Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations

September 15, 2016

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the September 15, 2016 meeting.

Although the Committee met on September 15, 2016, the necessary quorum was not achieved; however, the expertise, vote, and recommendations of the Committee members in attendance were captured and the Committee delivered the unofficial recommendations reflected below for review.

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: Xtampza™ ER** Non-prefer in the PDL class: *Analgesics Narcotics, Long-Acting* **Length of Authorization:** 6 months, or expected duration of therapy if less than 6 months. Xtampza™ ER (oxycodone extended-release capsule) is an opioid agonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. • Trial and failure of 2 different preferred long-acting narcotics; OR • Must have no history of opioid abuse or illicit drug use within the past 365 days; OR • Patient has current history of extended-release oxycodone use for previous opioid dependence and requires chronic pain management. **Age Limit** = ≥ 18 years of age **Quantity Limit** = 3 per day for the 9 mg, 13.5 mg, 18 mg, and 27 mg capsules. **Quantity Limit** = 8 per day for the 36 mg capsules. **Maximum Daily Dose =** 288mg	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote
2	**New Products to Market: Onzetra™ Xsail™** Non-prefer in PDL class: *Anti-Migraine; 5-HT1 Receptor Agonists* (*Antimigraines, Triptans)* **Length of Authorization:** 1 year Onzetra™ Xsail™ (sumatriptan succinate nasal powder) is a serotonin 5-HT1B/1D receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults. It is 11mg per nosepiece, there are 2 nosepieces per dose; 22mg is the full dose. This is not an inhaler or spray; the patient is to blow through the mouth into the piece which propels the powder into the nostril. • Documented therapeutic trial and treatment failure with ALL preferred drugs. • Sumatriptan generic oral and vial; Imitrex® Nasal; and Imitrex® Pen and Cartridge are covered without PA; clinical reason as to why sumatriptan generic oral and vial; Imitrex® Nasal; and Imitrex® Pen and Cartridge cannot be used. **Quantity Limit** = 16 doses per 30 days (2 kits; each kit has 8 doses)	**Passed** 6 For 0 Against
3	**New Products to Market: Nuplazid™** Non-prefer in the PDL class: *Second-Generation Antipsychotics* (*Antipsychotics)* **Length of Authorization**: 1 year Nuplazid™ (pimavanserin) tablet for oral use is a Selective Serotonin 5-HT2A Inverse Agonist/antagonist (SSIA). It is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. • Must have diagnosis of Parkinson's Disease; AND • Trial of dose adjustment or withdrawal of antiparkinson's medications prior to treatment with this agent (e.g., anticholinergics, amantadine, dopamine agonists, COMT inhibitors, selegiline) because these are known to cause hallucinations. **Age Limit =** ≥ 18 years of age **Quantity Limit** = 2 tablets per day (60 tablets per 30 days)	**Passed** 6 For 0 Against
4	**New Products to Market: Bevespi Aerosphere™** Non-prefer in the PDL class: *COPD Agents* **Length of Authorization:** 1 year Bevespi Aerosphere™ (glycopyrrolate and formoterol) is indicated for the long-term maintenance treatment of airflow obstruction in patients with Chronic Obstructive Pulmonary Disease (COPD) including chronic bronchitis and/or emphysema. • Must have diagnosis of COPD; AND • Documentation of spirometry measurement (FEV_1);AND • Must not use the medication for asthma or relief of acute symptoms or be using other Long-Acting Beta Adrenergics (LABAs); AND • Must have rescue therapy on file. **Age Limit =** ≥18 years of age **Quantity Limit:** 1 canister per 30 days	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote
5	**New Products to Market: Zinbryta™** Non-prefer in the PDL class: *Multiple Sclerosis Agents* **Length of Authorization:** 6 months Zinbryta™ (daclizumab) is a self-injectable subcutaneous injection of an interleukin-2 receptor blocking antibody indicated for use in adults with relapsing form of multiple sclerosis. • Must have documentation of relapsing form of multiple sclerosis (MS) as documented by laboratory report; (e.g., MRI); AND • Must have documentation of trial and failure of at least 2 other drugs indicated for the treatment of MS (due to safety profile, try other agents first); AND • Must have no history of hepatic impairment (ALT & AST < 2 times ULN) or disease; AND • Documentation of baseline transaminases and bilirubin levels and confirmation that levels will be checked monthly; AND • Documentation of negative tuberculosis (Tb), Hep B, and Hep C screening. **Age Limit =** ≥18 years of age **Quantity Limit:** 1 syringe (150mg) per 28 days.	**Passed** 6 For 0 Against
6	**New Products to Market: Venclexta®** Non-prefer in the PDL class: *Oral Oncology, Hematologic Cancer* (*Oncology Agents Oral)* **Length of Authorization:** 6 months Venclexta® (venetoclax) tablet for oral use is a BCL-2 inhibitor indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA-approved test, who have received at least one prior therapy. Available as a starter pack for the first 4 weeks followed by 4 x 100mg tablets orally per day. • Diagnosis of Chronic Lymphocytic Leukemia (CLL); AND • Prescriber to submit lab work documenting 17p deletion as detected by an FDA-approved test; AND • Must have received at least one prior therapy for the treatment of CLL and has either relapsed or developed progressive disease; AND • Is assessed for risk of tumor lysis syndrome; AND • Is not receiving a strong CYP3A Inhibitor. **Age Limit =** ≥18 years of age **Quantity Limit** = Starter Pack (42 tablets per 28 days – one time fill) Then 120 tablets per 30 days thereafter. **Maximum Daily Dosing** = 400mg	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote
7	**New Products to Market: Alecensa®** Non-prefer in PDL class: *Oral Oncology, Lung Cancer* (*Oncology Agents Oral)* **Length of Authorization:** 6 months Alecensa® (alectinib) 150mg capsules is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib (Xalkori®). • Must have a diagnosis of metastatic non-small cell lung cancer; AND • Must have anaplastic lymphoma kinase (ALK) mutation-positive NSCLC as confirmed by an FDA-approved test; AND • Must have an intolerance to, or has disease progression while on crizotinib (Xalkori®) **Age Limit =** ≥18 years of age **Quantity Limit** = 8 capsules per day (600mg twice daily)	**Passed** 6 For 0 Against
8	**New Products to Market: Tagrisso™** Non-prefer in PDL class: *Oral Oncology, Lung Cancer (Oncology Agents Oral)* **Length of Authorization:** 6 months Tagrisso™ (osimertinib) is indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR TKI therapy. Available as 40mg and 80mg tablets. (The 40mg tablet is reserved for those who need dose modifications due to adverse effects.) • Must have a diagnosis of metastatic non-small cell lung cancer; AND • Prescriber must submit lab work documenting the T790M mutation as detected by an FDA-approved test; AND • Must have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy (erlotinib, gefitinib, or afatinib). **Age Limit =** ≥18 years of age **Quantity Limit** = 1 tablet per day	**Passed** 6 For 0 Against
9	**New Products to Market: Cabometyx™** Prefer in PDL class: *Oral Oncology, Renal Cell Carcinoma (Oncology Agents Oral)* **Length of Authorization:** 6 months Cabometyx™ (cabozantinib) is a kinase inhibitor, available as 20mg, 40mg, or 60mg tablet. Indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy. • Must have diagnosis of advanced renal cell carcinoma; AND • Patient has received prior antiangiogenic therapy; AND • Not have severe hepatic impairment (Child-Pugh Class C) **Age Limit =** ≥18 years of age **Quantity Limit** = 2 tablets per day (60mg per day is the *recommended* dosing) **Maximum Daily Dosing** = 80mg per day	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote
10	**New Products to Market: Cotellic™** Non-prefer in the PDL class: *Oral Oncology, Skin Cancer* (*Oncology Agents Oral)* **Length of Authorization:** 6 months Cotellic™ (cobimetinib) 20mg tablets, indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. • Must have diagnosis of unresectable or metastatic melanoma with V600E or V600K mutations in the BRAF gene as determined by an FDA-approved diagnostic test; AND • Prescriber to submit lab work documenting this mutation; AND • Must be used with vemurafenib (Zelboraf®). **Quantity Limit** = 63 tablets per 28 days	**Passed** 6 For 0 Against

11	**Anticonvulsants**
	First Generation:
	• DMS to select preferred agent(s) based on economic evaluation; however, at least 6 unique chemical entities should be preferred.
	• Agents not selected as preferred will be considered non-preferred and require prior authorization.
	• For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days.
	• For any new chemical entity in the First-Generation Anticonvulsants 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 7 unique chemical entities should be preferred.
	• Agents not selected as preferred will be considered non-preferred and require prior authorization.
	• For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days.
	• For any new chemical entity in the Second-Generation Anticonvulsants class, require a PA until reviewed by the P&T Advisory Committee.
	
	New Product to Market: Briviact® (brivaracetam)
	Non-prefer in the PDL class: *Anticonvulsants: Second Generation*
	Length of Authorization: 1 year
	• Available as tablets, solution, and injection – interchangeable on an mg per mg basis. It is a Schedule V controlled substance indicated as adjunctive therapy for the treatment of partial-onset seizures in epileptic patients 16 years of age or older.
	• For approval, patient must:
	  • Be ≥ 16 years old; AND
	  • Have diagnosis of partial-onset seizures; AND
		Passed
		6 For
		0 Against

	Description of Recommendation	P & T Vote
	• Have tried and failed at least 1 other medication as adjunctive treatment for partial-onset seizures; AND • Patient is currently taking ≥ 1 other maintenance therapy for partial-onset seizures. **Limitation of use**: Do not approve if patient has chronic hepatic impairment (e.g., Child-Pugh Class A, B, or C,) or for end stage renal disease (ESRD) patients on dialysis. **Quantity Limit** = 200mg per day Carbamazepine Derivatives: • 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 prior authorization. • For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days. • For any new chemical entity in the Anticonvulsants, Carbamazepine Derivatives class, require a PA until reviewed by the P&T Advisory Committee.	
12	**Topical Antifungal Agents (Antifungals, Topical)** • DMS to select preferred agent(s) based on economic evaluation; however, at least agents representing multiple mechanisms of action as well as a combination product should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • Before utilization, the combination product miconazole/zinc oxide should be subject to trial and failure of conventional therapies for diaper dermatitis. • For any new chemical entity in the Antifungals, Topical class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against
13	**Minimally Sedating Antihistamines (Antihistamines, Minimally Sedating)** • 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 will require Prior Authorization. • For any new chemical entity in the Antihistamines, Minimally Sedating class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote
14	**Topical Antiparasitic Agents (Antiparasitics, Topical)** • 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 Antiparasitics, Topical class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against
15	**Topical Antiviral Agents (Antivirals, Topical)** • 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 Antivirals, Topical class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against
16	**Self-Injectable Epinephrine (Epinephrine, Self-Injectable)** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 product available in an adult and pediatric dose should be preferred. • Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. • For any new chemical entity in the Epinephrine, Self-injectable class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against
17	**Intranasal Rhinitis Agents (Intranasal Antihistamines, Anticholinergics, Corticosteroids)** • 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 to maintain quantity limits based on maximum daily dose. • For any new chemical entity in the Intranasal Rhinitis Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against
18	**Lipotropics, Statins** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 agent representing each of the treatment intensity levels (high-intensity, moderate-intensity and lower-intensity) should be preferred. • Continue quantity limits on agents in this class based on maximum recommended dose. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Lipotropics, Statins class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote
19	**Otic Antibiotics** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 single entity otic fluoroquinolone, one otic fluoroquinolone/steroid combination product and one non-fluoroquinolone combination product should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Otic Antibiotics class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against
20	**Phosphate Binders** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities, one of which should be a calcium based phosphate binder, should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Phosphate Binders class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against

Consent Agenda

The therapeutic classes listed in the below table have no changes to their currently posted Preferred Drug List (PDL) status.

21	• Alzheimer's Agents • Androgenic Agents • Angiotensin Modulators • Angiotensin Modulator Combinations • Antidepressants, Other • Antidepressants, SSRIs • Antihyperuricemics • Antipsoriatics, Oral • Beta-blockers • Bladder Relaxant Preparations • Erythropoiesis Stimulating Proteins • Leukotriene Modifiers • Nasal Preparations – Antibiotics • Otics, Anti-inflammatories • PAH Agents, Oral & Inhaled • Rosacea Agents, Topical • Ulcerative Colitis Agents • Vasodilators, Coronary	**Passed** 6 For 0 Against