Virginia's Department of Medical Assistance Services
Pharmacy and Therapeutics Committee Meeting

Thursday, September 17, 2020 - 10:00 a.m.

Please click on this link to join the WebEx
Audio Access: 866-692-4530; Pin 161 535 7780

This is an electronic public meeting held pursuant to Items 4-0.01(g) in House Bill 29 and House Bill 30.
The FOIA Councils "*Electronic Meetings Public Comment"* form for submitting feedback on this electronic meeting may be accessed at http://foiacouncil.dls.virginia.gov/sample%20letters/welcome.htm

Welcome and Comments from DMAS' Director	**Karen Kimsey**
Virginia's Secretary of Health & Human Resources	**Daniel Carey, MD, MHCM**
Call to Order	**Chethan Bachireddy, MD, CMO, Chair**
Approval of Minutes from April 20, 2020 Meeting	**P&T Committee Members**
Drug Utilization Review (DUR) Board Update	**Rachel Cain, PharmD**
PDL Management	**P&T Committee Members**

PDL Phase II – New Drug Review (Therapeutic Class)

Brand Drugs
Arazlo® (Acne Agents, Topical)
Avsola™ (Cytokine & Cam Antagonists) (Closed class)
Licart Patch (topical NSAIDS)
Lyumjev™ (Hypoglycemics, Insulin & Related Agents)
Nurtec® ODT (Antimigraine Agents, Other)
Trijardy® XR (Hypoglycemics, SGLT2) (Closed class)
Zeposia® (Multiple Sclerosis Agents)
Zilxi™ Foam (Rosacea Agents, Topical)

Generics Drugs and New Dosage Forms (additional information on P&T Committee web site)
Antipsoriatic, Topical TCR calcipotriene 0.005% foam & calcipotriene/betamethasone suspension new generic for Sorilux and Taclonex susp
Hypoglycemics, Metformin new generic for Riomet Solution
NSAIDS TCR: naproxen-esomeprazole DR new generic for Vimovo, ketorolac tromethamine new generic for SPRIX, indomethacin new generic for TIVORBEX
Opiate Dependence Treatments TCR naloxone HCL new a generic for EVZIO
Stimulants & Related Agents TCR methylphenidate ER new generic for Aptensio XR

PDL Phase I – Annual Review (Therapeutics Classes with Updates for P&T Committee Review)

Antibiotics/Anti-Infectives
Antibiotics, Vaginal

Antivirals
Hepatitis C Agents *(Closed Class)*

Cardiac Medications
Angiotensin Modulators *(includes ACEs, ARBs, & CCB combination products)*
Lipotropics, Other *(includes Bile Acid Sequestrants, Cholesterol Absorption Inhibitor agents, Fibric Acid derivatives, Microsomal Triglyceride Transfer Protein Inhibitors, Niacin derivatives, Oligonucleotide Inhibitors and Omega 3 agents)*
Pulmonary Arterial Hypertension Agents, Oral/Inhaled/Injectable *(includes Endothelin-1 agents, PDE-5 Inhibitors; Prostacyclin analogues, Prostacyclin Vasodilator, Soluble Guanylate Cyclase Stimulators)*

Central Nervous System
Anticonvulsants
Antipsychotics (includes oral and long-acting injectables) *(Closed Class – LA injectables only)*
Sedative Hypnotics

Dermatitis
Immunomodulators, Atopic Dermatitis

Gastrointestinal
Antiemetic/Antivertigo Agents
H. pylori Agents
Histamine-2 Receptor Antagonists (H-2RA)
Proton Pump Inhibitors
Ulcerative Colitis

Genitourinary
Bladder Relaxants

Ophthalmics
Allergic Conjunctivitis (includes Ophthalmic Antihistamines & Mast Cell Stabilizers)

Respiratory
Anti-Allergens, Oral
Bronchodilators, Long Acting Beta Adrenergics
Bronchodilators, Short Acting Beta Adrenergics
COPD *(includes Anticholinergics, Bronchodilators and Phosphodiesterase 4 (PDE4) Inhibitors)* *(Closed Class)*

Glucocorticoids *(includes nebulized solutions, metered dose inhalers and combinations)* *(Closed Class)*
Leukotriene Modifiers

PDL Phase I – Annual Review
(Therapeutics Classes without Significant Updates since Last Annual Review – Reviewed by the Department)

Blood Modifiers
Bile Salts
Phosphate Binders

Cardiac Medications
Angiotensin Modulators II *(includes Direct Renin Inhibitors & combination products)*
Antihypertensives, Sympatholytics *(Closed Class)*
Beta Blockers *(includes combination products)*
Calcium Channel Blockers *(includes dihydropyridine and non-dihydropyridine agents)*
Lipotropics, Statins

Central Nervous System
Alzheimer's Agents
Antidepressants, SSRI
Antidepressants, Other

Dermatitis
Steroids, Topical

Endocrine & Metabolic Agents
Glucocorticoids, oral
Growth Hormones *(Closed Class)*
Hereditary Angioedema (HAE)
Progestins for Cachexia

Gastrointestinal
GI Motility, Chronic

Genitourinary
BPH Agents *(includes Alpha Blockers, Androgen Hormone Inhibitors and Phosphodiesterase (PDE) 5 Inhibitors for BPH treatment)*

Ophthalmics
Antibiotics
Antibiotic/Steroid Combinations
Anti-Inflammatory Agents (includes Ophthalmic NSAIDS & Corticosteroids)
Glaucoma Agents *(includes Alpha-2 Adrenergics, Beta-blockers, Carbonic Anhydrase Inhibitors, Prostaglandin Inhibitors)*

Respiratory
Antibiotics, Inhaled *(Closed Class)*
Antihistamines Minimally Sedating
Cough & Cold Agents (Legend)
Epinephrine, Self-injected
Intranasal Rhinitis *(includes antihistamines and corticosteroids)*

Confidential Meeting (Pricing Information Discussion)	**P&T Committee, DMAS & MMA Staff Pursuant to 42 USC §1396r-8**
PDL Recommendations and Vote	**P&T Committee Members**
Criteria Discussion of Phase II New Drugs*	**P&T Committee Members**
Criteria Discussion of PDL Phase I Drug Classes*	**P&T Committee Members**

Next Meeting - tentatively scheduled for March 18, 2021

**Criteria discussions will be held for classes only if deemed PDL eligible by the P&T Committee during Drug Class Discussions.*

VIRGINIA FREEDOM OF INFORMATION ADVISORY COUNCIL
COMMONWEALTH OF VIRGINIA

ELECTRONIC MEETINGS
PUBLIC COMMENT FORM

WE NEED YOUR HELP--Please give us your feedback regarding how meetings using electronic communications technology compare to traditional meetings where everyone is present in the same room at the same time.

1. Name of the public body holding the meeting: _VA Dept of Medical Assistance Services Pharmacy & Therapeutics Committee Meeting
2. Date of the meeting: ____Thursday, September 17, 2020
3. What are your overall thoughts or comments about this meeting? _____

_____

4. Where did you attend this meeting -- main meeting location OR from a remote location? (circle one)

5. Technology used for the meeting (audio only or audio/visual, devices and/or software used--please be as specific as possible--for example, speakerphone, iPad, Skype, WebEx, Telepresence, etc.):
_____

6. Were you able to hear everyone who spoke at the meeting (members of the body and members of the public)?

Poor Excellent
1 2 3 4 5

COMMENT_____

7. How easy was it for you to obtain agenda materials for this meeting?

Easy Difficult
1 2 3 4 5

COMMENT_____

8. Could you hear/understand what the speakers said or did static, interruption, or any other technological problems interfere?

Easy Difficult
1 2 3 4 5

COMMENT_____

9. If the meeting used audio/visual technology, were you able to see all of the people who spoke?

Poorly Clearly
1 2 3 4 5

COMMENT_____

10. If there were any presentations (PowerPoint, etc.), were you able to hear and see them?

Poorly Clearly
1 2 3 4 5

COMMENT_____

11. Were the members as attentive and did they participate as much as you would have expected?

Less More
1 2 3 4 5

COMMENT_____

12. Were there differences you noticed in how the members interacted?

With the other members present:

Very Different No Difference
1 2 3 4 5

With members participating from other locations:

Very Different No Difference
1 2 3 4 5

With the public:

Very Different No Difference
1 2 3 4 5

COMMENT_____

13. Did you feel the technology was a help or a hindrance?

Hindered Helped
1 2 3 4 5

COMMENT_____

14. How would you rate the overall quality of this meeting?

Poor Excellent
1 2 3 4 5

COMMENT_____

THANK YOU. Please send your completed form by mail, facsimile or electronic mail to the FOIA Council using the following contact information:

Virginia Freedom of Information Advisory Council
General Assembly Building, Second Floor
201 North 9th Street, Richmond, Virginia 23219
foiacouncil@dls.virginia.gov/Fax: 804-371-8705/Tele: 866-448-4100

Virginia Medicaid Pharmacy & Therapeutics Committee Meeting

Debbie Moody, R.Ph., Director, Clinical Account Services
Nancy Eldin, Pharm.D., Pharmacist Account Executive
Jeni Hodzic, Lead Formulary Analyst

September 17, 2020

PDL Phase II – New Drug Review *(Therapeutic Class)*

Brand Drugs

- ARAZLO™ *(Acne Agents, Topical)*
- AVSOLA™*(Cytokine and CAM Antagonists)* *(Closed Class)*
- LICART™ Patch *(Topical NSAIDs)*
- LYUMJEV™ *(Hypoglycemics, Insulin & Related Agents)*
- NURTEC™ ODT *(Antimigraine Agents, Other)*
- TRIJARDY™ XR *(Hypoglycemics, SGLT2)* *(Closed class)*
- ZEPOSIA®, BAFIERTAM™ *(Multiple Sclerosis Agents)*
- ZILXI™ Foam *(Rosacea Agents, Topical)*

ARAZLO™ (Acne Agents, Topical)

ARAZLO™ (tazarotene)

- A retinoid approved for the topical treatment of acne vulgaris in patients 9 years of age and older.
- It is approved as a 0.045% lotion to be applied as a thin layer to the affected areas once daily.
- The eyes, mouth, paranasal creases, and mucus membranes should be avoided. (December 2019)

Recommend the drug be PDL Eligible

AVSOLA™ (Cytokine and CAM Antagonists) *(Closed Class)*

AVSOLA™ (infliximab-axxq)

- A TNF blocker and biosimilar to Remicade®

- It is indicated for the treatment of:
  - *Crohn's disease (CD) in adults and pediatric patients,*
  - *Ulcerative colitis (UC) in adults and pediatric patients,*
  - *Rheumatoid arthritis (RA) in combination with methotrexate,*
  - *Ankylosing spondylitis (AS),*
  - *Psoriatic arthritis (PsA),*
  - *Plaque psoriasis (PSO).*

- The usual dosing:
  - *for CD, UC, PsA, and PSO is 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks;*
  - *for RA in combination with MTX, 3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks;*
  - *for AS, 5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks.*

- Boxed warnings, precautions, and adverse reactions are consistent with other infliximab-containing products. (December 2019)

Recommend the drug be PDL Eligible

LICART™ Patch (Topical NSAIDs)

LICART™ Patch (diclofenac epolamine)

- Approved in adults for the topical treatment of acute pain due to minor strains, sprains, and contusions.
- Contraindications include a history of hypersensitivity to local diclofenac or any components of the product, history of asthma, urticarial, or allergic-type reactions after taking aspirin or other NSAIDs, and use in the setting of CABG surgery or non-intact or damaged skin.
- Warnings include hepatotoxicity, hypertension, heart failure and edema, renal toxicity, anaphylactic reactions, serious skin reactions, premature closure of fetal ductus arteriosus, and hematologic toxicity.
- Licart is approved as a 1.3% patch and should be applied once daily to the most painful area.

Recommend the drug be PDL Eligible

LYUMJEV™ (Hypoglycemics, Insulin & Related Agents)

LYUMJEV™ (insulin lispro-aabc)

- A rapid-active human insulin analog indicated to improve glycemic control in adults with diabetes mellitus.
- It is approved for IV and subcutaneous use in 100 units/mL in 10 mL multi-dose vials and 3mL single-patient use Kwikpen, Junior Kwikpen, Tempo pen, and cartridges.
- It is also available in 200 unit/mL 3 mL single-patient use KwikPen.
- Contraindications, warnings, and adverse effects are consistent with other insulin lispro-containing products. (June 2020)

Recommend the drug be PDL Eligible

NURTEC™ ODT (Antimigraine Agents, Other)

NURTEC™ ODT (rimegepant)

- A calcitonin gene-related peptide receptor (CGRP) antagonist, indicated for the acute treatment of migraine with or without aura in adults.
- It is not approved for the preventive treatment of migraine.
- It is available in 75 mg orally disintegrating tablets in packages containing 8 tablets.
- The maximum dose is 75 mg in a 24-hour period.
- The safety of treating more than 15 migraines in a 30-day period has not been established.
- The most common adverse reaction reported was nausea. (February 2020)

Recommend the drug be PDL Eligible

TRIJARDY™ XR (Hypoglycemics, SGLT2) *(Closed class)*

TRIJARDY™ XR (empagliflozin, linagliptin, and metformin)

- Approved as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.
- The indication also includes a statement that empagliflozin is indicated to reduce the risk of CV death in adults with T2DM and established CVD.
- The four tablet strengths available contain 1,000 mg of metformin extended release with empagliflozin and linagliptin in the following strengths: 5mg/2.5mg, 10mg/5mg, 12.5mg/2.5mg, and 25mg/5mg.
- The recommended starting dose should be individualized based on the patient's regimen prior to Trijardy™ XR with a maximum daily dose containing 25mg empagliflozin, 5mg linagliptin, and 2,000mg metformin.
- Black box warning, contraindications, warnings, adverse effects, and drug interactions are similar to those for the individual components. (January 2020)

Recommend the drug be PDL Eligible

ZEPOSIA® (Multiple Sclerosis Agents)

ZEPOSIA® (ozanimod)

- A sphingosine-1-phosphate receptor modulator approved for the treatment of relapsing forms of multiple sclerosis to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults.
- It is available as 0.23, 0.46, and 0.92 mg capsules with a recommended maintenance dose of 0.92 mg once daily following a 7-day titration.
- Prior to initiating therapy with Zeposia several patient evaluations are recommended including complete blood count, ophthalmic evaluation, cardiac evaluation, vaccination history, liver function tests, and a review of current and prior medications.
- Contraindications include a recent cardiac event or presence of second- or third-degree AV block or sick sinus syndrome without a pacemaker, severe untreated sleep apnea, and concomitant use of a MAOI.
- Warnings include risk of infection, bradyarrhythmia, liver injury, fetal risk, increased blood pressure, decreased respiratory function, and macular edema. (March 2020)

Recommend the drug be PDL Eligible

BAFIERTAM™ (Multiple Sclerosis Agents)- (continued)

BAFIERTAM™ (monomethyl fumarate)

- Approved for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults.
- It was approved through a 505 (b)(2) NDA.
- It is available as 95 mg delayed-release capsules with a recommended maintenance dose of 190 mg orally twice daily following an initial dose of 95 mg twice daily for 7 days.
- Prior to initiating therapy with Bafiertam, a complete blood cell count including lymphocyte count and liver function testing is recommended.
- Contraindications, warnings, and adverse reactions are similar to dimethyl fumarate containing products. (May 2020)

Recommend the drug be PDL Eligible

ZILXI™ Foam (Rosacea Agents, Topical)

ZILXI™ (minocycline) topical foam

- A tetracycline-class drug indicated for the treatment of inflammatory lesions of rosacea in adults.
- The topical foam should be applied at approximately the same time each day at least 1 hour before bedtime.
- It is available as a 1.5% topical foam

Recommend the drug be PDL Eligible

PDL Phase II – New Drug Review (Therapeutic Class)

Generic Drugs or New Dosage Forms

- *(Antipsoriatics, Topical)*
  - calcipotriene 0.005% foam (generic for Sorilux®)
  - calcipotriene/betamethasone suspension (generic for Taclonex® susp)

- *(Hypoglycemics, Biguanides)*
  - metformin (generic for Riomet® Solution)

- *(NSAIDs)*
  - naproxen-esomeprazole DR (generic for Vimovo®)
  - ketorolac tromethamine (generic for Sprix®)
  - indomethacin (generic for Tivorbex®)

- *(Opiate Dependence Treatments)*
  - naloxone HCL (authorized generic for Evzio®)

- *(Stimulants & Related Agents)*
  - methylphenidate ER (generic for Aptensio XR™)

Recommend the new generics and new dosage forms be PDL Eligible

PDL Phase I – Annual Review
Therapeutic Classes with Updates

Antibiotics, Vaginal

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Cleocin® ovules (clindamycin) Clindesse® cream (clindamycin) metronidazole gel (generic for MetroGel®/Vandazole®) Vandazole® gel (metronidazole)	*Cleocin® cream (clindamycin)* *clindamycin cream* *MetroGel-Vaginal® (metronidazole)* *Nuvessa® gel (metronidazole)*

- The U.S. Preventive Services Task Force (USPSTF) has issued final recommendations on the screening of bacterial vaginosis (BV) in pregnant persons to prevent preterm delivery.
  - They recommend against screening for BV in pregnant persons who are not at increased risk for preterm delivery (Grade D).
  - In pregnant persons who are at increased risk for preterm delivery, the current evidence is inadequate to determine the benefits and harms of screening for BV (Grade I). (April 2020)

Recommend that the class continue to be PDL Eligible

Hepatitis C Agents (Closed Class)

PREFERRED: SA REQUIRED (Clinical Criteria Apply)	NON-PREFERRED: SA REQUIRED (Clinical Criteria Apply)
Interferon	
Peg-Intron® *(peginterferon alfa-2b)* **Peg-Intron Redipen® *(peginterferon alfa-2b)***	*Pegasys® kit/syringe/vial (peginterferon alfa-2a)* ~~*Pegasys ProClick® (peginterferon alfa-2a)*~~
Protease Inhibitors	
	~~*Olysio™ (simeprevir)*~~
Nucleotide Analog NS5A & NS5B Polymerase Inhibitors & Combinations	
sofosbuvir /velpatasvir (generic Epclusa®)	*Epclusa® (velpatasvir/sofosbuvir)* *Sovaldi™ (sofosbuvir)* *Vosevi™ sofosbuvir/velpatasvir/voxilaprevir)*
NS5A, NS3/4A Inhibitor Combinations	
Mavyret™ (glecaprevir/pibrentasvir)	*Technivie™ (ombitasvir/paritaprevir/ritonavir)* *Viekira Pak™ / Viekira XR™ (ombitasvir/paritaprevir/ritonavir/dasabuvir)* *Zepatier™ (elbasvir/grazoprevir)*
NS5B & Protease Inhibitor Combinations	
	Harvoni® (ledipasvir/sofosbuvir) *ledipasvir/sofosbuvir (generic Harvoni®)*

Hepatitis C Agents (Closed Class) – (continued)

- Epclusa® (sofosbuvir/velpatasvir) is now approved for the treatment of HCV genotypes 1,2,3,4,5, and 6 in pediatric patients ≥ 6 years of age and weighing ≥ 17 kg.
    - It was previously only approved for treatment in adults.
    - The recommended dose in patients ≥ 6 years of age and weighing ≥ 17 kg to < 30 kg is 200/50 mg once daily.
    - The recommended dose in patients ≥ 6 years of age and weighing > 30 kg is 400/100 mg once daily. (March 2020)
- Epclusa (sofosbuvir/velpatasvir) is now approved for the treatment of HCV genotypes 1,2,3,4,5, and 6 in treatment-naïve and treatment-experienced liver transplant recipients with cirrhosis or with compensated cirrhosis.
    - The recommended dosage in this population is once daily for 12 weeks. (July 2020).

Hepatitis C Agents (Closed Class) – (continued)

- The American Association for the Study of Liver Disease (AASLD) and Infectious Diseases Society of America (IDSA) have updated their HCV guidelines.
  - *For the initial treatment of HCV infection in compensated cirrhosis, the glecaprevir/pibrentasvir (Mavyret) regimen has been shortened.*
  - *A new document regarding the simplified HCV treatment for treatment-naive patients without cirrhosis was added.*
  - *The retreatment of persons in whom prior therapy has failed guidance was updated regarding glecaprevir/pibrentasvir (Mavyret) failures and sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures.*
  - *The HCV Testing and Linkage to Care guidance was updated regarding universal screening for adults.*
  - *The HCV in Children section was updated regarding new treatment regimens for children 3 to 11 years old.*
  - *A new recommendation was added to the Management of Acute HCV Infection section for starting treatment without a waiting period.*
  - *The kidney transplant section has also updated treatment recommendations, and the Liver Transplantation section also has new information about transplanting organs from donors who are infected with HCV. (December 2019)*

Hepatitis C Agents (Closed Class) – (continued)

- The US Preventive Services Task Force has released a recommendation regarding screening for hepatitis C virus (HCV) infection in adolescents and adults.
  - *The task force is recommending screening for HCV infection in adults aged 18 to 79 years (recommendation grade B).*
  - *The recommendation expands the population of patients that are recommended to be screened as it applies to all adults aged 18 to 79 years, previously adults born between 1945 and 1965 were recommended for screening as well as others who were at high risk.*
  - *The new recommendation applies to asymptomatic adults, including those who are pregnant, within the recommended age range, including those without known liver disease.*
  - *For the majority of adults, a one-time screening is recommended; however individuals with continued risk for HCV (e.g., past or current injection drug use) should be screened periodically. (March 2020)*

Recommend that the class continue to be PDL Eligible

Angiotensin Modulators (includes ACEs, ARBs, & CCB combination products)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Angiotensin Receptor Blockers	
Entresto™ **irbesartan** **losartan** **olmesartan** **valsartan**	*Atacand®* *Avapro®* *Benicar®* *candesartan* *Cozaar®* *Diovan®* *Edarbi®* *~~eprosartan mesylate~~* *Micardis®* *Teveten®*
Angiotensin Receptor Blockers + Calcium Channel Blockers Combinations	
amlodipine/valsartan	*Azor®* *amlodipine/olmesartan* *amlodipine/olmesartan/HCTZ* *amlodipine/valsartan/HCTZ* *Exforge® & Exforge® HCT* *Tribenzor®*

Angiotensin Modulators (includes ACEs, ARBs, & CCB combination products) – (continued)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED	
Angiotensin Receptor Blockers + Diuretic Combinations		
irbesartan/HCTZ **losartan/HCTZ** **olmesartan/HCTZ** **valsartan/HCTZ**	*Atacand HCT®* *Avalide®* *Benicar HCT®* *candesartan/HCTZ* *Diovan HCT®* *Edarbyclor®* *Hyzaar®* *Micardis HCT®* *telmisartan/HCTZ* *Teveten HCT®*	
ACE Inhibitors		
benazepril **enalapril** **lisinopril** **ramipril**	*Accupril®* *Altace®* *captopril* *Epaned™ soln* *fosinopril* *Lotensin®* *Mavik®* *moexipril*	*Monopril®* *perindopril* *Qbrelis™* *quinapril* *ramipril* *trandolapril* *Univasc®* *Vasotec®* *Zestril®*

Angiotensin Modulators (includes ACEs, ARBs, & CCB combination products) – (continued)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
ACE Inhibitors + Calcium Channel Blocker Combinations	
amlodipine/benazepril	*Lotrel®* *Tarka®* *trandolapril-verapamil ER*
ACE Inhibitors + Diuretic Combinations	
benazepril/HCTZ **lisinopril/HCTZ** **enalapril/HCTZ**	*Accuretic®* *captopril/HCTZ* *fosinopril/HCTZ* *Lotensin HCT®* *moexipril/HCTZ* *quinapril/HCTZ* *Vaseretic®* *Zestoretic®*

Angiotensin Modulators (includes ACEs, ARBs, & CCB combination products) – (continued)

- Mylan has made a business decision to discontinue eprosartan 600mg tablets.
  - No other strengths or formulations of eprosartan will be available. (March 2020)

- Entresto™ (sacubitril/valsartan) is now indicated for the treatment of symptomatic heart failure with systemic left ventricular dysfunction in pediatric patients ≥ 1 year of age.
  - Dosing in pediatric patients is weight-based and administered orally twice daily.
  - The dose may be titrated every 2 weeks or as tolerated.
  - The package insert contains instructions for preparing a 4mg/mL oral suspension prior to dispensing for patients unable to swallow the tablets. (October 2019)

Recommend that the class continue to be PDL Eligible

Lipotropics, Other (includes Bile Acid Sequestrants, Cholesterol Absorption Inhibitor Agents, Fibric Acid Derivatives, Microsomal Triglyceride Transfer Protein Inhibitors, Niacin Derivatives, Oligonucleotide Inhibitors and Omega 3 Agents)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Cholesterol Absorption Inhibitor (CAI) and /or Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitor	
ezetimibe (generic for Zetia®)	*Nexletol™ (bempedoic acid)* *Nexlizet™ (bempedoic acid/ ezetimibe)* *Zetia® (ezetimibe)*
Lipotropics – Omega 3 Fatty Acids	
	Lovaza® (omega 3 acid ethyl esters) *omega-3 acid ethyl esters (generic for Lovaza®)* *Vascepa® (icosapent ethyl)*
Bile Acid Sequestrants	
cholestyramine powder reg & light **colestipol tab** **Prevalite®** **Welchol ® tab**	*Colestid® granule/packet/tab* *colesevelam tab and Pkt (generic Welchol)* *colestipol HCl granules* *Questran® powder/powder Light* *Welchol® ~~Chewable bar~~/ packet*
Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors	
	Praluent® *Repatha®*

Lipotropics, Other (includes Bile Acid Sequestrants, Cholesterol Absorption Inhibitor Agents, Fibric Acid Derivatives, Microsomal Triglyceride Transfer Protein Inhibitors, Niacin Derivatives, Oligonucleotide Inhibitors and Omega 3 Agents) – (continued)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Fibric Acid Derivatives	
fenofibrate (generic Tricor® 48mg, 145mg) **gemfibrozil**	*Antara®* *fenofibrate (generics for Antara® , Fenoglide® & Lipofen®)* *fenofibrate (generics for Triglide®)* *fenofibric acid* *Fenoglide®* *Fibricor®* *Lipofen®* *Lofibra®* *Lopid®* *Tricor®* *Triglide®* *Trilipix™*
Microsomal Triglyceride Transfer Protein Inhibitor	
	Juxtapid ™
Niacin Derivatives	
niacin ER	*Niaspan®* *Niacor®*

NEXLIZET™ (bempedoic acid and ezetimibe)

- Approved as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or established ASCVD who require additional LDL-C lowering.
- Approved through a 505 (b)(2) NDA.
- It is available as a fixed dose combination tablet containing 180 mg of bempedoic acid and 10 mg of ezetimibe.
- Warnings, contraindications, warnings, drug interactions, and adverse reactions are similar to bempedoic acid and ezetimibe containing products. (February 2020)

NEXLETOL™ (bempedoic acid)

- Approved as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or established ASCVD who require additional LDL-C lowering.
- Approved through a 505 (b)(2) NDA.
- It is tablet containing 180 mg of bempedoic acid and the recommended dose is 1 tablet orally once daily with or without food.
- Warnings, contraindications, warnings, drug interactions, and adverse reactions are similar to bempedoic acid containing products. (February 2020)

Lipotropics, Other (includes Bile Acid Sequestrants, Cholesterol Absorption Inhibitor Agents, Fibric Acid Derivatives, Microsomal Triglyceride Transfer Protein Inhibitors, Niacin Derivatives, Oligonucleotide Inhibitors and Omega 3 Agents) – (continued)

- **Vascepa® (icosapent ethyl)** is now approved for use as an adjunct to maximally tolerated statin therapy to reduce the risk of MI, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with triglyceride levels ≥ 150mg/dL and established CV disease or DM and 2 or more risk factors for CV disease based on the results of the REDUCE-IT trial.

  – *Vascepa® is already approved as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500mg/dL) hypertriglyceridemia.*

  – *The dose for all indications is 4 grams per day as either 4 – 0.5gm capsule twice daily with food or 2 – 1gm capsules twice daily with food. (December 2019)*

Recommend that the class continue to be PDL Eligible

Pulmonary Arterial Hypertension (PAH) Agents, Oral/Inhaled

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Inhaled Prostacyclin Analogues	
Ventavis® (iloprost)	*Tyvaso® (treprostinil)*
Oral Endothelin Receptor Antagonist	
Letairis® (ambrisentan) **Tracleer® tab (bosentan)**	*ambrisentan (generic Letairis)* *bosentan (generic Tracleer®)* *Opsumit® (macitentan)* *Tracleer® susp (bosentan)*
Phosphodiesterase 5 Inhibitors (PDE-5)	
Alyq (tadalafil 20mg) **sildenafil tab/susp** **tadalafil**	*Adcirca™ (tadalafil)* *Revatio® tab/susp/inj (sildenafil)*
Prostacyclin Vasodilator and Receptor Agonist	
	Orenitram™ (treprostinil) *Uptravi® (selexipag)*
Soluble Guanylate Cyclase Stimulators	
	Adempas® (riociguat)

- Orenitram™ (treprostinil) is now approved to delay disease progression in the treatment of pulmonary arterial hypertension (PAH; WHO Group 1).
    - Orenitram™ was previously approved to improve exercise capacity for patients with PAH. (October 2019)

Recommend that the class continue to be PDL Eligible

Anticonvulsants

PREFERRED	NON-PREFERRED
Barbiturates	
phenobarbital elixir/tablet **primidone (generic for Mysoline®)**	*Mysoline® (primidone)*
Benzodiazepines	
clobazam (generic Onfi® tab) **clonazepam tablet (generic for Klonopin®)** **diazepam rectal & Device rectal**	*clobazam (generic Onfi® susp)* *clonazepam ODT* *Diastat® rectal* *Diastat® AcuDial™ rectal* *Klonopin® (clonazepam)* *Nayzilam® spray (midazolam)* *Onfi® susp/tab* *Sympazan™ film (clobazam)* *Valtoco® spray (diazepam)*
Cannabidiol	
	Epidiolex® (cannabidiol)

Anticonvulsants – (continued)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Other Anticonvulsants	
Gabitril®	*Banzel® susp/tab*
lamotrigine tab	*Briviact®*
lamotrigine chew tab	*Diacomit®*
lamotrigine XR	*felbamate susp/tab*
levetiracetam soln/tab	*Felbatol® susp/tab*
levetiracetam ER	*Fintepla®*
Vimpat® soln/tab	*Fycompa® susp/tab*
topiramate tab/sprinkle	*Keppra® soln/tab*
zonisamide	*Keppra® XR*
	Lamictal® XR
	Lamictal® ODT/ODT dose pk
	Lamictal® tab/dose pk
	Lamictal® XR dose pk
	lamotrigine tab dose pk & ODT
	Potiga®
	Qudexy ™ XR
	Sabril® powder pack/tab
	tiagabine
	Topamax® tab/sprinkle
	Trokendi™ XR
	vigabatrin (generic Sabril® tab)
	Xcopri®
	Zonegran®

Anticonvulsants - (continued)

PREFERRED	NON-PREFERRED
Carbamazepine Derivatives	
carbamazepine chewable tab/susp/tab **carbamazepine ER** **carbamazepine XR** **oxcarbazepine susp & tab**	*Aptiom®* *Carbatrol®* *Equetro® cap* *Oxtellar™ XR* *Tegretol® susp/tab* *Tegretol® XR* *Trileptal® susp/tab* *vigabatrin powder pack*
Hydantoins	
phenytoin cap/chew tab/susp **phenytoin ext cap**	*Dilantin® cap* *Dilantin® Infatab, susp* *Peganone®* *Phenytek®*
Succinimides	
ethosuximide cap/syrup	*Celontin®* *Zarontin® cap/syrup*
Valproic Acid and Derivatives	
divalproex tab/sprinkle **divalproex ER** **valproic acid**	*Depakene® cap/syrup* *Depakote® ER & sprinkle*

Anticonvulsants – (continued)

XCOPRI® (cenobamate)

- Indicated for the treatment of partial onset seizures in adults.
- Approved as 12.5mg, 25mg, 50mg, 100mg, 150mg, and 200mg tablets.
- The recommended maintenance dose is 200 mg daily with a maximum dose of 400 mg daily.
- Xcopri should be taken once daily and may be used in combination with other AEDs or as monotherapy.
- Contraindications include hypersensitivity to cenobamate or any inactive ingredient and familial short QT syndrome.
- Warnings include Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and multi-organ hypersensitivity, QT shortening, suicidal behavior and ideation, neurological adverse reactions, and withdrawal seizures if discontinued abruptly.
- Common adverse reactions include somnolence, fatigue, diplopia, and headache.
- Xcopri is a DEA schedule V medication. (November 2019)

Anticonvulsants – (continued)

FINTEPLA®(fenfluramine)

- Indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.
- Patients who are not also receiving stiripentol may benefit from a dosage increase up to 0.35 mg/kg twice daily up to a maximum daily dosage of 26 mg.
- Patients receiving stiripentol and clobazam in addition to Fintepla may increase to a maximum of 0.2 mg/kg twice daily up to a maximum daily dose of 17mg.
- Fintepla has a boxed warning for patients with valvular heart disease and pulmonary arterial hypertension due to its serotonergic properties.
- Baseline and periodic ECG monitoring is recommended.
- Contraindications include hypersensitivity reactions and concomitant administration within 14 days of an MAOI.
- Additional warnings include decreased appetite and weight, somnolence, sedation, and lethargy, suicidal ideation and behavior, serotonin syndrome, increased blood pressure, glaucoma, and withdrawal seizures if discontinued abruptly.
- Common adverse reactions include decreased appetite, somnolence, sedation, lethargy, diarrhea, constipation, abnormal ECG, fatigue, malaise, asthenia, ataxia, balance disorder, gait disturbance, increased blood pressure, drooling, salivary hypersecretion, pyrexia, upper respiratory tract infection, vomiting, decreased weight, falls, and status epilepticus.
- Fintepla is a DEA schedule IV medication and is only available through a restricted FINTEPLA REMS program. (July 2020)

Anticonvulsants – (continued)

- Keppra®; Keppra® XR (levetiracetam) are now approved for the treatment of partial onset seizures in patients ≥ 1 month of age as monotherapy.
  - It was previously approved as adjunctive therapy for this indication.
  - Dosing is weight-based and comparable to adjunct dosing. (October 2019)

- Sabril® (vigabatrin) is now approved for use in the treatment of refractory complex partial seizures in patients as young as 2 years of age.
  - It was previously only approved in patients ≥ 10 years of age.
  - The recommended dose for the expanded pediatric indication is based on body weight and is divided into 2 daily doses.
  - Sabril is also approved for the treatment of infantile seizures in patients 1 month to 2 years of age. (January 2020)

Anticonvulsants – (continued)

- Epidiolex® (cannabidiol) has been descheduled by the DEA and is no longer considered to be a controlled substance.
  - It was previously designated as a Schedule V controlled substance. (April 2020)

- Epidiolex® (cannabidiol) is now approved for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome in patients ≥ 1 year of age.
  - It was previously approved for these indications in patients ≥ 2 years of age.
  - Epidiolex is also now approved for the treatment of seizures associated with tuberous sclerosis complex in patients ≥ 1 year of age.
  - Dosing is weight based for twice daily administration for all indications. (August 2020)

Anticonvulsants – (continued)

- VALTOCO® (diazepam nasal spray), CIV
  - A benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older.
  - Nasal spray: 5 mg, 7.5 mg, or 10 mg of diazepam in 0.1 mL.
  - Dosage is dependent on the patient's age and weight.
    - *Maximum Dosage and Treatment Frequency: Do not use more than 2 doses to treat a single episode.*
  - The most common adverse reactions (at least 4%) were somnolence, headache, and nasal discomfort.
  - A contraindication is acute narrow angle glaucoma
  - Antiepileptic drugs (AEDs), including Valtoco, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication.
  - Black Box Warning: Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.

Recommend that the class continue to be PDL Eligible

Antipsychotics

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED	
Atypical		
aripiprazole tablet (generic for Abilify®)	*Abilify® tab/IM inj*	*Saphris® SL*
clozapine tablet (generic for Clozaril®)	*Abilify Mycite®(with sensor)*	*Secuado®Patch*
Latuda® tablet *(lurasidone)*	*aripiprazole ODT, soln*	*Seroquel® IR/XR*
olanzapine IM, ODT, tablet (generic for Zyprexa®)	*Caplyta™ Capsule*	*~~Symbyax®~~*
quetiapine tablet (generic for Seroquel®)	*Clozaril®*	*Versacloz™*
quetiapine ER tablet (generic for Seroquel XR®)	*clozapine ODT*	*Vraylar™*
risperidone ODT/solution/tablet (generic for Risperdal®)	*Fanapt® tab & titration pk*	*Zyprexa® tab/IM/Zydis*
ziprasidone capsule (generic for Geodon®)	*Fazaclo®*	
	Geodon® tab, IM	
	Invega®	
	Nuplazid™ tab, cap	
	olanzapine/fluoxetine	
	paliperidone ER	
	Rexulti® tab	
	Risperdal® ODT/soln/tab	

Antipsychotics – (continued)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Typical	
amitriptyline/perphenazine tablet (generic for Etrafon®/Triavil®)	*fluphenazine elixir/soln/tablet (generic for Prolixin®)*
chlorpromazine tablet (generic for Thorazine®)	*Haldol® IM (haloperidol)*
fluphenazine decanoate	*Moban® tablet (molindone)*
haloperidol decanoate	*molindone tablet (generic for Moban®)*
haloperidol lactate conc	*Orap® tablet (pimozide) – only indicated for Tourette's*
haloperidol tab	*pimozide tablet (generic for Orap®)*
loxapine capsule (generic for Loxitane®)	
perphenazine tablet (generic for Trilafon®)	
trifluoperazine tablet (generic for Stelazine®)	
thiothixene capsule (generic for Navane®)	
thioridazine tablet (generic for Mellaril®)	
Long Acting Injectable (Closed Class)	
Abilify Maintena® *(aripiprazole)*	*Perseris™ (risperidone)*
Aristada® IM injection *(aripiprazole lauroxil)*	*Zyprexa® Relprevv™ (olanzapine)*
Aristada® Initio (aripiprazole lauroxil)	
Invega Sustenna® *(paliperidone palmitate)*	
Invega Trinza® *(paliperidone palmitate)*	
Risperdal Consta® *(risperidone)*	

Antipsychotics – (continued)

- The FDA issued a Drug Safety Communication strengthening warnings regarding bowel concerns in patients taking clozapine.
  - Constipation that may occur with clozapine can, uncommonly, progress to serious bowel complications.
  - The FDA is advising that HCPs evaluate bowel function prior to starting clozapine, avoid prescribing with anticholinergics, counsel patients on this risk, evaluate bowel habits throughout treatment, monitor for symptoms associated with complications, and consider prophylactic laxative treatment if the patient has a history of constipation or bowel obstruction. (January 2020)
- Geodon® IM is now available as a generic. (January 2020)
- Eli Lilly will discontinue Symbyax® 6/50 mg and 12/50 mg capsules. Distribution will continue until the end of December 2020. (July 2020)

Antipsychotics – (continued)

CAPLYTA™ (lumateperone)

- Indicated for the treatment of schizophrenia in adults.
- Approved as 42 mg capsules with the recommended dose of 42 mg once daily with food.
- There is a boxed warning, consistent with other atypical antipsychotics, for increased mortality in elderly patients with dementia-related psychosis.
- Additional warnings include neuroleptic malignant syndrome, tardive dyskinesia, metabolic changes, leukopenia, neutropenia, and agranulocytosis, orthostatic hypotension and syncope, seizures, and potential for cognitive and motor impairment.
- The most common adverse reactions in clinical trials were somnolence/sedation and dry mouth. (January 2020)

Antipsychotics – (continued)

SECUADO® (asenapine)

- A transdermal formulation of asenapine, approved through the 505b2 pathway, indicated for the treatment of adults with schizophrenia.
- Available in 3.8 mg/24 hr, 5.7 mg/24 hr, and 7.6 mg/24 hr transdermal systems.
- The recommended starting dose is 3.8mg/24 hrs with dose titration after 1 week.
- The transdermal patch may be applied to the hip, abdomen, upper arm, or upper back area.
- Contraindications, warnings, and adverse reactions are similar to asenapine-containing products.
- The first and only FDA-approved transdermal system for adults with schizophrenia.

Recommend that the class continue to be PDL Eligible

Sedative Hypnotics

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Non-Benzodiazepine	
zolpidem (generic for Ambien)	*Ambien® (zolpidem)* *Ambien CR® (zolpidem extended release)* *Belsomra® (suvorexant)* *Dayvigo™ (lemborexant)* *doxepin tablet (generic for Silenor®)* *Edluar™ (zolpidem sublingual)* *eszopiclone (generic for Lunesta®)* *Hetlioz (tasimelteon)* *Intermezzo® (zolpidem sublingual)* *Lunesta® (eszopiclone)* *Rozerem® (ramelteon)* *Silenor® (doxepin)* *Sonata® (zaleplon)* *zaleplon (generic for Sonata®)* *zolpidem SL tablet (generic for Intermezzo®)* *zolpidem CR (generic for Ambien CR®)* *Zolpimist® (zolpidem oral spray)*
Benzodiazepine	
temazepam 15 & 30 mg	*estazolam* *flurazepam* *Halcion®* *Restoril®* *temazepam 7.5 mg & 22.5 mg* *triazolam*

Sedative Hypnotics - (continued)

DAYVIGO™ (lemorexant)

- An orexin receptor antagonist that is indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance, in adults.
- Approved as 5 mg and 10 mg tablets.
- The recommended dose is 5 mg taken immediately before going to bed with at least 7 hours remaining before the planned time of awakening.
- The dose may be increased to a max of 10 mg based on clinical response and tolerability.
- The time to sleep onset may be delayed if Dayvigo is taken with or shortly following a meal.
- Contraindicated in patients with narcolepsy.
- Warnings include CNS depressant effects and daytime impairment, sleep paralysis and cataplexy-like symptoms, complex sleep behaviors, compromised respiratory function, worsening of depression/suicidal ideation, and need to evaluate co-morbid diagnoses if insomnia persists.
- The most common adverse reaction was somnolence. (January 2020)

Recommend that the class continue to be PDL Eligible

Immunomodulators, Atopic Dermatitis

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Elidel®	*Eucrisa™* *Dupixent®* *pimecrolimus (generic for Elidel)* *Protopic®* *tacrolimus*

- Eucrisa™ (crisaborole) is now approved for the topical treatment of mild to moderate atopic dermatitis in patients ≥ 3 months of age.
    - It was previously approved for use in patients ≥ 2 years old.
    - Dosing remains the same for all ages, apply a thin layer to the affected area twice daily. (March 2020)

Immunomodulators, Atopic Dermatitis - (continued)

- Dupixent® (dupilumab) is now approved for the treatment of patients ≥ 6 years of age with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
  - Dupixent was previously approved for this indication in patients ≥ 12 years of age.
  - The recommended dosing for pediatric patients 6 to 17 years of age is based on body weight with patients 15 to < 30 kg receiving an initial dose of 600 mg (two 300 mg injections) followed by 300 mg every 4 weeks.
  - For patients 30 kg to < 60 kg, the initial dose is 400 mg (two 200 mg injections) followed by 200 mg every other week.
  - For patients ≥ 60 kg, the initial dose is 600 mg (two 300 mg injections) followed by 300 mg every other week.
  - The pre-filled syringe dose for pediatric patients 6 to 11 years of age should be administered by a caregiver. (May 2020)
- Dupixent is now available in a 300 mg/2mL single-dose prefilled pen for use in adults and adolescents 12 years of age and older.
  - It was previously available as a single-dose prefilled syringe in 300 mg/2 mL and 200 mg/1.14 mL strengths that should be used to administer doses by a caregiver to children 6 to 11 years of age. (June 2020)

Recommend that the class continue to be PDL Eligible

Antiemetic/Antivertigo Agents

PREFERRED: NO SA REQUIRED (Clinical Criteria may apply)	NON-PREFERRED: SA REQUIRED (Clinical Criteria may apply)
Cannabinoids (delta-9THC derivatives)	
dronabinol capsule (generic for Marinol®)	*Cesamet® (nabilone)* *Marinol® (dronabinol)* *Syndros™ solution (dronabinol)*
5-HT3 Receptor Blockers	
ondansetron ODT (generic for Zofran ODT®) **ondansetron tablet (generic for Zofran®)**	*Aloxi® (palonosetron)* *Akynzeo® (netupitant/palonosetron)* *Anzemet® (dolasetron)* *granisetron tablet* ~~*Granisol® (granisetron)*~~ *ondansetron solution (generic for Zofran®)* *palonosetron (generic Aloxi)* *Sancuso® patch (granisetron)* *Zofran® ODT/solution/tablet (ondansetron)* *Zuplenz® film (ondansetron)*
NK-1 Receptor Antagonist	
	aprepitant capsule/pack (generic for Emend®) *Cinvanti™ (Intraven)* *Emend® capsule/Bi-pack/Combo pack/suspension (aprepitant)* *fosaprepitant (generic Emend®)* *Varubi™ IV & tablet (rolapitant)*

Antiemetic/Antivertigo Agents – (continued)

PREFERRED: NO SA REQUIRED (Clinical Criteria may apply)	NON-PREFERRED: SA REQUIRED (Clinical Criteria may apply)
Other	
meclizine **metoclopramide** **promethazine**	*Antivert®* *Bonjesta™* *Compazine® supp/tab* *Compro®* *Diclegis®* *dimenhydrinate* *doxylamine succinate/ vit B6* *Metozolv® ODT* *metoclopramide ODT* *Phenergan®* *prochlorperazine supp* *promethazine 50mg supp* *Reglan®* *scopolamine (generic Transderm-Scop®)* *Tigan®* *Transderm-Scop®* *trimethobenzamide* *Vistaril®*

Antiemetic/Antivertigo Agents – (continued)

- Cinvanti® (aprepitant) is now approved for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single dose regimen in adults with other antiemetic agents.
    - It was already approved for nausea and vomiting associated with MEC and acute and delayed nausea and vomiting associated with highly emetogenic cancer chemotherapy.
    - For this new indication, the recommended single dose regimen is: Cinvanti 130mg IV with 12 mg oral dexamethasone and a 5-HT3 antagonist. (October 2019)
- Akynzeo® (fosnetupitant/palonosetron) is now available in a new single dose 20 mL vial for IV infusion (235mg fosnetupitant/0.25mg palonosetron).
    - It was previously only available as a capsule (300mg netupitant/0.5mg palonosetron) and a lyophilized powder in a single dose vial for reconstitution (235mg fosnetupitant/0.25mg palonosetron). (August 2020)

Recommend that the class continue to be PDL Eligible

H. Pylori Treatment

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Pylera®	*Helidac®* *Omeclamox®-Pak* *lansoprazole/amoxicillin/ clarithromycin* *Prevpac®* *Talicia®*

H. Pylori Treatment – (continued)

TALICIA® (omeprazole magnesium, amoxicillin, and rifabutin)

- Components are indicated for the treatment of *Helicobacter pylori* infection in adults.
- Hypersensitivity Reactions: Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of Talicia.
  - *If hypersensitivity reactions occur, discontinue Talicia and institute immediate therapy (e.g., anaphylaxis management).*
- *Clostridioides difficile*-Associated Diarrhea (CDAD): Evaluate if diarrhea occurs.
- Reduction in the Efficacy of Hormonal Contraceptives: Additional non-hormonal highly effective methods of contraception should be used while taking Talicia.
- Acute Interstitial Nephritis (AIN): Observed in patients taking (Proton Pump Inhibitors (PPIs) and penicillins. Discontinue Talicia if AIN develops.
- Cutaneous and Systemic Lupus Erythematosus: Mostly cutaneous; new onset or exacerbation of existing disease; discontinue Talicia and evaluate.
- Most common adverse reactions (≥1%) were diarrhea, headache, nausea, abdominal pain, chromaturia, rash, dyspepsia, oropharyngeal pain, vomiting, and vulvovaginal candidiasis.

Recommend that the class continue to be PDL Eligible

Histamine II Receptor Antagonists

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
famotidine (OTC & RX) **famotidine oral susp (OTC/RX)**	*cimetidine tab/syrup (OTC/RX)* *nizatidine cap/susp* *Pepcid ® susp/tab (OTC/RX)*

- Ranitidine will no longer be available OTC or prescription due to safety concerns of exposure to NMDA.
  - The NMDA impurity has been found to increase with time and when stored at temperatures greater than room temperature. (April 2020)

Recommend that the class continue to be PDL Eligible

Proton Pump Inhibitors

Proton Pump Inhibitors	
PREFERRED: NO SA REQUIRED	**NON-PREFERRED: SA REQUIRED**
omeprazole (RX) **pantoprazole (Protonix)**	*Aciphex® DR tab/sprinkle* *Dexilant®* *esomeprazole magnesium* *esomeprazole strontium* *lansoprazole cap* *Nexium®* *omeprazole OTC* *omeprazole magnesium OTC* *omeprazole/sodium bicarbonate* *Prevacid® RX, OTC & Solutab* *rabeprazole DR tab* *Prilosec® Rx & Susp* *Protonix®* *Zegerid® cap/OTC/susp packet*

Proton Pump Inhibitors– (continued)

- An update to the International Consensus Recommendations on the Management of Patients with Nonvariceal Upper GI Bleeding addresses the role of pharmacological management.
  - It is recommended that high risk patients with bleeding ulcers with successful endoscopic treatment receive high-dose PPI therapy (IV loading dose, then continuous infusion) for 3 days.
  - It is suggested this is followed by oral PPI twice daily through 14 days, followed by once daily treatment for a total duration dependent on the severity of the bleeding lesion.
  - PPI therapy is suggested as secondary prophylaxis for patients with previous ulcer bleeding who are receiving antiplatelet or anticoagulant therapy. (November 2019)

Proton Pump Inhibitors– (continued)

- The American Gastroenterological Association (AGA) and the Joint Task Force on Allergy-Immunology Practice Parameters (JTF) has issued a clinical practice guideline on the management of eosinophilic esophagitis (EoE).
- Recommendations include: for patients with symptomatic esophageal eosinophilia;
  - proton pump inhibition is suggested over no treatment;
  - topical glucocorticosteroids are recommended over no treatment;
  - topical glucocorticosteroids are suggested rather than oral glucocorticosteroids.
- In patients in remission after a short-term course of topical glucocorticosteroids continuation of topical glucocorticosteroids are suggested over discontinuation of treatment.
- The use of anti-IgE therapy is suggested against for EoE.
- Additional recommendations pertain to use of an elemental diet, an empiric 6-food elimination diet, allergy testing-based elimination diet, as well as which therapies are only recommended in the context of a clinical trial. (May 2020)

Proton Pump Inhibitors– (continued)

- A study published in the American Journal of Gastroenterology reported that of a sample of 53,130 participants, 6.4% tested positive for SARS-CoV-2.
- After adjusting for sociodemographic, lifestyle, and clinical variables, they reported a dose-related increased odds in those on a proton pump inhibitor (PPI); odds ratio, 2.15 with once-daily dosing, 3.67 with twice daily dosing.
- Longer use of twice daily dosing (> 6 months versus ≤ 6 months) was associated with a higher risk of positive COVID-19 test (OR, 3.81 versus 2.31, respectively).
- Of those who tested positive, 96.5% were symptomatic for COVID-19.
- Increased risk was not seen with H2RAs and use of lower-dose H2RAs was associated with slightly decreased odds for reporting a positive test. Source: ***https://journals.lww.com/ajg/Documents/AJG-20-1811_R1(PUBLISH%20AS%20WEBPART).pdf*** (July 2020)

Recommend that the class continue to be PDL Eligible

Ulcerative Colitis

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Ulcerative Colitis – Oral	
Apriso® **Pentasa®** **sulfasalazine DR & IR**	*Asacol ®HD* *Azulfidine® IR & DR* *balsalazide disodium* *budesonide ER (generic Uceris™)* *Colazal®* *Delzicol™* *Dipentum* *Giazo™* *Lialda®* *mesalamine (generic Asacol® HD)* *mesalamine (generic Lialda®)* *Uceris™ tablet*
Ulcerative Colitis – Rectal	
mesalamine rectal supp **mesalamine enema**	*Canasa® rectal supp* *mesalamine kit* *Rowasa® enema/kit* *SFRowasa®* *Uceris™ foam*

Ulcerative Colitis – (continued)

- The American Gastroenterological Association (AGA) has published updated clinical practice guidelines regarding the management of moderate to severe ulcerative colitis (UC).

- Recommendations are provided for the management of adult outpatients as well as hospitalized adults with acute severe UC.

- The following agents are recommended over no treatment for adults with moderate to severe UC: infliximab, adalimumab, golimumab, vedolizumab, tofacitinib, or ustekinumab.

- For patients who are biologic naïve, infliximab or vedolizumab are suggested rather than adalimumab for induction of remission.

- In moderate to severe outpatients, early use of biologics with or without immunomodulator therapy is suggested rather than gradual step up to these agents following failure of 5-aminosalicylates. (January 2020)

Recommend that the class continue to be PDL Eligible

Bladder Relaxants

Urinary Antispasmodics (Bladder Relaxant)	
PREFERRED: NO SA REQUIRED	**NON-PREFERRED: SA REQUIRED**
oxybutynin tab/syrup **oxybutynin ER** **solifenacin** **Toviaz™**	*darifenacin ER (generic Enablex®)* *Detrol® & Detrol® LA* *Ditropan® & Ditropan® XL* *~~Enablex®~~* *flavoxate* *Gelnique™ gel/gel Pump* *Myrbetriq™* *Oxytrol® transdermal includes for Woman OTC* *Sanctura XR* *trospium IR & ER* *tolterodine IR & ER* *VESIcare®*

- Allergan has made a business decision to permanently discontinue all strengths of Enablex®. Generic versions are available. (June 2020)

Recommend that the class continue to be PDL Eligible

Ophthalmics for Allergic Conjunctivitis

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Antihistamines	
Alaway OTC® **ketotifen fumerate** **Pazeo®** **Zaditor® OTC**	*azelastine hcl 0.05% drops* *Bepreve®* *Elestat®* *epinastine 0.05% eye drops* *Ilevro™ 0.3% (QL)* *Lastacaft®* *olopatadine* *Optivar®* *Patanol®* *Pataday®* *Zerviate ™*
Mast Cell Stabilizers	
cromolyn sodium	*Alocril®* *Alomide®*

Ophthalmics for Allergic Conjunctivitis - (continued)

- FDA approved 2 OTC formulations of Pataday® (olopatadine).
  - Pataday Twice Daily Relief (0.1%; former Patanol® Rx version) is approved as a 5 mL bottle for patients 2 years of age and older and is dosed as 1 drop into the affected eye every 6 to 8 hours (maximum of twice per day).
  - Pataday Once Daily Relief (0.2%; former Pataday Rx version) is approved as a 2.5 mL bottle for patients 2 years of age and older and is dosed as 1 drop into the affected eye once daily. (February 2020)
- FDA approved an OTC formulation of Pazeo® (olopatadine 0.7%) to Pataday Once Daily Relief Extra Strength 0.7%.
  - It is approved as a 2.5 mL bottle for adults and children ≥ 2 years of age for the temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair, and dander.
  - It is dosed as 1 drop in the affected eye(s) once daily. (July 2020)

Recommend that the class continue to be PDL Eligible

Anti-Allergens, Oral

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Grass Pollen	
	Oralair®
Peanut	
	Palforzia®

Anti-Allergens, Oral – (continued)

PALFORZIA® [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp]

- An oral immunotherapy (OIT) indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut.
- It is approved for use in patients with a confirmed diagnosis of peanut allergy.
- The initial dose escalation may be administered to patients aged 4 through 17 years.
- Up-dosing and maintenance dosing may be continued in patients 4 years of age and older.
- Palforzia can cause anaphylaxis, which may be life-threatening and can occur at any time during Palforzia therapy
- Prescribe injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use
- Contraindicated in patients with uncontrolled asthma and history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease
- The most common adverse reactions reported in subjects (incidence ≥ 5% and at least 5 percentage points greater than that reported in subjects treated with placebo) are abdominal pain, vomiting, nausea, oral pruritus, oral paresthesia, throat irritation, cough, rhinorrhea, sneezing, throat tightness, wheezing, dyspnea, pruritus, urticaria, anaphylactic reaction, and ear pruritus
- Palforzia is available only through a restricted program called the Palforzia REMS because of the risk of anaphylaxis

Recommend that the class continue to be PDL Eligible

Bronchodilators, Long Acting Beta Adrenergics

Long Acting Beta Adrenergics (LABA) MDIs or Nebulizers	
PREFERRED: NO SA REQUIRED	**NON-PREFERRED: SA REQUIRED**
Foradil® **Serevent Diskus®**	*Arcapta® Neohaler* *Brovana®* *Perforomist®* *Striverdi® Respimat*

- Sunovion has made a business decision to discontinue Arcapta® Neohaler. (March 2020)

Bronchodilators, Long Acting Beta Adrenergics – (continued)

- The American Thoracic Society (ATS) issued guidelines on the pharmacologic management of COPD.
  - Key recommendations include for patients with COPD and dyspnea or exercise intolerance, combination with a LABA and LAMA are recommended over LABA or LAMA monotherapy (strong recommendation).
  - For patients with dyspnea or exercise intolerance despite LABA/LAMA combination therapy, addition of inhaled corticosteroids (ICS) is advised if ≥ 1 COPD exacerbation in the prior year that required antibiotics, oral steroids, or hospitalization.
  - Patients who have been on LABA/LAMA/ICS, ATS suggests stopping the ICS if no exacerbations in the past year.
  - ATS recommends against maintenance oral corticosteroid therapy in patients with frequent and severe exacerbations while on optimal therapy. (April 2020)

Recommend that the class continue to be PDL Eligible

Bronchodilators, Short Acting Beta Adrenergics

Short Acting Metered Dose Inhalers or Devices	
PREFERRED: NO SA REQUIRED	**NON-PREFERRED: SA REQUIRED**
Proair® HFA **Proventil® HFA**	*albuterol HFA (Proair HFA)* *albuterol HFA (Ventolin HFA)* *albuterol HFA (Proventil HFA)* *levalbuterol tartrate HFA* *ProAir® Digihaler™* *ProAir® RespiClick* *Ventolin® HFA* *Xopenex® HFA*
Short Acting Nebulizers	
albuterol sulfate (premixed)	*levalbuterol soln* *Xopenex®*

- Proventil® HFA is now available as a generic.
  - The authorized generic was previously approved. (April 2020)

Recommend that the class continue to be PDL Eligible

COPD (includes Anticholinergics, Bronchodilators and Phosphodiesterase 4 (PDE4) Inhibitors) – (Closed Class)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Anoro Ellipta™ (umeclidinium/vilanterol)	*Daliresp® (roflumilast)*
Atrovent HFA® (ipratropium bromide)	*Duaklir Pressair (aclidinium/formoterol)*
Bevespi Aerosphere™ (glycopyrrolate/formoterol)	*Incruse™ Ellipta® (umeclidinium)*
Combivent® Respimat (ipratropium/albuterol)	*Lonhala™ Magnair™ (glycopyrrolate)*
ipratropium bromide (generic for Atrovent® neb solution)	*~~Seebri® Neohaler (glycopyrrolate)~~*
ipratropium/albuterol neb solution (generic for DuoNeb®)	*Spiriva® Respimat (tiotropium)*
Spiriva® (tiotropium)	*Tudorza Pressair® (aclidinium)*
Stiolto™ Respimat (tiotropium/olodaterol)	*~~Utibron® Neohaler (indacaterol/glycopyrrolate)~~*
	Yupelri™ (revefenacin)

- Sunovion has made a business decision to discontinue Seebri® Neohaler and Utibron® Neohaler. (March 2020)

COPD (includes Anticholinergics, Bronchodilators and Phosphodiesterase 4 (PDE4) Inhibitors) – (Closed Class) (continued)

- Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2020 global strategy for prevention, diagnosis and management of COPD has been released.

- Overall guiding principles are unchanged from 2019 update.

- Changes for 2020 edition include
  1) additional details on the use of eosinophils as efficacy biomarker for ICS,

  2) refined use of non-drug therapies, and

  3) clarified exacerbation diagnosis by providing additional details on alternative diagnoses.

- Corresponding with these updates...
  1) a new figure was added to address factors to consider when ICS therapy is started in combination with one or two long-acting bronchodilators (blood eosinophil count, asthma, exacerbation history);

  2) a new table providing key points for use of non-pharmacological treatments was added;

  3) the differential diagnosis of exacerbations table was added.

- Lastly, another new figure regarding management of COPD based on severity of airflow obstruction, symptoms, exacerbation history, risk factor exposure, and comorbidities was added. (November 2019)

COPD (includes Anticholinergics, Bronchodilators and Phosphodiesterase 4 (PDE4) Inhibitors) – (Closed Class) (continued)

- The American Thoracic Society (ATS) issued guidelines on the pharmacologic management of COPD.
  - Key recommendations include for patients with COPD and dyspnea or exercise intolerance, combination with a LABA and LAMA are recommended over LABA or LAMA monotherapy (strong recommendation).
  - For patients with dyspnea or exercise intolerance despite LABA/LAMA combination therapy, addition of inhaled corticosteroids (ICS) is advised if ≥ 1 COPD exacerbation in the prior year that required antibiotics, oral steroids, or hospitalization.
  - Patients who have been on LABA/LAMA/ICS, ATS suggests stopping the ICS if no exacerbations in the past year.
  - ATS recommends against maintenance oral corticosteroid therapy in patients with frequent and severe exacerbations while on optimal therapy. (April 2020)

Recommend that the class continue to be PDL Eligible

Glucocorticoids (includes nebulized solutions, metered dose inhalers and combinations) – (Closed Class)

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
Inhaled Corticosteroids: Combination Products (Glucocorticoid and Beta Adrenergic)	
Dulera® (mometasone/formoterol) **fluticasone/salmeterol powder (generic for Advair Diskus)** **Symbicort® (budesonide / formoterol)** **Wixela® (fluticasone/ salmeterol)**	*Advair® Diskus & HFA (salmeterol/fluticasone)* *Airduo™ Respiclick (fluticasone/salmeterol)* *Breztri Aerosphere™ (budesonide/formoterol fumarate/glycopyrrolate)* *Breo® Ellipta™ (fluticasone/vilanterol)* *fluticasone/salmeterol (generic for Airduo™)* *Trelegy® Ellipta (fluticasone/umeclidinium/vilanterol)*
Inhaled Corticosteroids: Nebulizer Solution	
budesonide neb solution (generic for Pulmicort®)	*Pulmicort Respules® (budesonide)*
Inhaled Corticosteroids: Metered Dose Inhalers	
Flovent Diskus® & HFA(fluticasone) **Pulmicort Flexhaler® (budesonide)**	*Aerospan™ (flunisolide)* *Alvesco® (ciclesonide)* *Armonair™ Respiclick® (fluticasone)* *Arnuity™ Ellipta® (fluticasone)* *Asmanex HFA® (mometasone)* *QVAR® & QVAR® Redihaler (beclomethasone)*

Glucocorticoids (includes nebulized solutions, metered dose inhalers and combinations) – (Closed Class)– (continued)

Breztri Aerosphere™ (budesonide/formoterol fumarate/glycopyrrolate)

- Indicated for the maintenance treatment of patients with COPD.
- It is not indicated for the relief of acute bronchospasm or for the treatment of asthma.
- It is available as a pressurized MDI containing budesonide 160 mcg, glycopyrrolate 9 mcg, and formoterol fumarate 4.8 mcg per inhalation and is dosed as 2 oral inhalations twice daily.
- It was approved via a 505b2 NDA.
- Contraindications, warnings, and adverse reactions are consistent with products containing budesonide, formoterol fumarate, or glycopyrrolate. (July 2020)

Glucocorticoids (includes nebulized solutions, metered dose inhalers and combinations) – (Closed Class)– (continued)

- Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2020 global strategy for prevention, diagnosis and management of COPD has been released.
- Overall guiding principles are unchanged from 2019 update.
- Changes for 2020 edition include
  1) additional details on the use of eosinophils as efficacy biomarker for ICS,
  2) refined use of non-drug therapies, and
  3) clarified exacerbation diagnosis by providing additional details on alternative diagnoses.
- Corresponding with these updates...
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Glucocorticoids (includes nebulized solutions, metered dose inhalers and combinations) – (Closed Class)– (continued)

- The American Thoracic Society (ATS) issued guidelines on the pharmacologic management of COPD.
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  - Patients who have been on LABA/LAMA/ICS, ATS suggests stopping the ICS if no exacerbations in the past year.
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Recommend that the class continue to be PDL Eligible

Leukotriene Modifiers

PREFERRED: NO SA REQUIRED	NON-PREFERRED: SA REQUIRED
montelukast tabs/chewable tabs	*Accolate®* *Singulair® tabs/chew tabs/granules* *montelukast granules* *zafirlukast* *Zyflo™* *Zyflo CR™* *zileuton ER*

Leukotriene Modifiers – (continued)

- The FDA has recommended a Boxed Warning be added to the prescribing information for montelukast (Singulair®) due to the potential for serious behavior and mood-related changes, including the potential for suicidal ideation or behavior.
- Product labeling already addressed the potential for these serious side effects; however the FDA has determined a stronger warning is warranted especially since there are a number of alternative medications for the conditions for which montelukast is used.
- The FDA is recommending montelukast only be used for allergic rhinitis when other allergy medications are not tolerated or do not provide adequate symptom control.
- In asthma patients, prescribers should evaluate the benefits versus risks of montelukast prior to prescribing.
- In addition, the FDA is requiring a new patient Medication Guide providing details on these risks. (March 2020)

Recommend that the class continue to be PDL Eligible

PDL Phase I – Annual Review
Therapeutic Classes Without Updates
(Reviewed by the Department)

Therapeutic Classes Without Significant Updates Since Last Annual Review (Reviewed by the Department)

Blood Modifiers

- **Bile Salts**
- **Phosphate Binders**

Cardiac Medications

- **Angiotensin Modulators II *(includes Direct Renin Inhibitors & combination products)***
- **Antihypertensives, Sympatholytics *(Closed Class)***
- **Beta Blockers *(includes combination products)***
- **Calcium Channel Blockers *(includes dihydropyridine and non-dihydropyridine agents)***
- **Lipotropics, Statins**

Central Nervous System

- **Alzheimer's Agents**
- **Antidepressants, SSRI**
- **Antidepressants, Other**

Therapeutic Classes Without Significant Updates Since Last Annual Review (Reviewed by the Department) – (continued)

Dermatitis

- **Steroids, Topical**

Endocrine & Metabolic Agents

- **Glucocorticoids, Oral**
- **Growth Hormones *(Closed Class)***
- **Hereditary Angioedema (HAE)**
- **Progestins for Cachexia**

Gastrointestinal

- **GI Motility, Chronic**

Genitourinary

- **BPH Agents *(includes Alpha Blockers, Androgen Hormone Inhibitors and Phosphodiesterase (PDE) 5 Inhibitors for BPH treatment)***

Therapeutic Classes Without Significant Updates Since Last Annual Review (Reviewed by the Department) – (continued)

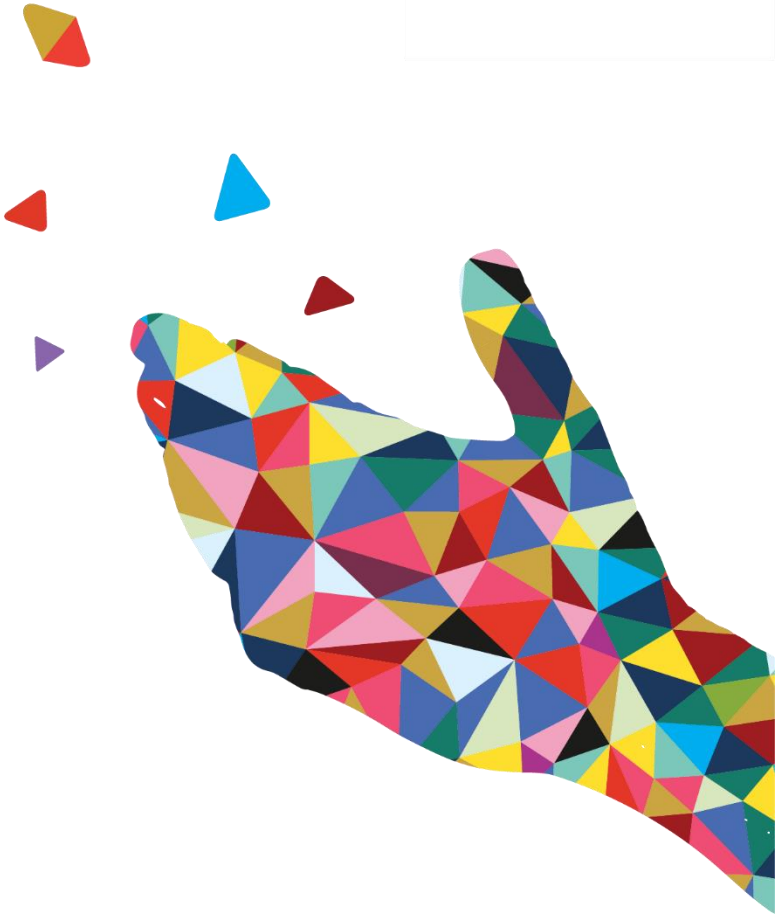
Ophthalmics

- **Antibiotics**
- **Antibiotic/Steroid Combinations**
- **Anti-Inflammatory Agents *(includes Ophthalmic NSAIDS & Corticosteroids)***
- **Glaucoma *(includes Alpha-2 Adrenergics, Beta-Blockers, Carbonic Anhydrase Inhibitors, Prostaglandin Inhibitors)***

Respiratory

- **Antibiotics, Inhaled *(Closed Class)***
- **Antihistamines Minimally Sedating**
- **Cough & Cold Agents (Legend)**
- **Epinephrine, Self-Injected**
- **Intranasal Rhinitis *(includes Antihistamines and Corticosteroids)***

Recommend that these classes continue to be PDL Eligible



THANKS

BREAK FOR FINANCIAL MEETING