Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations

November 17, 2016

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **November 17, 2016** meeting.

Pending is the review of the recommendations and final decisions by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services.

	Description of Recommendation	P & T Vote
1	**New Products to Market: Qbrelis™** Non-prefer in PDL class: *Angiotensin Receptor Blockers (Angiotensin Modulators)* **Length of Authorization:** 1 year Qbrelis (lisinopril) oral solution is indicated for the treatment of hypertension in adults and pediatric patients equal to or greater than 6 years of age, as adjunct therapy for systolic heart failure in adults, and for reduction of mortality in acute myocardial infarction (AMI) in adults. **Approval Criteria:** ▪ 6 - 17 years of age; AND ▪ Have diagnosis of hypertension; AND ▪ Have eGFR > 30mL/min/1.73m2; AND ▪ Not be able to take an oral capsule or tablet. **OR** ▪ Patient must not be pregnant; AND ▪ ≥ 18 years of age; AND ▪ Have diagnosis of heart failure, acute myocardial infarction, or hypertension; AND ▪ Not be able to take an oral capsule or tablet. **Quantity Limit** = adults: 40mg per day; pediatrics - 0.61mg per kg per day or 40mg per day, whichever is lower (to be determined during the clinical review of the PA request).	**Passed** 8 For 0 Against 1 Abstain

	Description of Recommendation	P & T Vote
2	**New Products to Market: Byvalson™** Non-prefer in the PDL class: *Angiotensin Modulator + Combinations (Angiotensin Modulator Combinations)* **Length of Authorization**: 1 year Byvalson (nebivolol/valsartan) is the combination of a beta-blocker and an angiotensin II receptor blocker (ARB) available as a 5mg/80mg tablet. It is indicated for the treatment of hypertension (HTN). **Approval Criteria:** Patient has had a trial and failure of 2 first-line HTN therapies comprised of multiple single agents used in combination (e.g., Calcium Channel Blocker [CCB] + Angiotensin Converting Enzyme Inhibitor [ACEI]). **Quantity Limit** = 1 tablet per day	**Passed** 9 For 0 Against
3	**New Products to Market: Zurampic®** Non-prefer in PDL class: *Antihyperuricemics* **Length of Authorization:** 1 year Zurampic (lesinurad) 200mg tablets are indicated for use in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone. **Approval Criteria:** ▪ ≥ 18 years of age; AND ▪ Have symptomatic hyperuricemia associated with gout; AND ▪ Have documented trial and failure of xanthine oxidase inhibitor monotherapy at maximum tolerated dose; AND ▪ Using lesinurad in combination with a xanthine oxidase inhibitor; AND ▪ Patient does not have severe renal impairment (CrCl < 45mL/min), ESRD, kidney transplant, or is on dialysis; AND ▪ Patient does not have tumor lysis syndrome or Lesch-Nyhan syndrome. **Quantity Limit** = 1 tablet per day	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
4	**New Products to Market: Relistor®** (oral) Non-prefer in PDL class: *GI Motility Agents* (*GI Motility, Chronic)* **Length of Authorization:** 6 months Relistor (methylnaltrexone bromide) tablets are indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. **Approval Criteria:** ▪ ≥ 18 years of age; AND ▪ Patient does not have known or suspected mechanical gastrointestinal obstruction; AND ▪ If patient is female, must not currently be breastfeeding; AND ▪ Response to standard laxative therapy is inadequate (<3 bowel movements in preceding 7 days). Standard therapy is defined as routine, scheduled use of 3 or more of the following: ▪ Dietary changes ▪ Stool softeners ▪ Stimulant laxatives ▪ Osmotic or saline laxatives ▪ Bulk forming laxatives ▪ Lubricants **Quantity Limit** = 3 tablets per day	**Passed** 9 For 0 Against
5	**New Products to Market: Epclusa®** Prefer in PDL class: *Hepatitis C Agents; (Hepatitis C Agents)* Prefer for Genotypes 2 and 3 ONLY. **Length of Authorization:** 12 weeks Epclusa (sofosbuvir/velpatasvir) 400mg/100mg tablets is a fixed-dose combination of a nucleotide analog NS5B polymerase inhibitor (sofosbuvir) and an NS5A inhibitor (velpatasvir) indicated for the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection, with or without compensated cirrhosis, or with decompensated cirrhosis in combination with ribavirin. All class criteria must be met for approval. **Quantity Limit**: 28 tablets per 28 days.	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
6	**New Products to Market: Otovel™** Non-prefer in PDL class: *Otic Antibiotics* **Length of Authorization**: 7 days Otovel™ (ciprofloxacin/fluocinolone acetonide) solution, for otic use, is a combination of an antibacterial and a corticosteroid. Each single-dose vial contains ciprofloxacin 0.3% along with fluocinolone acetonide 0.025%. Otovel solution is indicated for the treatment of acute otitis media with tympanostomy tubes in pediatric patients aged 6 months and older due to *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis*, and *Pseudomonas aeruginosa*, for duration of no more than 7 days. **Criteria for Approval:** ▪ Patient is ≥ 6 months of age; AND ▪ Diagnosis of acute otitis media; AND ▪ Patient has tympanostomy tubes; AND ▪ Patient does not have a viral infection of the external ear canal or any fungal otic infection.	**Passed** 9 For 0 Against
7	**Antipsychotics:** **First Generation:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities, at least 1 representing an agent from each of the potency groups, should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require prior authorization. ▪ Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back. ▪ For any new chemical entity in the *First Generation Antipsychotics* class, require a PA until reviewed by the P&T Advisory Committee. **Second Generation:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 5 unique chemical entities should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require prior approval. ▪ Continue quantity limits on agents in this class. ▪ Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back. For any new chemical entity in the *Second-Generation Antipsychotics* class, require a PA until reviewed by the P&T Advisory Committee. **NOTE: grandfathering is allowed for those taking either formulation (ODT or solution) of aripiprazole prior to the status change. **Injectables:** ▪ DMS to select preferred agent(s) based on economic evaluation. Generic formulations of first generation injectable antipsychotics should be preferred. Additionally, 2 unique second generation injectable antipsychotics, 1 of which should have a duration of action of 2 weeks or longer, should be preferred.	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
	▪ Agents not selected as preferred will be considered non-preferred and require prior approval. ▪ Continue quantity limits on agents in this class. ▪ Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back. ▪ For any new chemical entity in the *Antipsychotics* class, require a PA until reviewed by the P&T Advisory Committee. **Combination Products (Symbyax®):** ▪ DMS to select preferred agent(s) based on economic evaluation. ▪ Agents not selected as preferred will be considered non-preferred and require prior approval. ▪ Continue quantity limits on agents in this class. ▪ Allow continuation of therapy for non-preferred, single-source branded products via a 90-day look back. ▪ For any new chemical entity in the *Second Generation Antipsychotic and SSRI Combination* class, require a PA until reviewed by the P&T Advisory Committee.	
8	**Oncology Oral – Other** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 oral agent representing a Category 1 recommendation by the NCCN for each cancer type should be preferred. ▪ Continue quantity limits based on FDA-approved maximum dose. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ DMS to allow continuation of therapy for existing users of non-preferred, single-source branded products via a 90-day look back. ▪ For any new chemical entity in the *Oral Oncology, Other* class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
9	**Ophthalmics, Allergic Conjunctivitis** **Antihistamines:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Antihistamines* class, require a PA until reviewed by the P&T Advisory Committee. **Mast-Cell Stabilizers:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Mast Cell Stabilizers* class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
10	**Ophthalmics, Antibiotic-Steroid Combinations** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Antibiotics-Steroid Combinations* class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
11	**Ophthalmics, Anti-inflammatories** **NSAIDs:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic NSAIDs* class, require a PA until reviewed by the P&T Advisory Committee. **Anti-Inflammatory Steroids:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 3 unique chemical entities should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Anti-inflammatory Steroids* class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
12	**Ophthalmics, Anti-inflammatories/ Immunomodulators** **New Product to class:** Xiidra™ — Non-prefer **Length of Authorization**: 6 months initial; 1 year re-approval Xiidra (lifitegrast) 5% ophthalmic solution is a lymphocyte function-associated antigen-1 (LFA-1) antagonist approved for treating the signs and symptoms of dry eye disease in adults. **Initial Criteria Approval:** ▪ ≥ 17 years of age; AND ▪ Have a diagnosis of chronic dry eye disease (DED) (e.g., not associated with seasonal allergies) or chronic eye dryness secondary to Sjögren's syndrome; AND ▪ Have presence of conjunctival redness; AND ▪ Have 1 of the following: – Corneal fluorescein staining score of ≥ 2 points in any field on a 0 to 4 point scale; OR – Schirmer tear test (STT) of 1 to 10 mm in 5 minutes; AND ▪ NOT be using concurrent ophthalmic cyclosporine (Restasis); AND ▪ Have had an adequate trial and failure of over-the-counter (OTC) artificial tears (use of at least 4 times daily). **Renewal Criteria:** Patient must ▪ Have improvement in signs of DED as measured by at least 1 of the following: – Decrease in corneal fluorescein staining score; OR – Increase in number of mm per 5 minutes using Schirmer tear test; AND • Decrease in conjunctival redness; AND ▪ Have improvement in ocular discomfort; AND ▪ NOT be using concurrent ophthalmic cyclosporine (Restasis); AND ▪ Not be using supplemental artificial tears concurrently with lifitegrast (Xiidra). **Quantity Limit**: 60 single-use containers per 30 days. ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Immunomodulator* class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
13	**Ophthalmics, Glaucoma** **Beta-blockers:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Glaucoma, Beta-blockers* class, require a PA until reviewed by the P&T Advisory Committee. **Carbonic Anhydrase Inhibitors:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Glaucoma, Carbonic Anhydrase Inhibitors* class, require a PA until reviewed by the P&T Advisory Committee. **Combinations:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 combination product containing an ophthalmic beta-agonist should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Combinations for Glaucoma* class, require a PA until reviewed by the P&T Advisory Committee. **Direct-Acting Miotics:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Glaucoma Direct-Acting Miotics* class, require a PA until reviewed by the P&T Advisory Committee. **Prostaglandin Agonists:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ Continue current quantity limits on agents in this class. ▪ For any new chemical entity in the *Ophthalmic Glaucoma, Prostaglandin Analogs* class, require a PA until reviewed by the P&T Advisory Committee. **Sympathomimetics:** ▪ DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. ▪ Agents not selected as preferred will be considered non-preferred and require PA. ▪ For any new chemical entity in the *Ophthalmic Sympathomimetics* class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against

Consent Agenda

The P&T Committee had no recommended changes to the current Preferred Drug List (PDL) status for the therapeutic classes below.

	Therapeutic Classes	P & T Vote
14	• Antianginal & Anti-ischemic Agents • Antiarrhythmics, Oral • Antibiotics, Topical • Anticoagulants • Antiemetic & Antivertigo Agents • BPH Agents • Bronchodilators, Beta-Agonists • Calcium Channel Blockers • Cytokine & CAM Antagonists • H. Pylori Agents • Hepatitis C Agents (Interferons & Ribavirins) • Laxatives & Cathartics • Lipotropics, Other • Neuropathic Pain • Oncology Oral – Hematologic • Ophthalmics, Antibiotics • Ophthalmics, Antivirals • Ophthalmics, Mydriatics • Platelet Aggregation Inhibitors • Proton Pump Inhibitors • Stimulants & Related Agents • Thrombopoiesis Stimulating Proteins	**Passed** 9 For 0 Against