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 19, 2019** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration

New Product to Market:
Evenity™
	Non-prefer in the PDL class: *Bone Resorption Suppression and Related Agents*
	Length of Authorization: 1 year; no renewal
	• Evenity™ (romosozumab-aqqg) is a sclerostin inhibitor indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
	• Romosozumab-aqqg carries a limitation for use in that it should only be used for a maximum of 12 monthly doses because of decreased efficacy after that time. If further treatment for osteoporosis is necessary, it is recommended to switch to another anti-resorptive agent.
	Criteria for Approval:
	• Patient is a postmenopausal female; AND
	• Diagnosis of osteoporosis; AND
	• Member has 1 or more risk factors for fracture including, but not limited to:
	  ○ History of an osteoporotic fracture as an adult
	  ○ Parental history of hip fracture
	  ○ Low BMI
	  ○ Rheumatoid arthritis
	  ○ Alcohol intake (3 or more drinks per day)
	  ○ Current smoking
	  ○ History of oral glucocorticoids ≥ 5 mg/day of prednisone (or equivalent) for > 3 months; AND
	• Documented intolerance, contraindication or treatment failure/ineffective response to a minimum 12-month trial on previous therapy with:
	  ○ Bisphosphonates (oral or intravenous [IV]) such as alendronate, risedronate, or zoledronic acid; AND
	  ○ RANKL-blocking agents such as Prolia® (denosumab); OR
	• Patient has extremely low bone mineral density (BMD) defined as a T-score < -3.5 or a T-score < 2.5 with a history of fragility fractures; AND
	• Member has NOT had a myocardial infarction or stroke within the past 12 months.
	Age Limit: ≥ 18 years
	Quantity Limit: 2 syringes per 30 days

Single Agent Reviews	Options for Consideration

New Product to Market:
Skyrizi™
	Non-prefer in the PDL class: *Immunomodulators (Cytokines and CAM Antagonists)*
	Length of Authorization: 3 months
	• Skyrizi™ (risankizumab-rzaa) is an interleukin-23 antagonist indicated for the treatment of moderate-to-severe plaque psoriasis (PSO) in adults who are candidates for systemic therapy or phototherapy.
	Criteria for Approval:
	• Diagnosis of moderate to severe plaque psoriasis; AND
	• Symptoms persistent for ≥ 6 months with at least 1 of the following:
	  ○ Involvement of at least 10% of body surface area (BSA); OR
	  ○ Psoriasis Area and Severity Index (PASI) score of 12 or greater; OR
	  ○ Incapacitation due to plaque location (i.e., head and neck, palms, soles or genitalia); AND
	• Negative tuberculosis (TB) screening prior to initiating treatment; AND
	• Trial and failure of two of the following therapies:
	  ○ Methotrexate
	  ○ Cyclosporine
	  ○ Oral retinoid (e.g., Soriatane®, acitretin)
	  ○ Topical corticosteroids
	  ○ Phototherapy/UV light
	  ○ Coal tar preparations; AND
	• Trial and failure of, or contraindication to, a preferred immunomodulator (i.e., Enbrel® or Humira®); AND
	• Medication will not be used in combination with any other agent in the immunomodulator class.
	Renewal Criteria
	• Patient continues to meet criteria identified above; AND
	• Ongoing monitoring for TB; AND
	• Disease response (e.g., progress note) as indicated by improvement in signs and symptoms compared to baseline, such as redness, thickness, scaliness, and/or the amount of surface area involvement.
	Age Limit: ≥ 18 years
	Quantity Limit: 2 syringes per 12 weeks; call center to override loading dose

Single Agent Reviews	Options for Consideration
New Product to Market: **Mavenclad®**	Non-prefer in the PDL class: *Multiple Sclerosis Agents* **Length of Authorization:** 35 days initial; one 35 day renewal • Mavenclad® (cladribine) is a purine antimetabolite indicated for the treatment of adults with relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease. Due to its safety profile, use is generally recommended for patients who have had an inadequate response to or are unable to tolerate an alternate drug indicated to treat MS. **Criteria for Approval:** • Diagnosis of relapsing-remitting MS (RRMS) OR active secondary progressive MS (SPMS); AND • Patient has had an inadequate response to, or is unable to tolerate, at least 2 or more MS treatments; AND • Patient does NOT meet ANY of the following conditions: o Human immunodeficiency virus (HIV), hepatitis B or C infection, or tuberculosis (TB) infection; o Current cancer or malignancy; o Current systemic, or clinically significant local, infection; o Use of any other antineoplastic, immunosuppressive or immunomodulator drugs to treat other conditions; o Use of cladribine in combination with other MS agents; AND • Patient has had or will have ALL of the following: o Screening for hepatitis B/C, HIV, and TB infections; 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; AND o Baseline MRI ≤ 3 months before initiating the first treatment course; AND o For women of childbearing potential, a negative pregnancy test and counseling on contraception use during therapy. **Renewal Criteria:** • At least 43 weeks has/will have elapsed since the end of the first treatment course; AND • Continue to meet initial approval criteria; AND • Documentation of response to therapy (e.g., progress note). **Age Limit =** ≥ 18 years **Quantity Limit:** 100 mg per cycle (2 cycles per approval)

Single Agent Reviews	Options for Consideration
New Product to Market: **Mayzent®**	Non-prefer in the PDL class: *Multiple Sclerosis Agents* **Length of Authorization:** 1 year • Mayzent® (siponimod), a sphingosine 1-phosphate (S1P) receptor modulator, is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS), and active secondary progressive disease (SPMS), in adults. **Criteria for Approval:** • 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 siponimod in combination with another MS agent; o Prior use of alemtuzumab; AND • Patient has had or will have ALL of the following: o CYP2C9 variant genotyping testing to guide dosing; AND 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:** 2 mg: 1 per day; 0.25 mg: 4 per day

Single Agent Reviews	Options for Consideration
New Product to Market: **Piqray®**	Non-prefer in the PDL class: *Oral Oncology Agents – Breast (Oncology, Oral – Breast)* **Length of Authorization:** 1 year • Piqray® (alpelisib) a phosphatidylinositol-3-kinase (PI3K) inhibitor, is indicated for use in combination with fulvestrant for the treatment of men and postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PI3K-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen. **Criteria for Approval:** • If female, patient is postmenopausal; AND • Diagnosis of advanced or metastatic breast cancer that is: ○ Hormone receptor-positive (HR-positive); AND ○ HER2-negative; AND ○ PIK3CA-mutation positive as detected by an FDA-approved companion diagnostic; AND ○ Progressing during, or relapsing within 12 months following, endocrine-based treatment; AND • Patient has NOT previously received any of the following therapies: ○ Chemotherapy for advanced breast cancer; OR ○ Another PI3K inhibitor (e.g., copanlisib, duvelisib); OR ○ An mTOR inhibitor (e.g., everolimus); AND • Medication will be given in combination with fulvestrant. **Renewal Criteria:** • Continue to meet initial approval criteria; AND • Evidence, such as progress report, of disease response (e.g., lack of progression or decrease in tumor size and spread). **Age Limit =** ≥ 18 years **Quantity Limit:** 150 mg: 2 per day; 50/200 mg: 1 per day
New Product to Market: **Balversa™**	Non-prefer in the PDL class: *Oral Oncology Agents – Other (Oncology, Oral – Other)* **Length of Authorization:** 1 year • Balversa™ (erdafitinib), a kinase inhibitor that binds and inhibits enzymatic activity of fibroblast growth factor receptor (FGFR)1, FGFR2, FGFR3, FGFR4 and several other kinases, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) that has susceptible FGFR3 or FGFR2 genetic alterations and has progressed during or following ≥ 1 line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. **Criteria for Approval:** • Diagnosis of locally advanced or metastatic urothelial carcinoma; AND • Susceptible point mutation in fibroblast growth factor receptor (FGFR)-3 as determined by an FDA-approved companion diagnostic; AND • Disease progressed during, or relapsed within 12 months following, platinum-based chemotherapy; AND • Medication will be used as a single agent therapy. **Renewal Criteria:** • Continue to meet initial approval criteria; AND • Evidence, such as progress report, of disease response (e.g., lack of progression or decrease in tumor size and spread). **Age Limit =** ≥ 18 years **Quantity Limit:** 3, 4, and 5 mg tablets: 3, 2, and 1 per day (respectively)

Full Class Reviews	Options for Consideration
Angiotensin Modulator + CCB Combinations	**Angiotensin Modulator + CCB Combinations** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 distinct combinations should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Angiotensin Modulator + CCB Combinations* class, require PA until reviewed by the P&T Advisory Committee. **Clinical Criteria Review:** **Current Criteria:** Preferred agents containing an angiotensin receptor blocker (ARB) require step therapy through an ACE inhibitor. **Recommended Criteria:** Preferred agents are available without a step edit.
Antiarrhythmics, Oral **(Oral Anti-Arrhythmics)**	**Oral Anti-Arrhythmics** • 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 *Oral Anti-Arrhythmics* class, require PA until reviewed by the P&T Advisory Committee.
Anticoagulants	**Anticoagulants** • 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 *Anticoagulants* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class: Bevyxxa™** Non-prefer in the PDL class: *Anticoagulants* **Length of Authorization:** 42 days • Bevyxxa™ (betrixaban) is an oral factor Xa inhibitor indicated for the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE. The safety and efficacy of betrixaban has not been established in patients with prosthetic heart valves because that population has not been studied. **Criteria for Approval:** • Patient is hospitalized for an acute medical illness; AND • Intolerance, contraindication, or trial and failure of a preferred anticoagulant. **Age Limit =** ≥ 18 years **Quantity Limit:** up to 31 capsules per 30 days
Anticonvulsants **(Anticonvulsants: Carbamazepine Derivatives; Anticonvulsants: First Generation; Anticonvulsants: Second Generation)**	**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. **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 PA.

Full Class Reviews	Options for Consideration
	• 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: Diacomit™** Non-prefer in the PDL class: *Anticonvulsants: Second Generation (Anticonvulsants)* **Length of Authorization:** 1 year • Diacomit™ (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients ≥ 2 years of age taking clobazam. There are no clinical data to support the use of stiripentol as monotherapy in Dravet syndrome. **Criteria for Approval:** • Diagnosis of Dravet syndrome; AND • Prescriber is, or has a consultative relationship with, a neurology/epilepsy specialist; AND • Medication will be used in adjunct to ≥ 1 antiepileptic drug, including clobazam; AND • Trial and failure (e.g., incomplete seizure control) of at least 2 antiepileptic drugs; OR • Patient is continuing therapy (e.g., using ex-US supply). **Age Limit =** ≥ 2 years **Quantity Limit:** 250 mg: 12 per day; 500 mg: 6 per day
Antidepressants, Other **(Antidepressants: MAOIs; Antidepressants: Other; Antidepressants: SNRIs)**	**Antidepressants: MAOIs** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antidepressants: MAOIs* class, require PA until reviewed by the P&T Advisory Committee. **Antidepressants: Other** • 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 PA. • For any new chemical entity in the *Antidepressants: Other* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class: Spravato™** Non-prefer in the PDL class: *Antidepressants: Other* **Length of Authorization:** 4 weeks initial; 1 year renewal • Spravato™ (esketamine), classified as a Schedule III controlled substance, is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist approved for treatment-resistant depression (TRD) in conjunction with an oral antidepressant. **Criteria for Approval:** • Diagnosis of major depressive disorder (MDD) and prescriber has performed baseline depression assessment using any validated rating scale; AND • Prescribed by, or in consultation with, a psychiatrist or psychiatric mental health nurse practitioner (PMHNP); AND

Full Class Reviews	Options for Consideration
	• Trial and failure (defined as < 50% reduction in symptom severity using any validated depression rating scale) of ≥ 2 antidepressants from different classes for a duration of ≥ 6 weeks each at generally accepted doses in the current depressive episode, unless contraindicated or clinically significant adverse effects are experienced; AND • Trial and failure of antidepressant augmentation therapy for a duration of ≥ 6 weeks in the current depressive episode with ≥ 1 of the following, unless contraindicated or clinically significant adverse effects are experienced: o An atypical antipsychotic; OR o Lithium; OR o An antidepressant from a different class; AND • Used in conjunction with another antidepressant medication (not to be used as monotherapy); AND • If female of childbearing potential, NOT pregnant or planning to become pregnant; AND • Prescriber attests that: o Location is certified in the Spravato Risk Evaluation and Mitigation Strategies (REMS) program; AND o Dosing schedule has been reviewed with patient; AND o Patient understands and is committed to dosing schedule and requirements (e.g., office visits, transportation). **Renewal Criteria:** • Continue to meet initial approval criteria; AND • Prescriber attestation that patient has been compliant with doses/appointments; AND • Attestation or documentation of disease improvement or stabilization as evidenced by improvement on a validated depression rating scale. **Age Limit =** ≥ 18 years **Quantity Limit:** 1 kit (56 or 84 mg) per week; call center to override for twice weekly dosing **Antidepressants: SNRIs** • 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 PA. • For any new chemical entity in the *Antidepressants: SNRIs* class, require PA until reviewed by the P&T Advisory Committee.
Antimigraine, Other **(Antimigraine: CGRP Inhibitors)**	**Antimigraine: CGRP Inhibitors** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antimigraine: CGRP Inhibitors* class, require PA until reviewed by the P&T Advisory Committee. **Clinical Criteria Review: Emgality™ for Episodic Cluster Headache** Non-prefer for this indication/strength in the PDL class *Antimigraine: CGRP Inhibitors (Antimigraine, Other)* **Length of Authorization:** 3 months initial; 1 year renewal • Emgality™ (galcanezumab-gnlm) is a calcitonin gene-related peptide (CGRP) antagonist indicated in adults for the preventive treatment of migraine and treatment of episodic cluster headache. **Criteria for Approval:** • Diagnosis of episodic cluster headache; AND • Prescribed by, or in consultation with, a neurologist or headache specialist; AND • If female of childbearing potential, negative pregnancy screening.

Full Class Reviews	Options for Consideration
	Renewal Criteria: • Patient has an overall improvement in function with therapy; AND • If female of child-bearing age, continued monitoring for pregnancy. **Age Limit** = ≥ 18 years **Quantity Limit:** 300 mg per 30 days
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.
Antipsychotics **(First-Generation Antipsychotics; Second-Generation Antipsychotics; Antipsychotics: Injectable; Atypical Antipsychotic and SSRI Combinations)**	**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. **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. **Antipsychotics: Atypical Antipsychotic and SSRI Combinations** • Roll products up into Second-Generation Antipsychotics.
Anxiolytics **(Antianxiety Agents)**	**Antianxiety 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 *Antianxiety Agents* class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
Calcium Channel Blockers **(Calcium Channel Blockers (DHP); Calcium Channel Blockers (Non-DHP))**	**Calcium Channel Blockers (DHP)** • 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 *Calcium Channel Blockers (DHP)* class, require PA until reviewed by the P&T Advisory Committee. **Calcium Channel Blockers (Non-DHP)** • 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 *Calcium Channel Blockers (Non-DHP)* class, require PA until reviewed by the P&T Advisory Committee.
Neuropathic Pain	**Neuropathic Pain** • 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 *Neuropathic Pain* class, require PA until reviewed by the P&T Advisory Committee.
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 entity 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:	
Alzheimer's Agents	Lipotropics, Other
Angiotensin Modulators	Lipotropics, Statins
Antianginal & Anti-Ischemic	Movement Disorders
Antidepressants, SSRIs	PAH Agents, Oral and Inhaled
Antidepressants, Tricyclic	Platelet Aggregation Inhibitors
Antimigraine Agents, Triptans	Sedative Hypnotics
Beta-Blockers	Skeletal Muscle Relaxants
Bladder Relaxant Preparations	Smoking Cessation
BPH Treatments	