) indicated for the add-on maintenance treatment of patients with severe asthma 12 years of age and older, and with an eosinophilic phenotype.

- Limitations of Use:
 - Fasenra™ is not for the treatment of other eosinophilic conditions.
 - Fasenra™ is not for the relief of acute bronchospasm or status asthmaticus.

Dosing:

- Fasenra™ is supplied as a single-dose prefilled syringe containing 30mg benralizumab per 1mL.
- Fasenra™ should be administered via subcutaneous (SC) injection.
- The recommended dose is 30mg every 4 weeks for the first three doses, followed by 30mg every 8 weeks thereafter.

Contraindication(s):

- Known hypersensitivity to benralizumab or its excipients

Adverse Reactions: The most common adverse reactions (incidence ≥5%) include headache and pharyngitis.

Efficacy: The FDA approval of Fasentra™ is based on results from the WINDWARD program, including Phase 3 exacerbation trials, SIROCCO and CALIMA, and the Phase 3 oral corticosteroid (OCS)-sparing trial, ZONDA.

- Confirmatory trials SIROCCO and CALIMA (Trials 1 and 2) had inclusion criteria requiring patients to have a history of two or more asthma exacerbations requiring systemic corticosteroid treatment in the past 12 months and reduced lung function at baseline (prebronchodilator FEV₁ below 80% in adults, and below 90% in adolescents) despite regular treatment with high-dose ICS (Trial 1) or with medium or high dose ICS (Trial 2) plus a LABA with or without OCS and additional asthma controller medications. The primary endpoint for Trials 1 and 2 was the rate of asthma exacerbations in patients with baseline blood eosinophil counts ≥300 cells/μL who were taking high-dose ICS and LABA. In Trial 1, 35% of patients receiving Fasentra™ experienced an asthma exacerbation compared to 51% on placebo. In Trial 2, 40% of patients receiving Fasentra™ experienced an asthma exacerbation compared to 51% on placebo. Reductions in exacerbation rates were observed irrespective of baseline peripheral eosinophil counts; however, patients with a baseline blood eosinophil count ≥300 cells/μL showed a numerically greater response than those with counts <300 cells/μL. In both trials, patients with a history of three or more exacerbations within the 12 months prior to Fasentra™ randomization showed a numerically greater exacerbation response than those with fewer prior exacerbations.
- The ZONDA trial (Trial 3) required treatment with daily OCS (7.5 to 40mg per day) in addition to regular use of high-dose ICS and LABA with or without additional controller(s). The primary endpoint was percent reduction from baseline of the final OCS dose during weeks 24 to 28, while maintaining asthma control. Compared to placebo, patients receiving Fasentra™ achieved greater reductions in daily maintenance OCS dose, while maintaining asthma control. The median percent reduction in daily OCS dose from baseline was 75% in patients receiving Fasentra™ (95% CI: 60, 88) compared to 25% in patients receiving placebo (95% CI: 0, 33). Reductions of 50% or higher in the OCS dose were observed in 48 (66%) patients receiving Fasentra™ compared to 28 (37%) patients receiving placebo. The proportion of patients with a mean final dose less than or equal to 5mg at weeks 24 to 28 was 59% for Fasentra™ and 33% for placebo (odds ratio 2.74, 95% CI: 1.41, 5.31). Only patients with an optimized baseline OCS dose of 12.5mg or less were eligible to achieve a 100% reduction in OCS dose during the study. Of those patients, 52% (22 of 42) receiving Fasentra™ and 19% (8 of 42) on placebo achieved a 100% reduction in OCS dose. Exacerbations resulting in hospitalization and/or ER visit were also assessed as a secondary endpoint. In this 28-week trial, patients receiving Fasentra™ had 1 event while those on placebo had 14 events (annualized rate 0.02 and 0.32 respectively; rate ratio of 0.07, 95% CI: 0.01, 0.63).
- Change from baseline in mean FEV₁ was assessed in Trials 1, 2, and 3 as a secondary endpoint. Compared with placebo, Fasentra™ provided consistent improvements over time in the mean change from baseline in FEV₁.

Cost Comparison:

Medication	Cost Per Unit	Cost Per Year
Fasenra™ (benralizumab injection) 30mg/mL	\$4,752.11/mL	\$38,016.88*
Nucala® (mepolizumab) 100mg/vial	\$2,785.12/vial	\$36,206.56
Cinqair® (reslizumab) 100mg/10mL	\$860.00/vial	\$22,360.00 ⁺

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.

*Fasenra™ recommended dose is 30mg every 4 weeks for the first three doses, followed by once every 8 weeks thereafter.

+ Cinqair® cost based two vials at recommended dose of 3mg/kg once every 4 weeks.

Recommendations

The College of Pharmacy recommends the prior authorization of ArmonAir™ RespiClick® (fluticasone propionate), Trelegy™ Ellipta™ (fluticasone furoate/umeclidinium/vilanterol), Qvar® RediHaler™ (beclomethasone dipropionate), AirDuo™ RespiClick® (fluticasone propionate/salmeterol), and Fasenra™ (benralizumab) with the following criteria:

Arnuity™ Ellipta® (Fluticasone Furoate) and ArmonAir™ RespiClick® (Fluticasone Propionate)

Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 12 years of age or older; and
3. A patient-specific, clinically significant reason why Flovent® (fluticasone propionate) is not an option for the member.

Qvar® RediHaler™ (Beclomethasone Dipropionate HFA) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 4 years of age or older; and
3. A patient-specific, clinically significant reason why Qvar® (beclomethasone dipropionate HFA) is not an option for the member; and
4. A trial of all available Tier-1 inhaled corticosteroids or a patient-specific, clinically significant reason why they are not appropriate for the member.

AirDuo™ RespiClick® (Fluticasone Propionate/Salmeterol) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be at or above the minimum age indicated; and
3. Failure of both Advair® and Dulera® or a reason why Advair® and Dulera® are not appropriate for the member; and
4. Member must have used an inhaled corticosteroid for at least one month immediately prior; and
5. Member must be considered uncontrolled by provider [required rescue medication >2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids]; or
6. A clinical situation warranting initiation with combination therapy due to severity of asthma.

Inhaled Corticosteroids and Combination Products	
Tier-1	Tier-2
beclomethasone dipropionate (QVAR®)	beclomethasone dipropionate (Qvar® RediHaler™)
budesonide (Pulmicort®)	budesonide/formoterol (Symbicort®)
ciclesonide (Alvesco®)	fluticasone furoate (Arnuity® Ellipta®)
flunisolide (Aerospan®)	fluticasone furoate/vilanterol (Breo® Ellipta®)
fluticasone propionate (Flovent®)	fluticasone propionate (ArmonAir™ RespiClick®)
fluticasone/salmeterol (Advair®)	fluticasone propionate/salmeterol (AirDuo™ RespiClick®)
mometasone/formoterol (Dulera® HFA)	
mometasone furoate (Asmanex®)	

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

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

Trelegy™ Ellipta™ (Fluticasone Furoate/Umeclidinium/Vilanterol) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema; and
2. A four week trial of at least one long-acting beta₂ agonist (LABA) and a four week trial of one long-acting muscarinic antagonist (LAMA) within the past 90 days used concomitantly with an inhaled corticosteroid (ICS); and
3. A patient-specific, clinically significant reason why the member requires the triple combination therapy in place of the individual components or use of a LABA/ICS combination with a LAMA.

Fasenra™ (Benralizumab Injection) Approval Criteria:

1. An FDA approved indication for add-on maintenance treatment of patients with severe eosinophilic phenotype asthma; and
2. Member must be age 12 years or older; and
3. Member must have a baseline blood eosinophil count of 300 cell/μL or greater within the last six weeks of initiation of dosing; and
4. Member must have had at least two asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of high-dose inhaled corticosteroid (ICS) plus at least one additional controller medication; and
5. Member must have failed a high-dose ICS (≥880mcg/day fluticasone propionate or equivalent daily dose or ≥440mcg/day in ages 12 to 17 years) used compliantly for at least the past 12 months (for ICS/LABA combination medications, the highest approved dose meets this criteria); and
6. Member must have failed at least one other asthma controller medication used in addition to the high-dose ICS compliantly for at least the past three months; and
7. Fasenra™ must be administered in a healthcare setting by a healthcare professional prepared to manage anaphylaxis; and
8. Fasenra™ must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last twelve months (or be an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and

9. Initial approvals will be for the duration of six months after which time compliance will be evaluated for continued approval.
10. A quantity limit of 1 prefilled syringe per 56 days will apply.

Utilization Details of Maintenance Asthma and COPD Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
COMBINATION LABA/ICS PRODUCTS						
ADVAIR DISKU AER 250/50	5,765	1,822	\$2,002,520.05	\$11.49	\$347.36	18.08%
SYMBICORT AER 160/4.5	4,494	979	\$1,361,873.23	\$9.64	\$303.04	12.30%
ADVAIR HFA AER 115/21	3,911	1,118	\$1,309,004.99	\$10.85	\$334.70	11.82%
ADVAIR DISKU AER 500/50	2,104	579	\$959,775.53	\$15.13	\$456.17	8.67%
ADVAIR DISKU AER 100/50	1,793	636	\$498,170.78	\$9.13	\$277.84	4.50%
DULERA AER 200/5	1,301	445	\$361,688.03	\$9.06	\$278.01	3.27%
ADVAIR HFA AER 230/21	1,135	325	\$510,731.90	\$14.61	\$449.98	4.61%
SYMBICORT AER 80/4.5	901	235	\$228,838.66	\$8.05	\$253.98	2.07%
DULERA AER 100/5	835	295	\$232,070.74	\$8.89	\$277.93	2.10%
ADVAIR HFA AER 45/21	488	184	\$125,065.06	\$8.17	\$256.28	1.13%
BREO ELLIPTA INH 100/25	74	17	\$23,365.89	\$10.53	\$315.76	0.21%
SUBTOTAL	22,801	6,635	\$7,613,104.86	\$10.86	\$333.89	68.76%
INDIVIDUAL COMPONENT LABA PRODUCTS						
TIER-1						
SEREVENT DIS AER 50MCG	698	256	\$235,991.58	\$11.09	\$338.10	2.13%
FORADIL CAP AEROLIZE 12MCG	8	7	\$1,999.18	\$8.54	\$249.90	0.02%
SUBTOTAL	706	263	\$237,990.76	\$11.06	\$337.10	2.15%
TIER-2						
BROVANA NEB 15MCG	119	25	\$101,792.74	\$28.39	\$855.40	0.92%
PERFOROMIST NEB 20MCG	29	7	\$17,033.47	\$19.58	\$587.36	0.15%
STRIVERDI AER 2.5MCG	7	2	\$1,275.62	\$6.07	\$182.23	0.01%
SUBTOTAL	155	34	\$120,101.83	\$25.75	\$774.85	1.08%
INDIVIDUAL COMPONENT LAMA PRODUCTS						
TIER-1						
SPIRIVA CAP HNDHLR 18MCG	7,797	2,027	\$2,797,755.01	\$11.92	\$358.82	25.27%
SUBTOTAL	7,797	2,027	\$2,797,755.01	\$11.92	\$358.82	25.27%
TIER-2						
SPIRIVA SPR 2.5MCG	511	178	\$184,250.76	\$11.77	\$360.57	1.66%
INCRUSE ELPT INH 62.5MCG	50	12	\$15,425.47	\$10.28	\$308.51	0.14%
TUDORZA PRES AER 400MCG	27	9	\$8,690.65	\$10.73	\$321.88	0.08%
SUBTOTAL	588	199	\$208,366.88	\$11.60	\$354.37	1.88%
COMBINATION LABA/LAMA PRODUCTS						
ANORO ELLIPT AER 62.5/25	89	25	\$29,766.96	\$10.79	\$334.46	0.27%
SUBTOTAL	89	25	\$29,766.96	\$10.79	\$334.46	0.27%
PHOSPHODIESTERASE-4 ENZYME INHIBITOR PRODUCTS						
DALIRESP TAB 500MCG	212	30	\$65,992.42	\$10.48	\$311.29	0.60%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SUBTOTAL	212	30	\$65,992.42	\$10.48	\$311.29	0.60%
TOTAL	32,349	7,348*	\$11,073,368.79	\$11.20	\$342.31	100%

LABA = long-acting beta₂ agonist; LAMA = long-acting muscarinic antagonist; ICS = inhaled corticosteroid

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Utilization Details of Asthma Monoclonal Antibodies (Pharmacy Claims): Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
MONOCLONAL ANTIBODY PRODUCTS						
XOLAIR SOL 150MG	99	25	\$410,260.58	\$148.00	\$4,144.05	100%
TOTAL	99	25*	\$410,260.58	\$148.00	\$4,144.05	100%

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Utilization Details of Asthma Monoclonal Antibodies (Medical Claims): Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	TOTAL UNITS	COST/ CLAIM	% COST
MONOCLONAL ANTIBODY PRODUCTS						
OMALIZUMAB INJ 5MG (J2357)	61	8	\$159,155.10	4,920	\$2,609.10	100%
TOTAL	61	8*	\$159,155.10	4,920	\$2,609.10	100%

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Utilization Details of Inhaled Corticosteroids: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
INHALED CORTICOSTEROID PRODUCTS						
FLOVENT HFA AER 110MCG	19,664	8,300	\$4,422,324.32	\$6.35	\$224.89	31.51%
FLOVENT HFA AER 44MCG	16,227	7,298	\$2,752,192.90	\$5.24	\$169.61	19.61%
QVAR AER 40MCG	7,819	3,494	\$1,198,256.31	\$4.26	\$153.25	8.54%
QVAR AER 80MCG	5,100	2,031	\$1,030,376.37	\$5.70	\$202.03	7.34%
BUDESONIDE SUS 0.25MG/2ML	4,479	2,799	\$834,254.36	\$7.44	\$186.26	5.94%
BUDESONIDE SUS 0.5MG/2ML	4,259	2,213	\$949,757.67	\$8.57	\$223.00	6.77%
FLOVENT HFA AER 220MCG	3,064	1,397	\$1,076,004.49	\$9.32	\$351.18	7.67%
PULMICORT INH 90MCG	1,276	576	\$215,924.16	\$5.97	\$169.22	1.54%
PULMICORT INH 180MCG	1,203	618	\$256,778.71	\$5.39	\$213.45	1.83%
FLOVENT DISK AER 100MCG	1,001	402	\$176,303.27	\$5.60	\$176.13	1.26%
FLOVENT DISK AER 250MCG	655	221	\$148,653.47	\$7.42	\$226.95	1.06%
AEROSPAN AER 80MCG	577	246	\$112,824.46	\$5.65	\$195.54	0.80%
ASMANEX 60 AER 220MCG	575	224	\$123,605.86	\$6.44	\$214.97	0.88%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
ASMANEX 30 AER 220MCG	526	193	\$94,294.54	\$5.93	\$179.27	0.67%
FLOVENT DISK AER 50MCG	381	147	\$64,340.58	\$5.40	\$168.87	0.46%
ASMANEX 30 AER 110MCG	376	141	\$61,298.43	\$5.40	\$163.03	0.44%
ALVESCO AER 80MCG	375	145	\$88,025.99	\$7.46	\$234.74	0.63%
BUDESONIDE SUS 1MG/2ML	316	149	\$241,449.01	\$27.90	\$764.08	1.72%
ASMANEX HFA AER 100MCG	307	152	\$52,402.39	\$4.36	\$170.69	0.37%
ALVESCO AER 160MCG	219	81	\$51,727.74	\$7.57	\$236.20	0.37%
ASMANEX HFA AER 200MCG	140	80	\$28,618.80	\$5.57	\$204.42	0.20%
ASMANEX 120 AER 220MCG	128	75	\$37,463.37	\$5.90	\$292.68	0.27%
PULMICORT SUS 1MG/2ML	24	7	\$17,508.83	\$24.32	\$729.53	0.12%
ARNUITY ELPT INH 100MCG	2	1	\$323.92	\$5.40	\$161.96	0.00%
TOTAL	68,693	27,966*	\$14,034,709.95	\$6.14	\$204.31	100%

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

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Appendix J



Fiscal Year 2017 Annual Review of Anti-Emetic Medications and 30-Day Notice to Prior Authorize Varubi® IV (Rolapitant) and Cinvanti™ (Aprepitant)

Oklahoma Health Care Authority
December 2017

Current Prior Authorization Criteria

Kytril® and Sancuso® (Granisetron), Anzemet® (Dolasetron), Emend® (Aprepitant), and Emend® IV (Fosaprepitant) Approval Criteria:

1. An FDA approved diagnosis; and
2. A recent trial of ondansetron (within the past six months) used for at least three days or one cycle that resulted in an inadequate response is required for authorization in members receiving moderately emetogenic chemotherapy; and
3. No ondansetron trial is required for authorization of Emend® (aprepitant) in members receiving highly emetogenic chemotherapy; and
4. For Emend® (aprepitant) oral suspension, an age restriction of six years and younger will apply. Members older than six years of age will require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
5. Approval length will be based on duration of need.

Sustol® (Granisetron Subcutaneous Injection) Approval Criteria:

1. An FDA approved indication for use in the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens; and
2. Chemotherapy regimen must be listed on the prior authorization request; and
3. A recent trial of ondansetron (within the past six months) used for at least three days or one cycle that resulted in inadequate response is required for authorization in members receiving MEC; and
4. No ondansetron trial is required for authorization of granisetron in members receiving AC combination chemotherapy regimens; and
5. A patient-specific, clinically significant reason why the member cannot use Kytril® (granisetron hydrochloride injection); and
6. A quantity limit of one injection per chemotherapy cycle will apply.

Akynzeo® (Netupitant/Palonosetron) Approval Criteria:

1. An FDA approved diagnosis for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy; and
2. A previously failed trial of aprepitant (Emend®) that resulted in an inadequate response, or a patient-specific, clinically significant reason why aprepitant cannot be used must be provided; and

3. Approval length will be based on duration of need.
4. A quantity limit of one capsule per chemotherapy cycle will apply.

Varubi® (Rolapitant) Approval Criteria:

1. An FDA approved indication for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy; and
2. A previously failed trial of aprepitant (Emend®) that resulted in an inadequate response, or a patient-specific, clinically significant reason why aprepitant cannot be used must be provided; and
3. Approval length will be based on duration of need.
4. A quantity limit of two tablets per chemotherapy cycle will apply.

Marinol® and Syndros™ (Dronabinol) and Cesamet® (Nabilone) Approval Criteria:

1. Approval can be granted for six months for the diagnosis of HIV related loss of appetite; or
2. The diagnosis of chemotherapy induced nausea and vomiting requires the following:
 - a. A recent trial of ondansetron (within the past six months) used for at least three days or one cycle that resulted in inadequate response.
3. Approval length will be based on duration of need.
4. For Marinol® (dronabinol) and Cesamet® (nabilone), a quantity limit of 60 capsules per 30 days will apply.
5. For Syndros™ (dronabinol) oral solution, the quantity approved will be patient-specific depending on patient diagnosis, maximum recommended dosage, and manufacturer packaging.
6. For Syndros™ (dronabinol) oral solution, an age restriction of six years and younger will apply. Members older than six years of age will require a patient-specific, clinically significant reason why dronabinol oral capsules cannot be used.

Zuplenz® (Ondansetron Oral Soluble Film) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot take all other available formulations of generic ondansetron.

Diclegis® and Bonjesta® (Doxylamine/Pyridoxine) Approval Criteria:

1. An FDA approved diagnosis of nausea and vomiting associated with pregnancy that is not responsive to conservative management; and
2. Trials with at least two non-pharmacological therapies that have failed to relieve nausea and vomiting; and
3. A patient-specific, clinically significant reason why member cannot use over-the-counter (OTC) doxylamine and OTC Vitamin B₆ (pyridoxine); and
4. If the daily net cost of Bonjesta® (doxylamine/pyridoxine 20mg/20mg) is greater than the daily net cost of Diclegis® (doxylamine/pyridoxine 10mg/10mg), authorization of Bonjesta® would also require a patient-specific, clinically significant reason why the member cannot use Diclegis®.

Utilization of Anti-Emetic Medications: Fiscal Year 2017

Comparison of Fiscal Years for Anti-Emetic Medications: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2016	61,411	82,803	\$916,438.31	\$11.07	\$1.51	1,298,785	605,765
2017	68,620	92,975	\$1,285,157.11	\$13.82	\$1.97	1,482,942	652,960
% Change	11.70%	12.30%	40.20%	24.80%	30.50%	14.20%	7.80%
Change	7,209	10,172	\$368,718.80	\$2.75	\$0.46	184,157	47,195

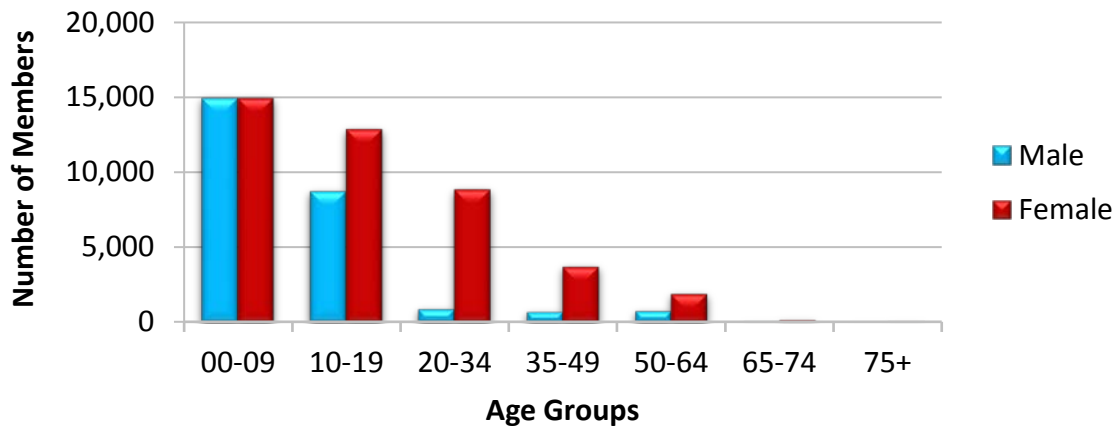
*Total number of unduplicated members. Costs do not reflect rebated prices or net costs.

Fiscal Year 2017 Utilization of Anti-Emetic Medications: Medical Claims

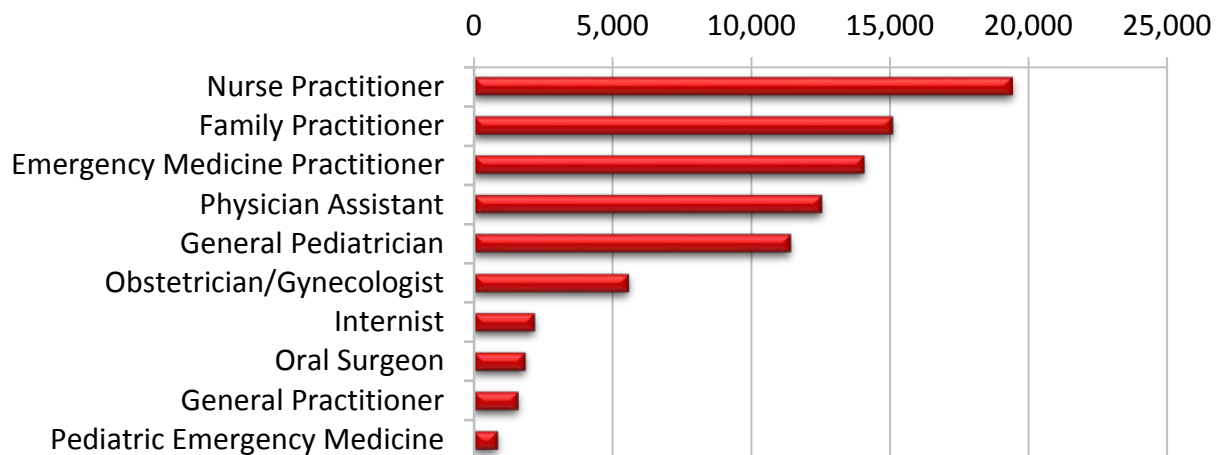
*Total Members	Total Claims	Total Cost	Cost/Claim	Claims/Member
642	4,403	\$950,252.56	\$215.82	6.86

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

Demographics of Members Utilizing Anti-Emetic Medications: Pharmacy Claims

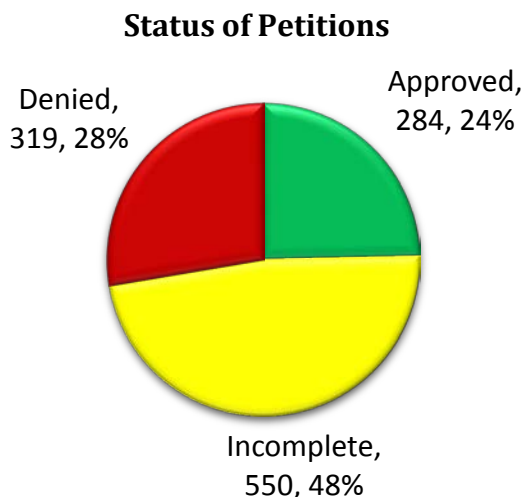


Top Prescriber Specialties of Anti-Emetic Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Anti-Emetic Medications

There were 1,153 prior authorization requests submitted for anti-emetic medications during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates^{1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16}

Anticipated Patent Expiration(s):

- Emend® [fosaprepitant for intravenous (IV) use]: March 2019
- Diclegis® [doxylamine/pyridoxine delayed-release (DR) tablets]: June 2021
- Aloxi® (palonosetron for IV use): July 2024
- Sustol® [granisetron subcutaneous (SC) injection]: September 2024
- Sancuso® (granisetron transdermal patch): January 2025
- Syndros™ (dronabinol oral solution): August 2028
- Varubi® (rolapitant tablets): October 2029
- Zuplenz® (ondansetron oral soluble film): July 2030
- Akynzeo® (netupitant/palonosetron capsules): September 2031
- Bonjesta® [doxylamine/pyridoxine extended-release (ER) tablets]: February 2033

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

- **October 2017:** The FDA approved an Abbreviated New Drug Application (ANDA) for aprepitant oral capsules (generic Emend®) for the prevention of chemotherapy induced nausea and vomiting (CINV) and the prevention of postoperative nausea and vomiting. This makes the second pharmaceutical company that has received approval by the FDA for the generic oral capsule formulation of Emend® (the first approval was in 2012). The College of Pharmacy will continue to monitor costs of generic aprepitant in comparison to the branded product, as well as other anti-emetic medications.
- **October 2017:** The FDA approved a New Drug Application (NDA) for Varubi® IV (rolapitant for IV use) in combination with other anti-emetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of

emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy (HEC). Varubi® (rolapitant) oral tablets were first FDA approved in 2015 for the same indication. Rolapitant is a substance P/neurokinin 1 (NK1) receptor antagonist and is available as 90mg oral tablets and as an injectable emulsion for IV use in a single-dose, ready-to-use vial (166.5mg/92.5mL). The injectable emulsion does not require reconstitution and is free of polysorbate 80, an excipient used to stabilize aqueous formulations of medications for parenteral administration that has been linked to hypersensitivity reactions, including anaphylaxis and irritation of the blood vessels resulting in infusion-site pain. Rolapitant is the first IV administered NK1 receptor antagonist approved by the FDA that does not contain polysorbate 80. Varubi® IV was FDA approved based on data demonstrating the bioequivalence of IV rolapitant to oral rolapitant. The recommended dosage of rolapitant is to administer one dose (180mg orally as a single dose or 166.5mg infused IV over 30 minutes) on day 1 of the chemotherapy cycle, in combination with dexamethasone and a 5-HT₃ receptor antagonist (e.g., ondansetron, granisetron, palonosetron). Rolapitant should be administered within two hours prior to initiation of chemotherapy. The wholesale acquisition cost (WAC) of Varubi® IV is \$295.08 per dose (one 166.5mg/92.5mL vial), compared to the oral tablets at \$561.80 per 180mg dose (two 90mg tablets).

- **November 2017:** The FDA approved an NDA for Cinvanti™ (aprepitant for IV use) in combination with other anti-emetic agents in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of HEC, including high-dose cisplatin, and prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC). Aprepitant is an NK1 receptor antagonist, and Cinvanti™ is available as an injectable emulsion for IV use in a single-dose vial (130mg/18mL). The injectable emulsion of aprepitant does not require reconstitution and is free of polysorbate 80. Other FDA approved formulations of aprepitant include aprepitant oral capsules (brand Emend® and generic formulations), aprepitant powder for oral suspension (brand Emend®), and IV fosaprepitant (brand Emend®), which is the prodrug of aprepitant and is available as a powder for IV solution (requires reconstitution prior to administration) that contains the excipient polysorbate 80. Emend® (oral aprepitant and IV fosaprepitant) has the same FDA approved indications as Cinvanti™. Cinvanti™ was FDA approved based on data demonstrating the bioequivalence of Cinvanti™ to Emend® IV, supporting its efficacy for the prevention of acute and delayed CINV following HEC and MEC. Bioequivalence studies of Cinvanti™ and Emend® IV showed subjects receiving Cinvanti™ reported fewer adverse events than those receiving Emend® IV, including substantially fewer infusion-site reactions. The recommended dosage of Cinvanti™ for HEC is to administer one dose (130mg aprepitant infused IV over 30 minutes) on day 1 of the chemotherapy cycle, in combination with dexamethasone and a 5-HT₃ receptor antagonist. For MEC, the recommended dosage of Cinvanti™ is to administer one dose (100mg aprepitant infused IV over 30 minutes) on day 1 of the chemotherapy cycle, in combination with dexamethasone, a 5-HT₃ receptor antagonist, and oral aprepitant. Cinvanti™ should be administered within 30 minutes prior to initiation of chemotherapy. Cost information is

not yet available for Cinvanti™; it is anticipated to be available commercially in January 2018.

News:

- **January 2017:** An analysis published by researchers in Toronto called into question the effectiveness of doxylamine/pyridoxine (brand Diclectin® in Canada; Diclegis® in the United States) for the management of nausea and vomiting of pregnancy. Doxylamine/pyridoxine was previously available in the United States under the brand name Bendectin®. Although multiple studies showed no increased risk of birth defects, the manufacturer voluntarily withdrew Bendectin® from the market in 1983 because of litigation. However, the FDA determined that Bendectin® was not withdrawn from the market for reasons of safety or effectiveness, and this determination permitted the FDA to approve ANDAs for the combination of doxylamine and pyridoxine for use in pregnancy. Diclegis® (doxylamine/pyridoxine) was approved by the FDA in 2013. The new analysis is based on an unpublished 1970s study (“8-way” Bendectin® Study) that aimed to evaluate the relative therapeutic efficacy of doxylamine, pyridoxine, and dicyclomine in the management of nausea and vomiting during pregnancy. The information was obtained from the FDA through the Freedom of Information Act and is part of a global initiative by the scientific community to bring to light or restore invisible and abandoned trials. The study included 2,308 patients at 14 clinics in the United States who were in the first 12 weeks of pregnancy with complaints of nausea or vomiting, and each patient was randomized to one of eight arms: placebo, doxylamine/pyridoxine/dicyclomine, doxylamine/pyridoxine, dicyclomine/pyridoxine, dicyclomine/doxylamine, doxylamine, pyridoxine, or dicyclomine. Each patient was instructed to take two tablets at bedtime and one additional tablet in the morning or afternoon if needed, for seven nights. Reported outcomes included the number of hours of nausea reported by patients, the frequency of vomiting reported by patients, and the overall efficacy of medication as judged by physicians. Data from 1,599 patients (69% of those randomized) were analyzed, and the proportion of patients who were “evaluated moderate or excellent” was greater in each of the seven active treatment groups when compared to placebo. However, there is a high risk of bias in these previously unpublished results given the high attrition rate in a 7-day trial, the lack of prespecified outcomes or analyses, and the exclusion of some data because of questionable data integrity. Therefore, it was concluded that the available information about this trial indicates it should not be used to support the efficacy of doxylamine, pyridoxine, or dicyclomine for the treatment of nausea and vomiting during pregnancy because of a high risk of bias.
 - The FDA required two studies – this 1970s study (referenced to show the efficacy of each ingredient individually) and a 2010 study (to show the efficacy of the combination of doxylamine and pyridoxine in the drug) – for the approval of Diclegis®. FDA spokeswoman Sarah Peddicord responded to this new analysis with the following statement, “Based on the available data, the FDA determined that Diclegis® has been shown to be safe and effective for the treatment of nausea and

vomiting in pregnant women who do not respond to conservative management. The FDA's determination remains unchanged."

- **July 2017:** The American Society of Clinical Oncology (ASCO) updated clinical practice guidelines for controlling nausea and vomiting related to cancer treatment. To develop the guideline update, the ASCO Expert Panel conducted a systematic review of the medical literature published between November 2009 and June 2016. The ASCO Expert Panel included members with expertise in medical oncology, radiation oncology, nursing, pharmacy, and health services research, as well as a patient representative. The co-chair of the ASCO Expert Panel, Paul J. Hesketh, MD, noted that "the adverse impact of inadequately controlled nausea and vomiting on patient's quality of life is well documented" and that "by following the ASCO Anti-Emetic Guideline clinicians have the opportunity to improve patient's quality of life by minimizing treatment induced emesis". Key recommendations of the guideline update include:
 - For adults receiving chemotherapy with a high risk for nausea and vomiting (e.g., cisplatin, the combination of an anthracycline and cyclophosphamide), olanzapine should be added to standard anti-emetic regimens (the combination of a 5-HT₃ receptor antagonist, an NK1 receptor antagonist, and dexamethasone); *quality of evidence: high, strength of recommendation: strong.*
 - Olanzapine, an atypical antipsychotic medication, is currently available generically as oral tablets, orally disintegrating tablets (ODTs), and an intramuscular (IM) injection, all of which are covered by SoonerCare without a prior authorization.
 - For adults receiving carboplatin-based chemotherapy or high-dose chemotherapy, and for children receiving chemotherapy with a high risk for nausea and vomiting, an NK1 receptor antagonist should be added to the standard anti-emetic regimen (the combination of a 5-HT₃ receptor antagonist and dexamethasone); *quality of evidence: high, strength of recommendation: strong.*
 - The ASCO Expert Panel recommends FDA-approved cannabinoids, dronabinol or nabilone, to treat nausea and vomiting that is resistant to standard anti-emetic therapies; *quality of evidence: intermediate, strength of recommendation: moderate.* Evidence remains insufficient to recommend medical marijuana for either prevention or treatment of nausea and vomiting in patients with cancer receiving chemotherapy or radiation therapy.

Pipeline:

- **February 2017:** Acacia Pharma announced positive results from its fourth and final pivotal Phase 3 study of Baremsis™ for the rescue treatment of patients who develop post-operative nausea and vomiting (PONV), despite having received prior anti-emetic prophylaxis. Baremsis™ (formally APD421) is an IV formulation of amisulpride, a selective dopamine antagonist. Amisulpride is not approved by the FDA for use in the United States, but is currently used in Europe and other countries to treat psychosis and schizophrenia. The Phase 3 rescue treatment trial compared two doses of Baremsis™ against placebo in patients with established nausea and/or vomiting after surgery, who had previously received prophylactic anti-emetics. The primary endpoint was the

successful resolution of the episode of PONV (no recurrence of vomiting or requirement for further anti-emetic rescue) in the 24-hour period after rescue treatment, termed a complete response. The optimum dose of Baremsis™ significantly improved the complete response rate when compared to placebo ($p=0.003$). Acacia Pharma has now completed four pivotal Phase 3 clinical studies of Baremsis™ successfully, all meeting their primary endpoint, and these will form the basis of the efficacy and safety package which the company aims to submit to the FDA as part of its NDA for Baremsis™. Two studies investigated the treatment of established PONV (one in patients who had received prior prophylaxis with standard anti-emetics, and one in patients who had not received any prophylaxis), and two studies investigated the prophylaxis of PONV alone, or in combination with standard anti-emetics. Acacia Pharma plans to submit an NDA for Baremsis™ to the FDA, seeking a broad and unique approval for the rescue treatment and prophylaxis of PONV, alone and in combination with other anti-emetics.

- **June 2017:** RedHill Biopharma announced positive top-line results from a randomized, double-blind, placebo-controlled, parallel group Phase 3 clinical study in the United States (the GUARD study) designed to evaluate the safety and efficacy of Bekinda® 24mg in patients suffering from acute gastroenteritis and gastritis. Bekinda® (formerly RHD-102) is a proprietary, bimodal ER, once-daily oral tablet formulation of ondansetron. Bekinda® 24mg is intended to provide patients with relief from nausea and vomiting symptoms for a full 24-hour period with a single oral tablet. The GUARD study successfully met its primary endpoint of efficacy in the treatment of acute gastroenteritis and gastritis, and Bekinda® was found to be safe and well tolerated for this indication. The GUARD study is intended to support potential future submissions of marketing applications in both the United States and Europe for this indication. If approved by the FDA, Bekinda® could become the first-ever 5-HT₃ receptor antagonist in the United States indicated for the treatment of acute gastroenteritis and gastritis, as well as the first once-daily oral formulation of ondansetron. Following a successful first Phase 3 study and a positive guidance meeting with the FDA, RedHill is designing a confirmatory Phase 3 study to support an NDA for Bekinda® 24mg for acute gastroenteritis and gastritis.
- **September 2017:** Helsinn Group submitted an NDA to the FDA for an IV formulation of fosnetupitant/palonosetron for the prevention of CINV. Fosnetupitant is a NK1 receptor antagonist, and palonosetron is a 5-HT₃ receptor antagonist. The Phase 3 safety study data revealed IV fosnetupitant/palonosetron to be safe and well tolerated with a similar safety profile to oral netupitant/palonosetron in patients with various solid tumors receiving HEC. Oral netupitant/palonosetron (Akynzeo®) was FDA approved in 2014 for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, HEC. The anticipated FDA response date for IV fosnetupitant/palonosetron is April 2018.
- **October 2017:** RedHill Biopharma announced positive top-line results from a randomized, double-blind, placebo-controlled Phase 2 clinical study in the United States designed to evaluate the safety and efficacy of Bekinda® 12mg (ondansetron ER) in patients with diarrhea-predominant irritable bowel syndrome (IBS-D). The Phase 2 study successfully met its primary endpoint, improving the primary efficacy outcome of

stool consistency response (per FDA guidance definition). Bekinda® 12mg improved stool consistency response by an absolute difference of 19.4% vs. placebo and compared favorably with previously reported efficacy outcome values for stool consistency response from studies of Xifaxan® (rifaximin) and Viberzi® (eluxadoline). Bekinda® 12mg was also shown to be safe and well tolerated. RedHill intends to pursue Phase 3 studies with Bekinda® 12mg and plans to meet with the FDA by early 2018 to discuss the path towards potential United States marketing approval.

Recommendations

The College of Pharmacy recommends the prior authorization of Varubi® IV (rolapitant for IV use) and Cinvanti™ (aprepitant for IV use) with the following criteria:

Varubi® and Varubi® IV (Rolapitant) Approval Criteria:

1. An FDA approved indication for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy; and
2. For oral Varubi® (rolapitant oral tablets), a previously failed trial of aprepitant (Emend®) that resulted in an inadequate response, or a patient-specific, clinically significant reason why aprepitant cannot be used must be provided; and
3. For Varubi® IV [rolapitant intravenous (IV) emulsion], a previously failed trial of IV fosaprepitant (Emend® IV) that resulted in an inadequate response, or a patient-specific, clinically significant reason why IV fosaprepitant cannot be used must be provided; and
4. Approval length will be based on duration of need.
5. A quantity limit of two tablets or two vials per chemotherapy cycle will apply.

Kytril® and Sancuso® (Granisetron), Anzemet® (Dolasetron), Emend® and Cinvanti™ (Aprepitant), and Emend® IV (Fosaprepitant) Approval Criteria:

1. An FDA approved diagnosis; and
2. A recent trial of ondansetron (within the past six months) used for at least three days or one cycle that resulted in an inadequate response is required for authorization in members receiving moderately emetogenic chemotherapy; and
3. No ondansetron trial is required for authorization of Emend® (aprepitant) in members receiving highly emetogenic chemotherapy; and
4. For Emend® (aprepitant) oral suspension, an age restriction of six years and younger will apply. Members older than six years of age will require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
5. For Cinvanti™ [aprepitant intravenous (IV) emulsion], a previously failed trial of IV fosaprepitant (Emend® IV) that resulted in an inadequate response, or a patient-specific, clinically significant reason why IV fosaprepitant cannot be used must be provided; and
6. Approval length will be based on duration of need.

Additionally, based on the current low net cost of Akynzeo® (netupitant/palonosetron), the College of Pharmacy recommends making Akynzeo® available without a prior authorization for members with cancer; however, Akynzeo® will follow the original criteria and require a

previously failed trial of aprepitant if the net cost increases compared to other available products. The changes to the current criteria are shown in red:

Akynzeo® (Netupitant/Palonosetron) Approval Criteria:

1. An FDA approved diagnosis for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy; and
2. A previously failed trial of aprepitant (Emend®) that resulted in an inadequate response, or a patient-specific, clinically significant reason why aprepitant cannot be used must be provided; and
3. Approval length will be based on duration of need.
4. A quantity limit of one capsule per chemotherapy cycle will apply.
5. Akynzeo® will not require a prior authorization for members with cancer and claims will pay at the point of sale if the member has a reported oncology diagnosis within the past 6 months of claims history.
 - a. Based on the current low net cost, Akynzeo® will not require a prior authorization for members with cancer; however, Akynzeo® will follow the original criteria and require a previously failed trial of aprepitant if the net cost increases compared to other available products.

Utilization Details of Anti-Emetic Medications: Fiscal Year 2017

Anti-Emetic Medications: Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/MEMBER	COST/CLAIM	% COST
ONDANSETRON PRODUCTS						
ONDANSETRON TAB 4MG ODT	57,323	47,261	\$691,942.56	1.21	\$12.07	53.84%
ONDANSETRON TAB 4MG	12,822	9,308	\$127,800.16	1.38	\$9.97	9.94%
ONDANSETRON TAB 8MG ODT	11,512	8,281	\$158,336.28	1.39	\$13.75	12.32%
ONDANSETRON SOL 4MG/5ML	6,090	5,492	\$152,173.65	1.11	\$24.99	11.84%
ONDANSETRON TAB 8MG	4,563	2,845	\$53,567.39	1.60	\$11.74	4.17%
ONDANSETRON INJ 40MG/20ML	28	7	\$236.40	4.00	\$8.44	0.02%
ONDANSETRON INJ 4MG/2ML	16	10	\$394.19	1.60	\$24.64	0.03%
SUBTOTAL	92,354	73,204	\$1,184,450.63	1.26	\$12.83	92.16%
GRANISETRON PRODUCTS						
GRANISETRON INJ 0.1MG/ML	205	55	\$2,835.94	3.73	\$13.83	0.22%
GRANISETRON INJ 4MG/4ML	163	41	\$6,281.91	3.98	\$38.54	0.49%
SANCUSO DIS 3.1MG	19	10	\$22,154.33	1.90	\$1,166.02	1.72%
GRANISETRON TAB 1MG	13	7	\$1,386.30	1.86	\$106.64	0.11%
SUBTOTAL	400	113	\$32,658.48	3.54	\$81.65	2.54%
DRONABINOL PRODUCTS						
DRONABINOL CAP 2.5MG	85	35	\$14,561.25	2.43	\$171.31	1.13%
DRONABINOL CAP 5MG	79	26	\$25,411.70	3.04	\$321.67	1.98%
DRONABINOL CAP 10MG	11	3	\$5,143.41	3.67	\$467.58	0.40%
SUBTOTAL	175	64	\$45,116.36	2.73	\$257.81	3.51%
APREPITANT AND FOSAPREPITANT PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/MEMBER	COST/CLAIM	% COST
EMEND SUS 125MG	8	4	\$2,572.64	2.00	\$321.58	0.20%
APREPITANT PAK 80 & 125MG	6	4	\$4,479.89	1.50	\$746.65	0.35%
EMEND PAK 80 & 125MG	4	3	\$3,398.40	1.33	\$849.60	0.26%
EMEND SOL 150MG	2	1	\$607.56	2.00	\$303.78	0.05%
EMEND CAP 40MG	2	2	\$281.65	1.00	\$140.83	0.02%
APREPITANT CAP 80MG	1	1	\$173.58	1.00	\$173.58	0.01%
SUBTOTAL	23	15	\$11,513.72	1.53	\$500.60	0.90%
DOXYLAMINE/PYRIDOXINE PRODUCTS						
DICLEGIS TAB 10-10MG	15	8	\$5,751.80	1.88	\$383.45	0.45%
SUBTOTAL	15	8	\$5,751.80	1.88	\$383.45	0.45%
ROLAPITANT PRODUCTS						
VARUBI TAB 90MG	8	3	\$5,666.12	2.67	\$708.27	0.44%
SUBTOTAL	8	3	\$5,666.12	2.67	\$708.27	0.44%
TOTAL	92,975	68,620*	\$1,285,157.11	1.35	\$13.82	100%

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Anti-Emetic Medications: Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER
PALONOSETRON INJ J2469	2,907	542	\$622,729.77	\$214.22	5.36
FOSAPREPITANT INJ J1453	1,161	315	\$323,000.99	\$278.21	3.69
GRANISETRON INJ J1626	314	69	\$1,202.21	\$3.83	4.55
APREPITANT CAPS J8501	21	13	\$3,319.59	\$158.08	1.62
TOTAL	4,403	642*	\$950,252.56	\$215.82	6.86

*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 09/2017. Last accessed 11/14/2017.

² U.S. Food and Drug Administration (FDA). ANDA Approval: Aprepitant Oral Capsules. Available online at: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207777>. Issued 10/12/2017. Last accessed 11/14/2017.

³ Emend® (Aprepitant) Package Insert. MedLibrary.org. Available online at: <https://medlibrary.org/lib/rx/meds/emend-1/>. Last revised 02/23/2012. Last accessed 11/14/2017.

⁴ Tesaro News Release: Tesaro Announces U.S. FDA Approval of Varubi® IV for Delayed Nausea and Vomiting Associated with Cancer Chemotherapy. Available online at: <http://ir.tesarobio.com/news-releases/news-release-details/tesaro-announces-us-fda-approval-varubir-iv-delayed-nausea-and>. Issued 10/25/2017. Last accessed 11/14/2017.

⁵ Varubi® (Rolapitant) Prescribing Information. Tesaro, Inc. Available online at: https://www.varubirx.com/application/files/9515/0897/2736/VARUBI_rolapitant_Full_Prescribing_Information-October2017.pdf. Last revised 10/2017. Last accessed 11/14/2017.

⁶ Varubi® (Rolapitant) Package Insert. MedLibrary.org. Available online at: <https://medlibrary.org/lib/rx/meds/varubi/>. Last revised 10/24/2017. Last accessed 11/14/2017.

⁷ Heron Therapeutics, Inc. Heron Therapeutics Announces U.S. FDA Approval of Cinvanti™ (Aprepitant) Injectable Emulsion for the Prevention of Acute and Delayed Chemotherapy-Induced Nausea and Vomiting (CINV). *Business Wire*. Available online at: <http://www.businesswire.com/news/home/20171109006358/en/Heron-Therapeutics-Announces-U.S.-FDA-Approval-CINVANTI%E2%84%A2>. Issued 11/09/2017. Last accessed 11/16/2017.

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- ⁸ Cinvanti™ (Aprepitant) Prescribing Information. Heron Therapeutics, Inc. Available online at: http://www.cinvanti.com/pdfs/CINVANTI_PI_11.9.17.pdf. Last revised 11/2017. Last accessed 11/16/2017.
- ⁹ Zhang R, Persaud N. 8-Way Randomized Controlled Trial of Doxylamine, Pyridoxine, and Dicyclomine for Nausea and Vomiting during Pregnancy: Restoration of Unpublished Information. *PLoS One* 2017; 12(1):e0167609.
- ¹⁰ Howard J. Morning Sickness Drug's Efficacy Called into Question. *CNN*. Available online at: <http://www.cnn.com/2017/01/04/health/diclegis-morning-sickness-drug-fda/index.html>. Issued 01/04/2017. Last accessed 11/21/2017.
- ¹¹ Cha AE. Study Raises Questions About Efficacy of Morning Sickness Pill Endorsed by Kim Kardashian. *The Washington Post*. Available online at: https://www.washingtonpost.com/news/to-your-health/wp/2017/01/04/study-raises-questions-about-efficacy-of-morning-sickness-pill-endorsed-by-kim-kardashian/?utm_term=.0fa905fe4181. Issued 01/04/2017. Last accessed 11/21/2017.
- ¹² Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol* 2017; 35(28):3240-3261.
- ¹³ Acacia Pharma. Acacia Pharma Announces Positive Results from its Fourth and Final Pivotal Trial of Baremsis™ for the Rescue Treatment of PONV. *PR Newswire*. Available online at: <https://www.prnewswire.com/news-releases/acacia-pharma-announces-positive-results-from-its-fourth-and-final-pivotal-trial-of-baremsis-for-the-rescue-treatment-of-ponv-613560103.html>. Issued 02/13/2017. Last accessed 11/21/2017.
- ¹⁴ RedHill Biopharma News Release: RedHill Biopharma Announces Successful Phase III Top-Line Results with Bekinda® for Acute Gastroenteritis. Available online at: <https://www.redhillbio.com/RedHill/Templates/showpage.asp?DBID=1&LNGID=1&TMID=178&FID=1365&PID=0&IID=5129>. Issued 06/14/2017. Last accessed 11/21/2017.
- ¹⁵ Helsinn News Release: Helsinn Group Announces Upcoming Presentation of Phase III Data of NEPA (Fosnetupitant/Palonosetron) IV at ESMO 2017. Available online at: <https://www.helsinn.com/news-and-events/helsinn-group-announces-upcoming-presentation-of-phase-iii-data-of-nepa-fosnetupitant-palonosetron-iv-at-esmo-2017/>. Issued 09/06/2017. Last accessed 11/21/2017.
- ¹⁶ RedHill Biopharma News Release: RedHill Biopharma Announces Positive Top-Line Results from Phase II Study of Bekinda® in Patients with IBS-D. Available online at: <https://www.redhillbio.com/RedHill/Templates/showpage.asp?DBID=1&LNGID=1&TMID=178&FID=1365&PID=0&IID=5150>. Issued 10/03/2017. Last accessed 11/21/2017.



Appendix K



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

Oklahoma Health Care Authority
December 2017

Introduction^{1,2,3}

Osteoarthritis (OA) is the most common joint disorder in the United States. The prevalence of symptomatic knee OA is approximately 10% of men and 13% of women 60 years of age and older. OA is a degenerative disorder of the articular cartilage associated with hypertrophic changes in the bone and is often asymmetric. Common signs and symptoms of knee OA include morning stiffness (usually lasting less than 30 minutes), pain on range of motion, joint locking or instability, joint effusion, crepitus on range of motion, presence of popliteal cysts, lateral instability, and valgus or varus deformity. There are several risk factors for OA including advancing age, obesity, past trauma/surgery, genetics, female gender, high levels of physical activity, and certain occupations.

There are four main categories for treatment of symptomatic OA: non-pharmacologic, pharmacologic, complementary/alternative, and surgical. Non-pharmacologic often starts with exercise, consisting of aerobic, muscle strengthening, range-of-motion exercises, weight loss, if obese, and bracing or splinting the affected knee. The first-line pharmacologic treatment of OA is acetaminophen. If acetaminophen fails to control symptoms, or if symptoms are moderate-to-severe, oral or topical non-steroidal anti-inflammatory drug (NSAID) therapy is recommended. Intra-articular corticosteroid injections are recommended for short-term (four to eight weeks) relief of OA pain of the knee. It is possible for a patient to repeat an intra-articular corticosteroid injection in the same joint; however, usual practice is to limit to four injections annually.

Zilretta™ (Triamcinolone Acetonide Extended-Release Injectable Suspension) Product Summary⁴

Indication: Zilretta™ [triamcinolone acetonide extended-release (ER) injectable suspension] is an ER synthetic corticosteroid for intra-articular injection for the management of OA pain of the knee.

- Limitation of Use: Zilretta™ is not intended for repeat administration.

Dosing:

- Zilretta™ is supplied as a single-dose kit containing a vial of Zilretta™ microsphere powder, a vial of sterile diluent, and sterile vial adaptor.
 - Zilretta™ should be refrigerated (2° to 8° C) before use.
 - If refrigeration is unavailable, Zilretta™ can be stored at room temperature for up to six weeks, then should be discarded.
- Once reconstituted, per reconstitution directions provided, Zilretta™ should be administered as a single intra-articular injection, delivering 32mg/5mL.

- Zilretta™ is recommended for intra-articular injection only and may not be suitable for use in small joints, such as the hand.
- The efficacy and safety of Zilretta™ for the management of OA pain of the shoulder and hip have not been evaluated.
- The efficacy and safety of repeat administration of Zilretta™ for the management of OA pain of the knee have not been evaluated.

Mechanism of Action: Triamcinolone acetonide is a corticosteroid with anti-inflammatory and immunomodulating properties. It binds to and activates the glucocorticoid receptor, leading to activation of anti-inflammatory transcription factors, such as lipocortins, and inhibition of inflammatory transduction pathways by blocking the release of arachidonic acid and preventing the synthesis of prostaglandins and leukotrienes.

Contraindication(s):

- Zilretta™ is contraindicated in patients who are hypersensitive to corticosteroids or any components of the product.

Warnings and Precautions:

- Administration of Zilretta™: Zilretta™ is only recommended for intra-articular injection and has not been evaluated and should not be administered by the epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes.
- Hypersensitivity Reactions: Rare instances of anaphylaxis have occurred in patients with hypersensitivity to corticosteroids. Cases of serious anaphylaxis, including death, have been reported in individuals receiving triamcinolone acetonide injection, regardless of route of administration. Appropriate care should be instituted upon occurrence of an anaphylactic reaction.
- Joint Infection and Damage: Intra-articular injection of corticosteroids may be complicated by joint infection. A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise are suggestive of septic arthritis. If this complication occurs and a diagnosis of septic arthritis is confirmed, an appropriate antimicrobial therapy should be instituted. Injection of a corticosteroid into an infected site should be avoided. Local injection of a corticosteroid into a previously infected joint or into an unstable joint is not usually recommended. Intra-articular injection may result in damage to joint tissue.
- Increased Risk of Infections: Corticosteroid injections via the intra-articular route are systemically absorbed. Patients who are on corticosteroids are more susceptible to infections than are healthy individuals. There may be decreased resistance and inability to localize infection when corticosteroids are used. Infection with any pathogen (e.g., viral, bacterial, fungal), in any location of the body may be associated with the use of corticosteroids alone or in combination with other immunosuppressive agents. With increasing doses of corticosteroids, the rate of occurrence of infectious complications increases. Corticosteroids can also mask some signs of current infection.
- Alterations in Endocrine Function: Corticosteroids can produce reversible hypothalamic-pituitary-adrenal axis suppression, with the potential for adrenal insufficiency after withdrawal of treatment, which may persist for months.

- **Electrolyte Effects:** Corticosteroids can cause elevations of blood pressure, salt and water retention, and increased excretion of potassium; however, these effects are less likely to occur with synthetic derivatives. All corticosteroids increase calcium excretion. Patients, especially those with congestive heart failure or hypertension, should be monitored for signs of edema, weight gain, and imbalance in serum electrolytes. Dietary salt restriction and potassium supplementation may be necessary.
- **Increased Intraocular Pressure:** Corticosteroid use may be associated with development or exacerbation of increased intraocular pressure. Patients with elevated intraocular pressure should be monitored for potential treatment adjustment.
- **Gastrointestinal (GI) Perforation:** Corticosteroid administration is associated with increased risk of GI perforation in patients with certain GI disorders such as active or latent peptic ulcers, diverticulosis, diverticulitis, ulcerative colitis, and in patients with fresh intestinal anastomoses. Corticosteroids should be avoided in these patients because signs of peritoneal irritation following GI perforation may be minimal or absent.
- **Alterations in Bone Density:** Corticosteroids decrease bone formation and increase bone resorption through their effect on calcium regulation and inhibition of osteoblast function. Special consideration should be given to patients with or at an increased risk of osteoporosis prior to initiating corticosteroid therapy.
- **Behavioral and Mood Disturbances:** Corticosteroid use may be associated with new or aggravated adverse psychiatric reactions ranging from euphoria, insomnia, mood swings, or personality changes to severe depression and psychotic manifestations. Special consideration should be given to patients with previous or current emotional instability or psychiatric illness before initiating corticosteroid therapy. Patients should be advised to report any new or worsening behavior or mood disturbances to their healthcare provider.

Adverse Reactions: The most commonly reported adverse reactions (incidence $\geq 1\%$) in clinical studies included sinusitis, cough, and contusions. The most commonly reported treatment-emergent injected knee adverse reactions with Zilretta™ (incidence $\geq 1\%$) were joint swelling and contusions.

Use in Specific Populations:

- **Pregnancy:** There are no data regarding the use of Zilretta™ in pregnant women to inform a drug associated risk of adverse developmental outcomes.
- **Lactation:** There are no available data on the presence of triamcinolone acetonide in either human or animal milk, the effect on the breastfed infant, or the effects of milk production. However, corticosteroids have been detected in human milk and may suppress milk production. It is not known if intra-articular administration of Zilretta™ could result in sufficient systemic absorption to produce detectable quantities in human milk.
- **Females of Reproductive Potential:** Corticosteroids may result in menstrual pattern irregularities such as deviations in timing and duration of menses and an increased or decreased loss of blood.
- **Pediatric Patients:** The safety and efficacy of Zilretta™ in pediatric patients have not been established.

- **Geriatric Patients:** No overall differences in safety or effectiveness were observed between elderly and younger subjects.

Efficacy: The efficacy of Zilretta™ was demonstrated in a multi-center, international, randomized, double-blind, parallel-arm, placebo- and active-controlled study in patients with OA pain of the knee. A total of 484 patients [Zilretta™ 32mg, N=161; placebo (saline), N=162; active control (triamcinolone immediate-release injection 40mg), N=161] were treated and followed for up to 24 weeks. Patients had a mean age of 62 years (range 40 to 85 years). A total of 25% of patients had received at least one prior corticosteroid intra-articular injection more than three months prior to study treatment. A total of 470 patients (97%) completed follow-up to week 12, the time for primary efficacy determination, and 443 (91.5%) completed to week 24. The primary efficacy endpoint was change at baseline at week 12 in the weekly mean of the Average Daily Pain intensity scores (ADP) as assessed by a 0 to 10 Numeric Rating Scale (NRS). Zilretta™ demonstrated a statistically significant reduction in pain intensity at week 12 versus placebo. However, a secondary analysis showed statistical significance was not demonstrated between the Zilretta™ and the active control treatment groups for the change from baseline at week 12.

Cost Comparison:

Medication	Cost Per Vial
Zilretta™ (triamcinolone acetonide ER 32mg/5mL injection)	\$570.00
triamcinolone acetonide 40mg/mL injection	\$8.76
methylprednisolone 40mg/mL injection	\$5.87

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

Recommendations

The College of Pharmacy recommends the prior authorization of Zilretta™ (triamcinolone acetonide ER injection) with the following criteria:

Zilretta™ [Triamcinolone Acetonide Extended-Release (ER) Injection] Approval Criteria:

1. An FDA approved diagnosis of osteoarthritis pain of the knee; and
2. Zilretta™ will only be approvable for use in the knee(s) for osteoarthritis pain; and
3. A patient-specific, clinically significant reason why the member cannot use Kenalog-40® (triamcinolone acetonide 40mg injection).
4. A quantity limit of 1 injection per knee per 12 weeks will apply.

¹ Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 Recommendations for the Use of Nonpharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip and Knee. *Arthritis Care & Research* 2012; 64(4):465-74.

² Sinusas K. Osteoarthritis: Diagnosis and Treatment. *Am Fam Physician* 2012; 85(1):49-56.

³ Zhang Y and Jordan JM. Epidemiology of Osteoarthritis. *Clin Geriatr Med* 2010; 26(3):366-69.

⁴ Zilretta™ Prescribing Information. Flexion Therapeutics, Inc. Available online at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208845s000lbl.pdf. Issued 10/2017. Last accessed 10/27/2017.



Appendix L

Fiscal Year 2017 Annual Review of Ophthalmic Allergy Medications and 30-Day Notice to Prior Authorize Zerviate™ (Cetirizine Ophthalmic Solution)

Oklahoma Health Care Authority
December 2017

Current Prior Authorization Criteria

Ophthalmic Allergy Medications		
Tier-1	Tier-2	Tier-3
cromolyn (Crolom®)	azelastine (Optivar®)	alcaftadine (Lastacaft®)
ketotifen (Alaway®, Zaditor® OTC)	olopatadine (Pazeo®)	bepotastine (Bepreve®)
	olopatadine (Patanol®)	emedastine (Emadine®)
		epinastine (Elestat®)
		lodoxamide (Alomide®)
		loteprednol (Alrex®)
		nedocromil (Alocril®)
		olopatadine (Pataday®)

OTC = Over-the-counter

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

Ophthalmic Allergy Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. A trial of one Tier-1 product for a minimum of two weeks in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

Ophthalmic Allergy Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Recent trials of one Tier-1 product and all available Tier-2 medications for a minimum of two weeks each that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

Utilization of Ophthalmic Allergy Medications: Fiscal Year 2017

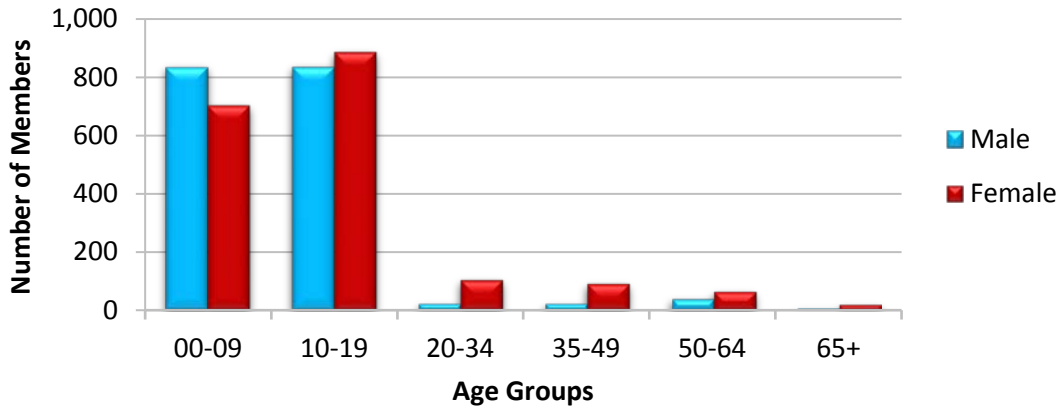
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2016	3,667	5,377	\$97,171.66	\$18.07	\$0.56	35,570	173,269
2017	3,629	5,419	\$99,785.69	\$18.41	\$0.57	35,882	174,346
% Change	-1.00%	0.80%	2.70%	1.90%	1.80%	0.90%	0.60%
Change	-38	42	\$2,614.03	\$0.34	\$0.01	312	1,077

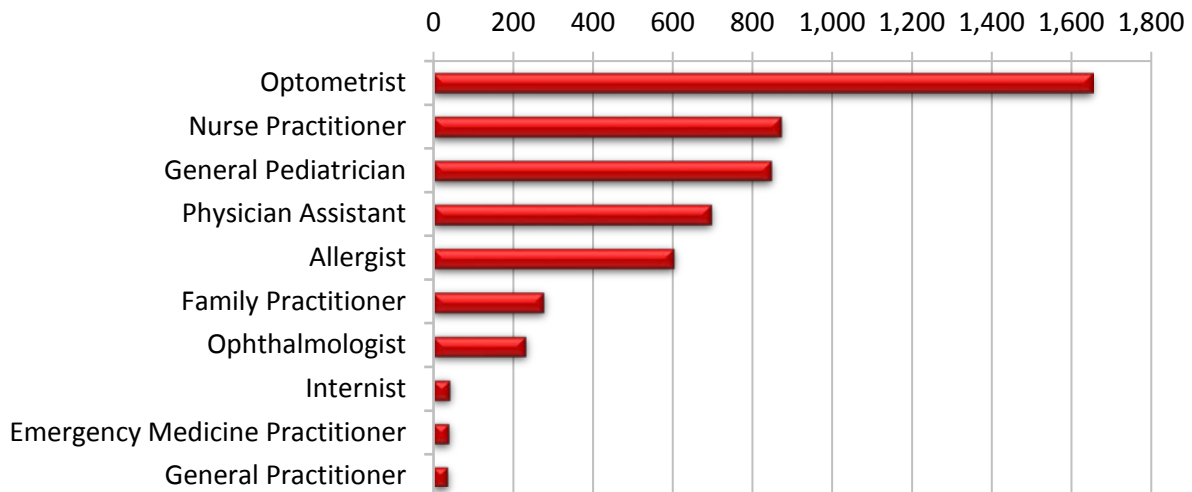
*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Demographics of Members Utilizing Ophthalmic Allergy Medications

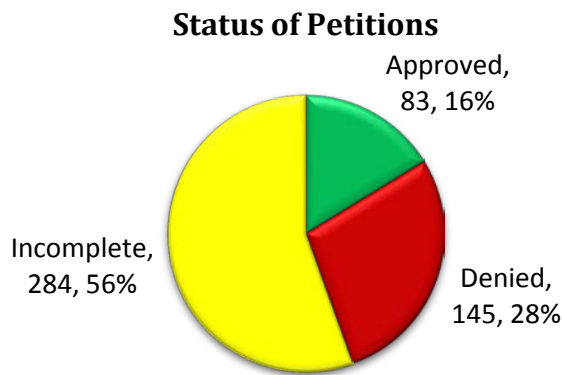


Top Prescriber Specialties of Ophthalmic Allergy Medications by Number of Claims



Prior Authorization of Ophthalmic Allergy Medications

There were 512 prior authorization requests submitted for ophthalmic allergy medications during fiscal year 2017. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2017.



Market News and Updates^{1,2,3}

Anticipated Patent Expiration(s):

- Pataday® (olopatadine): May 2024
- Bepreve® (bepotastine): September 2024
- Lastacaft® (alcaftadine): December 2027
- Pazeo® (olopatadine): May 2032
- Zerviate™ (cetirizine): January 2033

New Launch(es) and Approval(s):

- **June 2017:** Teva Pharmaceuticals announced the launch of generic Pataday® (olopatadine ophthalmic 0.2% solution) in the United States. Currently there are two manufacturers of generic olopatadine ophthalmic 0.2% solution, but the National Average Drug Acquisition Cost (NADAC) of \$111.85 per 2.5mL bottle remains comparable to other Tier-3 ophthalmic allergy medications. The College of Pharmacy will continue to monitor the cost of generic olopatadine in comparison to the branded product, as well as other ophthalmic allergy medications.
- **June 2017:** The U.S. Food and Drug Administration (FDA) approved Zerviate™ (cetirizine ophthalmic 0.24% solution) for the treatment of ocular itching associated with allergic conjunctivitis. Zerviate™ is the first topical ocular formulation of cetirizine.

Zerviate™ (Cetirizine Ophthalmic Solution) Product Summary⁴

Indication(s): Zerviate™ (cetirizine ophthalmic 0.24% solution) is a histamine-1 (H₁) receptor antagonist indicated for the treatment of ocular itching associated with allergic conjunctivitis.

Dosing:

- Zerviate™ is available as a sterile, aqueous ophthalmic solution containing cetirizine 0.24% (equivalent to cetirizine hydrochloride 0.29%) supplied in a 7.5mL or 10mL multi-dose ophthalmic bottle with a dropper tip.
- The recommended dose of cetirizine ophthalmic solution is one drop in each affected eye twice daily.
- Care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle to prevent contamination of the tip and solution.
- Patients should remove contact lenses prior to instillation of cetirizine ophthalmic solution; lenses can be reinserted after 10 minutes following administration.

Efficacy: The efficacy of cetirizine ophthalmic solution was evaluated in two randomized, placebo-controlled, conjunctival allergen challenge (CAC) clinical trials in patients with a history of allergic conjunctivitis. Patients were randomized to receive cetirizine ophthalmic solution or vehicle ophthalmic solution and onset and duration of action were evaluated via an ocular itching severity score ranging from 0 (no itching) to 4 (incapacitating itch) at several time points after CAC administration. A one-unit difference compared to vehicle is considered a clinically meaningful change in the ocular itching severity score. Patients treated with cetirizine ophthalmic solution demonstrated statistically and clinically significantly less ocular itching compared to vehicle at 15 minutes and 8 hours after treatment [Study 1: 15 minutes post-treatment, treatment difference: -1.38 (-1.72, -1.05); 8 hours post-treatment, treatment difference: -0.93 (-1.26, -0.61)].

Cost Comparison:

Medication	Package Size	Price per mL	Price per Bottle
Zerviate™ (cetirizine ophthalmic 0.24% solution)	7.5mL or 10mL	Not Available	Not Available
ketotifen ophthalmic 0.025% solution	5mL	\$1.49	\$7.45
olopatadine ophthalmic 0.1% solution	5mL	\$4.56	\$22.80

Costs do not reflect rebated prices or net costs.

Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Recommendations

The College of Pharmacy recommends the following:

- The placement of Zerviate™ (cetirizine ophthalmic solution) into Tier-3 of the Ophthalmic Allergy Product Based Prior Authorization category. Current Tier-3 criteria would apply.
- Moving Elestat® (epinastine) from Tier-3 to Tier-2 based on net cost. Current Tier-2 criteria would apply.

Ophthalmic Allergy Medications		
Tier-1	Tier-2	Tier-3
cromolyn (Crolom [®])	azelastine (Optivar [®])	alcaftadine (Lastacaft [®])
ketotifen (Alaway [®] , Zaditor [®] OTC)	epinastine (Elestat[®])	bepotastine (Bepreve [®])
	olopatadine (Pazeo [®])	cetirizine (Zerviate[™])
	olopatadine (Patanol [®])	emedastine (Emadine [®])
		lodoxamide (Alomide [®])
		loteprednol (Alrex [®])
		nedocromil (Alocril [®])
		olopatadine (Pataday [®])

OTC = Over-the-counter

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

Ophthalmic Allergy Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. A trial of one Tier-1 product for a minimum of two weeks in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

Ophthalmic Allergy Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Recent trials of one Tier-1 product and all available Tier-2 medications for a minimum of two weeks each that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

Utilization Details of Ophthalmic Allergy Medications: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TIER-1 PRODUCTS					
CROMOLYN PRODUCTS					
CROMOLYN SOD SOL 4%	492	385	\$6,493.98	\$0.41	\$13.20
SUBTOTAL	492	385	\$6,493.98	\$0.41	\$13.20
KETOTIFEN PRODUCTS					
KETOTIF FUM DRO 0.025%	3,165	2,239	\$42,462.41	\$0.43	\$13.42
ALAWAY DRO 0.025%	1,335	937	\$17,836.41	\$0.38	\$13.36
ALAWAY CHILD DRO 0.025%	28	28	\$396.32	\$0.46	\$14.15
EYE ITCH REL DRO 0.025%	9	8	\$160.77	\$0.60	\$17.86
SUBTOTAL	4,537	3,175	\$60,855.91	\$0.41	\$13.41
TIER-1 SUBTOTAL	5,029	3,544	\$67,349.89	\$0.41	\$13.39
TIER-2 PRODUCTS					
AZELASTINE PRODUCTS					
AZELASTINE DRO 0.05%	63	23	\$2,009.95	\$1.03	\$31.90
SUBTOTAL	63	23	\$2,009.95	\$1.03	\$31.90

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
OLOPATADINE PRODUCTS					
OLOPATADINE DRO 0.1%	199	71	\$8,015.61	\$1.42	\$40.28
PAZEO DRO 0.7%	94	40	\$16,604.76	\$6.18	\$176.65
SUBTOTAL	293	110	\$24,620.37	\$2.96	\$84.03
TIER-2 SUBTOTAL	356	130	\$26,630.32	\$2.59	\$74.80
TIER-3 PRODUCTS					
ALCAFTADINE PRODUCTS					
LASTACRAFT SOL 0.25%	2	1	\$397.59	\$6.63	\$198.80
SUBTOTAL	2	1	\$397.59	\$6.63	\$198.80
LOTEPREDNOL PRODUCTS					
ALREX SUS 0.2%	2	2	\$386.42	\$6.44	\$193.21
SUBTOTAL	2	2	\$386.42	\$6.44	\$193.21
OLOPATADINE PRODUCTS					
PATADAY SOL 0.2%	29	5	\$4,872.54	\$5.70	\$168.02
OLOPATADINE SOL 0.2%	1	1	\$148.93	\$4.96	\$148.93
SUBTOTAL	30	5	\$5,021.47	\$5.67	\$167.38
TIER-3 SUBTOTAL	34	7	\$5,805.48	\$5.78	\$170.75
TOTAL	5,419	3,629*	\$99,785.69	\$0.57	\$18.41

*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 09/2017. Last accessed 11/13/2017.

² Teva Pharmaceuticals. Teva Announces Exclusive Launch of Generic Pataday® in the United States. *Business Wire*. Available online at: http://www.tevapharm.com/news/teva_announces_exclusive_launch_of_generic_pataday_in_the_united_states_06_17.aspx. Issued 06/09/2017. Last accessed 11/14/2017.

³ Han DH. FDA Approves Zerviate for Allergic Conjunctivitis. *MPR*. Available online at: <http://www.empr.com/news/cetirizine-ophthalmic-solution-ocular-itching-zerviate/article/665808/>. Issued 06/01/2017. Last accessed 11/14/2017.

⁴ Zerviate™ Prescribing Information. Akorn, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208694s000lbl.pdf. Last revised 05/2017. Last accessed 11/13/2017.



Appendix M



Industry News and Updates

Oklahoma Health Care Authority

December 2017

Introduction

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

News and Updates^{1,2,3}

News:

- **Clemastine:** Findings of a Phase 2 trial of clemastine fumarate in patients with multiple sclerosis were published online in *The Lancet*. Clemastine, an over-the-counter (OTC) allergy medication, has previously been shown to promote myelin regeneration and restore neural function in rats. Researchers from the University of California-San Francisco tested the effect of the medication in 50 patients with relapsing multiple sclerosis with chronic demyelinating optic neuropathy. In the double-blind trial, 25 patients received clemastine for 90 days followed by placebo for 60 days, and 25 patients received placebo for 90 days followed by clemastine for 60 days. Researchers used visual evoked potentials (VEPs) to assess the medication's effect. The neural signal from the eye to the back of the brain was significantly faster than it was at baseline in patients taking clemastine. Furthermore, the improvement persisted after patients were switched from clemastine to placebo, suggesting durability of the myelin repair.
- **Eczema:** A researcher found that children whose mothers had a dog while they were pregnant were significantly less likely to develop atopic dermatitis, or eczema, as toddlers. Dr. Gagandeep Cheema, MD, and colleagues examined data from 749 maternal-child pairs in the Wayne County Health Environment Allergy and Asthma Longitudinal Study (WHEALS) cohort. They reported that at age 2 years, children with prenatal exposure to a dog had a significantly reduced risk of eczema compared to children whose mothers were not exposed to a dog (OR 0.48, 95% CI: 0.30 to 0.76, p=0.002). However, the significance of the effect did not extend into older childhood. Dr. Cheema stated that the mechanism for the protective effect of prenatal dog exposure on a child developing eczema remains elusive. She hypothesized that dogs have the potential to alter the developing infant microbiome and "skew away from the Th2 pathway."
- **Pain Medications:** Results of a randomized clinical trial of 411 emergency department patients with moderate-to-severe acute extremity pain were published in the *Journal of the American Medical Association*. In the study, all patients with acute extremity pain were given acetaminophen plus either ibuprofen or one of three opioids: codeine, hydrocodone, or oxycodone. The primary outcome of the study was the between-group difference in decline in pain two hours after ingestion of medication. An 11-point

numerical rating scale (NRS) was used to assess pain intensity, in which 0 indicates no pain and 10 indicates the worst pain possible. The baseline mean NRS pain score was 8.7. In this trial, there was no statistically significant or clinically important differences in pain reduction at two hours between the treatment groups. In the ibuprofen plus acetaminophen group, mean pain scores decreased by 4.3 (95% CI: 3.6 to 4.9); 4.4 (95% CI: 3.7 to 5.0) with oxycodone and acetaminophen; 3.5 (95% CI: 2.9 to 4.2) with hydrocodone and acetaminophen; and 3.9 (95% CI: 3.2 to 4.5) with codeine and acetaminophen.

¹ Tumolo J. Can an OTC Allergy Drug Restore Function in Patients with MS? *Managed Health Care*. Available online at: <https://www.managedhealthcareconnect.com/content/can-otc-allergy-drug-restore-function-patients-ms>. Issued 10/30/2017. Last accessed 11/01/2017.

² Walker M. Dogs: Mom's Best Friend for Reducing Eczema Risk in Toddlers? *MedPage Today*. Available online at: <https://www.medpagetoday.com/meetingcoverage/acaai/68908>. Issued 10/31/2017. Last accessed 11/01/2017.

³ Chang AK, Bijur PE, Esses D, et al. Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department. *JAMA* 2017; 318(17):1661-1667. doi:10.1001/jama.2017.16190



Appendix N



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 1st, 2017

FDA approves first biosimilar for the treatment of certain breast and stomach cancers

The FDA approved Ogivri™ (trastuzumab-dkst) as a biosimilar to Herceptin® (trastuzumab) for the treatment of patients with breast or metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma) whose tumors overexpress the HER2 gene (HER2+). Ogivri™ is the first biosimilar approved in the U.S. for the treatment of breast cancer or stomach cancer and the second biosimilar approved in the U.S. for the treatment of cancer.

As with any treatment, health care professionals should review the prescribing information in the labeling for detailed information about the approved uses.

Biological products are generally derived from a living organism and can come from many sources, such as humans, animals, microorganisms, or yeast. A biosimilar is a biological product that is approved based on data showing that it is highly similar to a biological product already approved by the FDA (reference product) and has no clinically meaningful differences in terms of safety, purity, and potency (i.e., safety and effectiveness) from the reference product, in addition to meeting other criteria specified by law.

The FDA's approval of Ogivri™ is based on review of evidence that included extensive structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamic data, clinical immunogenicity data, and other clinical safety and effectiveness data that demonstrated Ogivri™ is biosimilar to Herceptin®. Ogivri™ has been approved as a biosimilar, not as an interchangeable product.

Common expected side effects of Ogivri™ for the treatment of HER2+ breast cancer include headache, diarrhea, nausea, chills, fever, infection, congestive heart failure, insomnia, cough, and rash. Common expected side effects of Ogivri™ for the treatment of HER2+ metastatic stomach cancer include low levels of certain white blood cells (neutropenia), diarrhea, fatigue, anemia, inflammation of the mouth (stomatitis), weight loss, upper respiratory tract infections, fever, low levels of blood platelets (thrombocytopenia), mucosal inflammation, common cold, and unusual taste sensation (dysgeusia). Serious expected side effects of Ogivri™ include worsening of chemotherapy-induced neutropenia. Like Herceptin®, the labeling for Ogivri™ contains a Boxed Warning to alert health care professionals and patients about increased risks of heart disease (cardiomyopathy), infusions reactions, pulmonary toxicity, and embryo-fetal toxicity. Patients should stop taking Ogivri™ if cardiomyopathy, life-threatening allergic reactions (anaphylaxis), swelling below the skin (angioedema), inflammation of the lungs (interstitial pneumonitis), or fluid in the lungs (acute respiratory distress syndrome) occur. Patients should be advised of the potential risk to a developing fetus and to use effective contraception. The FDA granted approval of Ogivri™ to Mylan GmbH. Herceptin® was approved in September 1998 and is manufactured by Genentech, Inc.

FDA NEWS RELEASE

For Immediate Release: December 1st, 2017

FDA approves first once-monthly buprenorphine injection, a medication-assisted treatment option for opioid use disorder

Agency encourages safe adoption and more widespread use of FDA-approved treatments to help combat opioid addiction

The FDA approved Sublocade™, the first once-monthly injectable buprenorphine product for the treatment of moderate-to-severe opioid use disorder (OUD) in adult patients who have initiated treatment with a transmucosal (absorbed through mucus membrane) buprenorphine-containing

product. It is indicated for patients that have been on a stable dose of buprenorphine treatment for a minimum of seven days.

Buprenorphine for the treatment of OUD is currently approved to be administered as a tablet or film that dissolves in the mouth, or as an implant. Sublocade™ provides a new treatment option for patients in recovery who may value the benefits of a once-monthly injection compared to other forms of buprenorphine, such as reducing the burden of taking medication daily as prescribed. An independent FDA advisory committee supported the approval of Sublocade™ at a meeting held last month.

Improving access to prevention, treatment and recovery services, including the full range of medication-assisted treatments (MAT), is a focus of the FDA's ongoing work to reduce the scope of the opioid crisis and one part of the U.S. Department of Health and Human Services' Five-Point Strategy to Combat the Opioid Crisis.

OUD is the diagnostic term used for a chronic neurobiological disease characterized by a problematic pattern of opioid use leading to significant impairment or distress and includes signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances for no legitimate medical purpose or, if another medical condition is present that requires opioid treatment, the opioid is used in doses far greater than the amount needed for treatment of that medical condition.

MAT is a comprehensive approach that combines approved medications (currently, methadone, buprenorphine, or naltrexone) with counseling and other behavioral therapies to treat patients with OUD. Regular adherence to MAT with buprenorphine reduces opioid withdrawal symptoms and the desire to use opioids, without causing the cycle of highs and lows associated with opioid misuse or abuse. At proper doses, buprenorphine also decreases the pleasurable effects of other opioids, making continued opioid abuse less attractive. According to the Substance Abuse and Mental Health Services Administration, patients receiving MAT for their OUD cut their risk of death from all causes in half.

Sublocade™ should be used as part of a complete treatment program that includes counseling and psychosocial support. Sublocade™ is a drug-device combination product that utilizes buprenorphine and the Atrigel Delivery System in a pre-filled syringe. It is injected by a health care professional (HCP) subcutaneously as a solution, and the delivery system forms a solid deposit, or depot, containing buprenorphine. After initial formation of the depot, buprenorphine is released by the breakdown of the depot. In clinical trials, Sublocade™ provided sustained therapeutic plasma levels of buprenorphine over the one-month dosing interval.

The safety and efficacy of Sublocade™ were evaluated in two clinical studies (one randomized controlled clinical trial and one open-label clinical trial) of 848 adults with a diagnosis of moderate-to-severe OUD who began treatment with buprenorphine/naloxone sublingual film. Once the dose was determined stable, patients were given Sublocade™ by injection. A response to MAT was measured by urine drug screening and self-reporting of illicit opioid use during the six-month treatment period. Results indicated that Sublocade™-treated patients had more weeks without positive urine tests or self-reports of opioid use, and a higher proportion of patients had no evidence of illicit opioid use throughout the treatment period, compared to the placebo group.

The most common side effects from treatment with Sublocade™ include constipation, nausea, vomiting, headache, drowsiness, injection site pain, itching at the injection site, and abnormal liver function tests. The safety and efficacy of Sublocade™ have not been established in children or adolescents less than 17 years of age. Clinical studies of Sublocade™ did not include participants over the age of 65 years.

The FDA is requiring postmarketing studies to assess which patients would benefit from a higher dosing regimen, to determine whether Sublocade™ can be safely initiated without a dose stabilization period of sublingual buprenorphine, to assess the feasibility of administering Sublocade™ at a longer inter-dose interval than once-monthly, and to determine a process for transitioning patients with long-term stability on a transmucosal buprenorphine dose to a monthly dose of Sublocade™ without the use of a higher dose for the first two months of treatment (loading dose).

Sublocade™ has a boxed warning that provides important safety information, including the risks of intravenous (IV) self-administration. If the product were to be administered IV rather than subcutaneously, the solid mass could cause occlusion, tissue damage, or embolus which can lead to death. Sublocade™ must be prescribed and dispensed as part of a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the product is not distributed directly to patients. Sublocade™ will be

provided to HCPs through a restricted program, administered only by HCPs in a health care setting, and will require health care settings and pharmacies that dispense Sublocade™ to complete an enrollment form attesting that they have procedures in place to ensure that Sublocade™ is dispensed only to HCPs and not directly to patients.

The FDA granted this application Priority Review and Fast Track designations.

The FDA granted the approval of Sublocade™ to Indivior Inc.

FDA NEWS RELEASE

For Immediate Release: November 6th, 2017

FDA approves first treatment for certain patients with Erdheim-Chester Disease, a rare blood cancer

The FDA expanded the approval of Zelboraf® (vemurafenib) to include the treatment of certain adult patients with Erdheim-Chester Disease (ECD), a rare cancer of the blood. Zelboraf® is indicated to treat patients whose cancer cells have a specific genetic mutation known as BRAF V600. This is the first FDA-approved treatment for ECD.

ECD is a slow-growing blood cancer that originates in the bone marrow. ECD causes an increased production of histiocytes, a type of white blood cell. Excess histiocytes can result in tumors infiltrating many organs and tissues throughout the body, including the heart, lungs, brain and others. ECD is estimated to affect 600 to 700 patients worldwide. Approximately 54% of patients with ECD have the BRAF V600 mutation. Patients with ECD have very limited life expectancies.

Zelboraf® is a kinase inhibitor that works by blocking certain enzymes that promote cell growth.

The efficacy of Zelboraf® for the treatment of ECD was studied in 22 patients with BRAF-V600-mutation positive ECD. The trial measured the percent of patients who experienced a complete or partial reduction in tumor size (overall response rate). In the trial, 11 patients (50%) experienced a partial response and 1 patient (4.5%) experienced a complete response.

Common side effects of Zelboraf® in patients with ECD include joint pain, small, raised bumps (maculopapular rash), hair loss, fatigue, prolonged QT interval, and skin growths (papilloma).

Severe side effects of Zelboraf® include the development of new cancers (skin cancer, squamous cell carcinoma, or other cancers), growth of tumors in patients with BRAF wild-type melanoma, hypersensitivity reactions (anaphylaxis and DRESS syndrome), severe skin reactions (Stevens-Johnson Syndrome and toxic epidermal necrolysis), heart abnormalities (QT prolongation), hepatotoxicity, photosensitivity, severe reactions in the eye (uveitis), immune reactions after receiving radiation treatment (radiation sensitization and radiation recall), kidney failure, and thickening of tissue in the hands and feet (Dupuytren's contracture and plantar fascial fibromatosis). Zelboraf® can cause harm to a developing fetus; women should be advised of the potential risk to the fetus and to use effective contraception.

The FDA granted this application Priority Review and Breakthrough Therapy designations for this indication. Zelboraf® also received Orphan Drug designation for this indication, which provides incentives to assist and encourage the development of drugs for rare diseases.

The FDA granted the approval of Zelboraf® to Hoffman-LaRoche, Inc.

Safety Announcements

FDA works to help relieve the IV fluid shortages in wake of Hurricane Maria

[11/14/2017] The FDA is actively working with drug manufacturers to address critical shortages of IV fluids aggravated by Hurricane Maria's impact on Puerto Rican drug manufacturing facilities.

Because the hurricane disrupted Baxter International's IV fluid production facilities in Puerto Rico, the FDA has not objected to the temporary import from Baxter facilities in Ireland, Australia, Mexico, and Canada and from B. Braun in Germany. B. Braun recently announced they were slowing production. It is important to note that when FDA exercises regulatory discretion with respect to importation of a medically necessary drug from another country, the agency evaluates the foreign firms and drug products to ensure they are of adequate quality and do not pose undue risks to patients. A letter from the company explaining that the drug is being imported to address a shortage is posted on the FDA Drug Shortages webpage and accompanies the drug when it is shipped.

In addition to the temporary imports, the FDA continues to expedite review of drug applications that may help relieve shortages. The agency recently approved Fresenius Kabi and Laboratorios Grifols saline products and anticipates that availability of these products will help address the shortage. Although Hurricane Maria affected Baxter's facilities in Puerto Rico, there have been limited supplies of IV fluids since 2014. Since that time, the approved manufacturers Pfizer/Hospira and now ICU Medical, Baxter, and B. Braun, have worked with the FDA to meet steadily increasing demands for IV fluids. Since 2014, the FDA has encouraged the firms with FDA-approved saline products to add capacity to meet increased U.S. demand and has searched for additional manufacturers to help prevent future shortages. The agency anticipates this situation will improve over time and will continue to address this shortage.

Safety Announcements

FDA Drug Safety Communication: FDA to evaluate increased risk of heart-related death and death from all causes with the gout medicine febuxostat (Uloric®)

[11/15/2017] The FDA is alerting the public that preliminary results from a safety clinical trial show an increased risk of heart-related death with febuxostat (Uloric®) compared allopurinol. The FDA required the Uloric® drug manufacturer, Takeda Pharmaceuticals, to conduct this safety study when the FDA approved the medicine in 2009. Once the FDA receives the final results from the manufacturer, they will conduct a comprehensive review and will update the public with any new information.

Febuxostat is FDA-approved to treat gout in adults. Gout happens when a naturally occurring substance in the body called uric acid builds up and causes sudden attacks of redness, swelling, and pain in one or more joints. Febuxostat works by lowering uric acid levels in the blood.

Health care professionals should consider this safety information when deciding whether to prescribe or continue patients on febuxostat. Patients should talk to their health care professionals if they have any questions or concerns. Patients should not stop taking their medicine without first consulting with their health care professional.

The febuxostat drug labels already carry a Warning and Precaution about cardiovascular events because the clinical trials conducted before approval showed a higher rate of heart-related problems in patients treated with febuxostat compared to allopurinol. These problems included heart attacks, strokes, and heart-related deaths. As a result, the FDA required an additional safety clinical trial after the drug was approved and on the market to better understand these differences, and that trial was finished recently.

The safety trial was conducted in over 6,000 patients with gout treated with either febuxostat or allopurinol. The primary outcome was a combination of heart-related death, non-deadly heart attack, non-deadly stroke, and a condition of inadequate blood supply to the heart requiring urgent surgery. The preliminary results show that overall, febuxostat did not increase the risk of these combined events compared to allopurinol. However, when the outcomes were evaluated separately, febuxostat showed an increased risk of heart-related deaths and death from all causes.

The FDA is continuing to evaluate this safety issue and will update the public when they have more information. They urge health care professionals and patients to report side effects involving febuxostat or other medicines to the FDA MedWatch program.

Current Drug Shortages Index (as of December 1st, 2017):

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

[Amino Acids](#)

Currently in Shortage

[Aminocaproic Acid Injection, USP](#)

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

[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, 0.1 mg/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 (Thytolar) 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
Promethazine (Phenergan) Injection	Currently in Shortage
Ranitidine Injection, USP	Currently in Shortage

Rocuronium Bromide Injection	<i>Currently in Shortage</i>
Sacrosidase (Sucraid) Oral Solution	<i>Currently in Shortage</i>
Sclerosol Intrapleural Aerosol	<i>Currently in Shortage</i>
Sincalide (Kinevac) Lyophilized Powder for Injection	<i>Currently in Shortage</i>
Sodium Acetate Injection, USP	<i>Currently in Shortage</i>
Sodium Bicarbonate Injection, USP	<i>Currently in Shortage</i>
Sodium Chloride 0.9% Injection Bags	<i>Currently in Shortage</i>
Sodium Chloride 23.4% Injection	<i>Currently in Shortage</i>
Sodium Phosphate Injection	<i>Currently in Shortage</i>
Sterile Talc Powder	<i>Currently in Shortage</i>
Technetium Tc99m Succimer Injection (DMSA)	<i>Currently in Shortage</i>
Theophylline Extended Release Tablets and Capsules	<i>Currently in Shortage</i>
Tolmetin Sodium Tablets, USP	<i>Currently in Shortage</i>