Kentucky Department for Medicaid Services
Drug Review and Options for Consideration

The following table lists the Agenda items scheduled as well as the Options for Consideration to be presented and reviewed at the September 15, 2016 meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
New Products to Market: **Xtampza™ ER**	Non-prefer in the PDL class: *Analgesics Narcotics, Long* **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 two different preferred long-acting narcotics; OR ▪ Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include: – Adverse reaction to preferred drugs – Allergy to preferred drugs – Contraindication to preferred drugs ▪ 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 sue for previous opioid dependence and requires chronic pain management. **Age Limit** = 18 years and older **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. (288mg is the maximum daily dosage)

Single Agent Reviews	Options for Consideration
New Products to Market: **Onzetra™ Xsail™**	Non-prefer in PDL class: *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. ▪ Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include: – Adverse reaction to all preferred drugs – Allergy to all preferred drugs – Contraindication to all preferred drugs ▪ 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)
New Products to Market: **Nuplazid™**	Non-prefer in the PDL class: *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, (ex; anticholinergics, amantadine, dopamine agonists, COMT inhibitors, selegiline) because these are known to cause hallucinations. **Age Limit =** 18 years and older **Quantity Limit** = 2 tablets per day (60 tablets per 30 days)
New Products to Market: **Bevespi Aerosphere™**	Non-prefer in the PDL class: *COPD* **Length of Authorization:** 1 year ▪ Bevespi Aerosphere™ (glycopyrrolate and formoterol) is indicated for the long-term maintenance treatment of airflow obstruction in patients with COPD including chronic bronchitis and/or emphysema. ▪ Must have diagnosis of COPD; AND ▪ Must not use the medication for asthma or relief of acute symptoms or be using other LABAs (long acting beta adronergics); AND ▪ Must have rescue therapy on file. **Age Limit =** 18 years and older

Single Agent Reviews	Options for Consideration
	Quantity Limit: 1 canister per 30 days
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 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 Tb (tuberculosis), Hep B, and Hep C screening. **Age Limit =** 18 years and older **Quantity Limit:** 1 x 150mg syringe per 28 days.
New Products to Market: **Venclexta®**	Non-prefer in the PDL class: *Oncology Agents Oral - hematologic* **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 symdrome; AND ▪ Is not receiving a strong CYP3A Inhibitor. **Age Limit =** 18 years or older **Maximum Daily Dosing** = 400mg **Quantity Limit** = Starter Pack (42 tablets/30 days – one time fill) Then 120 tablets per 30 days thereafter.
New Products to Market: **Alecensa®**	Non-prefer in PDL class: *Oncology Agents Oral - Lung* **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®).

Single Agent Reviews	Options for Consideration
	▪ 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 or older **Quantity Limit** = 8 capsules per day (600mg twice daily)
New Products to Market: **Tagrisso™**	Non-prefer in PDL class: *Oncology Agents Oral - Lung* **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 or older **Quantity Limit** = 1 tablet per day
New Products to Market: **Cabometyx™**	Prefer in PDL class: *Oncology Agents Oral - Renal* **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 or older **Quantity Limit** = 2 tablets per day (60mg per day is the *recommended* dosing) **Maximum Daily Dosing** = 80mg/day
New Products to Market: **Cotellic™**	Non-prefer in the PDL class: *Oncology Agents Oral - Skin* **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

Single Agent Reviews	Options for Consideration
	▪ Prescriber to submit lab work documenting this mutation; AND ▪ Must be used with vemurafenib (Zelboraf®). **Limitation of Use:** Cotellic™ is not indicated for treatment of patients with wild-type BRAF melanoma. **Quantity Limit** = 63 tablets/28 days

Full Class Reviews	Options for Conseration
	Agents in the following Therapeutic Classes are subject to status changes from what is on the current Preferred Drug List.
Anticonvulsants	New addition to the class: Briviact® (brivaracetam) **Length of Authorization:** 1 year ▪ Available as tablets, solution, and injection – interchangable on a 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** – 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/day First Generation: ▪ DMS to select preferred agent (s) based on economic evaluation; however, at least six 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 seven 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. Carbamazepine Derivatives: ▪ DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred.

Full Class Reviews	Options for Conseration
	▪ 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.
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.
Antihistamines, Minimally Sedating	▪ DMS to select preferred agent (s) based on economic evaluation; however, at least one 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.
Antiparasitics, Topical	▪ DMS to select preferred agent (s) based on economic evaluation; however, at least one 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.
Antivirals, Topical	▪ DMS to select preferred agent (s) based on economic evaluation; however, at least one 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.
Epinephrine, Self-injectable	▪ DMS to select preferred agent (s) based on economic evaluation; however, at least one 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.
Intranasal Rhinitis Agents	▪ DMS to select preferred agent(s) based on economic evaluation; however, at least one unique chemical entity should be preferred.

Full Class Reviews	Options for Conseration
	▪ 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.
Lipotropics, Statins	▪ DMS to select preferred agent(s) based on economic evaluation; however, at least one 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.
Otic Antibiotics	▪ DMS to select preferred agent (s) based on economic evaluation; however, at least one 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.
Phosphate Binders	▪ DMS to select preferred agent (s) based on economic evaluation; however, at least two 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.

Consent Agenda	Options for Consideration	
	For the following therapeutic classes, there are no recommended changes to the currently posted Preferred Drug List agent statuses.	
	▪ 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