Kentucky Department for Medicaid Services
Drug Review and Options for Consideration

The following tables list the Agenda items as well as the Options for Consideration that are scheduled to be presented and reviewed at the **September 17, 2020** special called meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
New Product to Market: **Xepi™**	Non-prefer in the PDL class: *Antibiotics, Topical* **Length of Authorization:** Date of service; no renewals • Xepi™ (ozenoxacin) is a quinolone antimicrobial indicated for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older. **Criteria for Approval** • Diagnosis of impetigo; AND • Trial and failure with a preferred agent (e.g., mupirocin ointment); AND • Not have an affected body surface area (BSA) exceeding 100 cm^2 or 2% of total BSA, whichever is greater; AND • Will not be used for more than 5 days. **Quantity Limit**: Up to 45 grams per fill

Single Agent Reviews	Options for Consideration
New Product to Market: **Zeposia®**	Non-prefer in the PDL class: *Multiple Sclerosis Agents* **Length of Authorization:** 1 year • Zeposia® (ozanimod) is a sphingosine 1-phosphate (S1P) receptor modulator indicated 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. **Criteria for Approval:** • Initially prescribed by a neurologist or multiple sclerosis specialist (non-specialist may renew and refill); AND • Patient has a diagnosis of a relapsing form of multiple sclerosis (MS): relapsing-remitting MS (RRMS) active secondary progressive MS (SPMS), or clinically isolated syndrome (CIS); AND • Patient has had an inadequate response to, or is unable to tolerate, 1 or more preferred MS agent; AND • Patient does NOT meet ANY of the following conditions: o Presence of contraindicated cardiovascular comorbidities (e.g., recent heart attack or stroke, heart failure); o Current systemic or clinically significant local infection; o Use of any other antineoplastic, immunosuppressive or immunomodulating drugs to treat other conditions; o Use of ozanimod in combination with another MS agent; o Prior use of alemtuzumab; AND • Patient has had or will have ALL of the following: o Screening for clinically significant drug interactions; AND o Baseline electrocardiogram (ECG), liver function tests (LFTs) and ophthalmic evaluation; AND o If pre-existing non-contraindicated cardiac disease (e.g., arrhythmia), cardiology consultation and follow-up will be conducted prior to and during treatment; AND o Testing for antibodies to the varicella zoster virus (VZV) OR have received immunization for VZV at least 4 to 6 weeks prior to beginning therapy. **Renewal Criteria:** • Continue to meet initial approval criteria; AND • Documentation of response to therapy (e.g., progress note). **Age Limit**: ≥ 18 years **Quantity Limit**: 1 per day

Full Class Reviews	Options for Consideration
Alzheimer's Agents	**Alzheimer's Agents** • 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 *Alzheimer's Agents* class, require PA until reviewed by the P&T Advisory Committee.
Anticonvulsants **(Anticonvulsants: First Generation; Anticonvulsants: Second Generation; Anticonvulsants: Carbamazepine Derivatives)**	**Anticonvulsants: First Generation** • DMS to select preferred agent(s) based on economic evaluation; however, at least 8 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 *Anticonvulsants: First Generation* class, require PA until reviewed by the P&T Advisory Committee. **Anticonvulsants: Second 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 PA. • For any new chemical entity in the *Anticonvulsants: Second Generation* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class:** Xcopri® (cenobamate) Non-prefer in this PDL class. **Length of Authorization:** 1 year • Xcopri® (cenobamate) is indicated for the treatment of partial-onset seizures in adult patients. **Criteria for Approval**: • Patient has a confirmed diagnosed of partial-onset seizures; AND • Trial and failure of a preferred agent; AND • NOT have familial QT syndrome; AND • NOT have severe hepatic impairment (Child-Pugh Class C). **Age Limit**: ≥ 18 years **Quantity Limits**: - 1 per day: 50 mg, 100 mg tablets; titration blister packs - 2 per day: 150 mg, 200 mg tablets; 250 and 350 mg maintenance blister packs **Anticonvulsants: 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 PA. • For any new chemical entity in the *Anticonvulsants: Carbamazepine Derivatives* class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
Antimigraine, Other **(Antimigraine: CGRP Inhibitors)**	**Antimigraine: CGRP Inhibitors** • 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 *Antimigraine: CGRP Inhibitors* class, require PA until reviewed by the P&T Advisory Committee.

Antiparkinson's Agents
 	
(Parkinson's Disease)
	Parkinson's Disease
	• 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 PA.
	• For any new chemical entity in the *Parkinson's Disease* class, require PA until reviewed by the P&T Advisory Committee.
	
	New agent in the class: Kynmobi™ (apomorphine)
	Non-prefer in this PDL class.
	Length of Authorization: 1 year
	• Kynmobi™ (apomorphine) is a non-ergoline dopamine agonist indicated for the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease (PD).
	Criteria for Approval:
	• Diagnosis of Parkinson's disease (PD); AND
	• Receiving PD therapy with carbidopa/levodopa; AND
	• Experiencing "off" episodes with carbidopa/levodopa for at least 2 hours per day; AND
	• Trial and failure of at least 2 adjunctive therapies, such as:
	  ○ Dopamine agonists (e.g., pramipexole, ropinirole);
	  ○ Monoamine oxidase-B inhibitors (e.g., selegiline)
	  ○ Catechol-O-methyltransferase inhibitors (e.g., entacapone); AND
	• Patient will be offered a non-5HT3 antagonist antiemetic (e.g., trimethobenzamide); AND
	• NONE of the following contraindications:
	  ○ Receiving concomitant 5-HT_3 antagonists (e.g., ondansetron); OR
	  ○ Major psychiatric disorder.
	Renewal Criteria:
	• Patient has clinically meaningful response to treatment (e.g., patient shows a reductions in time of "off" episodes.)
	Age Limit: ≥ 18 years
	Quantity Limit: 5 per day

Antipsychotics **(First-Generation Antipsychotics; Second-Generation Antipsychotics; Antipsychotics: Injectable)**	**First-Generation Antipsychotics** • 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 PA. • For any new chemical entity in the *First-Generation Antipsychotics* class, require PA until reviewed by the P&T Advisory Committee. **Second-Generation Antipsychotics** • 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 PA. • For any new chemical entity in the *Second-Generation Antipsychotics* class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
	New agent in the class: Caplyta® (lumateperone) Non-prefer in this PDL class. **Length of Authorization:** 1 year • Caplyta® (lumateperone) is an atypical antipsychotic indicated for the treatment of schizophrenia in adults. **Criteria for Approval:** • Diagnosis of schizophrenia; AND • Trial and failure of ≥ 2 preferred antipsychotics. **Renewal Criteria:** • Attestation or documentation (e.g., progress note) of disease improvement and/or stabilization. **Age Limit**: ≥ 18 years **Quantity Limit**: 1 per day **Antipsychotics: Injectable** • 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 PA. • For any new chemical entity in the *Antipsychotics: Injectable* class, require PA until reviewed by the P&T Advisory Committee.
Lipotropics, Other **(Familial Hypercholesterolemia Agents; Lipotropics: Bile Acid Sequestrants; Lipotropics: Fibric Acid Derivatives; Lipotropics: Niacin Derivatives; Lipotropics: Omega-3 Fatty Acids; Lipotropics: Other; Lipotropics: PCSK9s)**	**Familial Hypercholesterolemia Agents** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Familial Hypercholesterolemia Agents* class, require PA until reviewed by the P&T Advisory Committee. **Lipotropics: Bile Acid Sequestrants** • 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 *Lipotropics: Bile Acid Sequestrants* class, require PA until reviewed by the P&T Advisory Committee. **Lipotropics: Fibric Acid 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 PA. • For any new chemical entity in the *Lipotropics: Fibric Acid Derivatives* class, require PA until reviewed by the P&T Advisory Committee. **Lipotropics: Niacin Derivatives** • 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 *Lipotropics: Niacin Derivatives* class, require PA until reviewed by the P&T Advisory Committee. **Lipotropics: Omega-3 Fatty Acids** • 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.

Full Class Reviews	Options for Consideration
	• For any new chemical entity in the *Lipotropics: Omega-3 Fatty Acids* class, require PA until reviewed by the P&T Advisory Committee. **Lipotropics: Other (formerly Lipotropics: Cholesterol Absorption Inhibitor)** • 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 *Lipotropics: Other* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class:** Nexletol™ (bempedoic acid) and Nexlizet™ (bempedoic acid/ezetimibe) Non-prefer in this PDL class. **Length of Authorization:** 1 year • Nexletol™ (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor and Nexlizet™ (bempedoic acid/ezetimibe) contains an ACL inhibitor and a cholesterol absorption inhibitor. Both agents are indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of low-density lipoprotein-cholesterol (LDL-C). • For both agents, the effect on cardiovascular (CV) morbidity and mortality has not been determined. **Criteria for Approval:** • Prescribed initially by, or in consultation with a cardiologist, lipid specialist, endocrinologist, vascular medicine or other applicable specialist; AND • Documentation of low-density lipoprotein cholesterol (LDL-C) prior to/without bempedoic acid therapy; AND • Diagnosis of heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease; AND • Trial and failure to achieve LDL goal after 3 months of high intensity statin therapy (e.g., rosuvastatin 40 mg daily); OR • Patient does not tolerate statins (≥ 2 statin trials of any length were unsuccessful due to adverse effects); AND • Maximum tolerated doses of lipid-lowering therapies (e.g., statin, ezetimibe, omega-3-acid ethyl esters) will continue to be used with bempedoic acid. **Renewal Criteria:** • Documentation (e.g., progress note or lab report) that demonstrate a reduction in LDL-C when compared to the baseline values. **Age Limit**: ≥ 18 years **Quantity Limit**: 1 per day **Lipotropics: PCSK9s** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Lipotropics: PCSK9s* class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
Neuropathic Pain	**Neuropathic Pain** • 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 *Neuropathic Pain* class, require PA until reviewed by the P&T Advisory Committee.
PAH Agents, Oral and Inhaled (Pulmonary Arterial Hypertension (PAH) Agents)	**Pulmonary Arterial Hypertension (PAH) Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 4 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 *Pulmonary Arterial Hypertension (PAH) Agents* class, require PA until reviewed by the P&T Advisory Committee.
Sedative Hypnotics	**Sedative Hypnotics** • 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 *Sedative Hypnotics* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class:** Dayvigo™ (lemborexant) Non-prefer in this PDL class. **Length of Authorization:** 60 days; 1 year renewal • Dayvigo™ (lemborexant) is an orexin receptor antagonist indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. It is a Schedule IV controlled substance. **Criteria for Approval:** • Diagnosis of insomnia; AND • Trial and failure of ≥ 2 preferred sedative hypnotics. **Renewal Criteria:** • Attestation or documentation (e.g., progress note) of efficacy; AND • Meets sedative hypnotic class criteria for therapy beyond 60 days. **Age Limit**: ≥ 18 years **Quantity Limit**: 1 per day
Stimulants and Related Agents (Narcolepsy Agents; Stimulants and Related Agents)	**Narcolepsy Agents** • 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 *Narcolepsy Agents* class, require PA until reviewed by the P&T Advisory Committee. **Stimulants and Related Agents** • 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 PA. • For any new chemical entity in the *Stimulants and Related Agents* class, require 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 (PDL) status**; these may be voted on as a group:	
• Angiotensin Modulator Combinations • Angiotensin Modulators • Antianginal & Anti-ischemic • Antiarrhythmics, Oral • Anticoagulants • Antidepressants, Other • Antidepressants, SSRIs • Antidepressants, Tricyclic • Antimigraine Agents, Triptans • Axiolytics	• Beta-Blockers • Bladder Relaxant Preparations • BPH Treatments • Calcium Channel Blockers • Lipotropics, Statins • Movement Disorders • Platelet Aggregation Inhibitors • Skeletal Muscle Relaxants • Smoking Cessation