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 30, 2021** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
New Product to Market: **Qelbree™** Oral extended-release capsule 100mg,150mg, 200mg	Non-prefer in the PDL class: *Stimulants and Related Agents* **Length of Authorization:** 1 year • Viloxazine (Qelbree) is a selective norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age. **Criteria for Approval:** • Patient has a diagnosis of attention deficit hyperactivity disorder (ADHD) according to the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5); AND • Patient has a history of trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to 1 preferred agent, unless otherwise specified. **Therapeutic duplication limit**: • Patient is limited to one long-acting and one short-acting CNS agent for ADHD at a time within the quantity/dosing limits. **Quantity Limit**: 100 mg ER capsule: 30 capsules/30 days 150 mg ER capsule: 60 capsules/30 days 200 mg ER capsule: 60 capsules/30 days (Maximum of 400 mg once daily) **Age Limit**: none
New Product to Market: **Zegalogue®** Single-dose autoinjector and single-dose prefilled syringe 0.6mg/0.6mL	Non-prefer in the PDL class: *Endocrine and Metabolic agents: glucagon agents* **Length of Authorization:** 1 year • Dasiglucagon (Zegalogue) is a glucagon analog and a glucagon receptor agonist that is indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and older. **Criteria for Approval:** • Patient has a history of trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to 1 preferred agent, unless

Single Agent Reviews	Options for Consideration
	otherwise specified. **Age Limit**: ≥ 6 years **Quantity Limit**: none
New Product to Market: **Koselugo™** Oral capsule 10mg, 25 mg	Non-PDL drug class agent requiring PA - *Oral Oncology* **Length of Authorization:** 6 months initial, 6 months renewal • Selumetinib (Koselugo) is a mitogen-activated protein kinase 1 and 2 (MEK1/2) inhibitor indicated for the treatment of pediatric patients ≥ 2 years of age with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN). **Criteria for Approval:** **Initial Approval Criteria** • Patient is ≥ 2 years of age; AND • Patient has a confirmed diagnosis of NF1, as defined by either of the following: o Patient has positive genetic testing for NF1 as evidenced by heterozygous pathogenic variants in NF1-gene; OR o Patient ≥ 1 of the below diagnostic criteria for NF1 listed below: ▪ ≥ 6 café-au-lait macules (≥ 0.5 cm in pre-pubertal subjects or ≥ 1.5 cm in post-pubertal subjects); OR ▪ Freckling in axilla or groin; OR ▪ Optic glioma; OR ▪ ≥ 2 Lisch nodules; OR ▪ A distinctive bony lesion (dysplasia of the sphenoid bone or dysplasia or thinning of long bone cortex); OR ▪ A first-degree relative with NF1; AND • Patient has symptomatic plexiform neurofibromas (PN); AND • Patient's PN are inoperable (e.g., PN could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN); AND • Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; AND • Selumetinib will NOT be used in combination with other MEK inhibitors (e.g., binimetinib, cobimetinib, trametinib). **Renewal Criteria** • Patient must continue to meet the above initial criteria; AND • Patient has documented disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread; AND • Patient has NOT experienced any treatment-restricting adverse effects (e.g., cardiomyopathy, ocular toxicities [retinal vein occlusion or retinal pigment epithelial detachment], severe diarrhea, severe skin rashes, rhabdomyolysis, bleeding); AND • LVEF has NOT had an absolute decrease from baseline ≥ 10% and is NOT below the lower limit of normal (LLN).

Single Agent Reviews	Options for Consideration
	Age Limit: ≥ 2 years **Quantity Limit**: 100mg daily
New Product to Market: **Ponvory™** Oral tablet 2mg, 3mg, 4mg, 5mg, 6mg, 7mg, 8mg, 9mg, 10mg and 20mg	Non-prefer in the PDL class: *Multiple Sclerosis agents* **Length of Authorization:** 1 year • Ponesimod (Ponvory), 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:** **Initial Approval Criteria** • 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 • NOT used in combination with another MS agent • Patient has a baseline heart rate (HR) ≥ 55 beats per minute (bpm) • If patient is of child-bearing potential, patient is taking effective contraception; • 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 Presence of Mobitz Type II second- or third-degree atrioventricular (AV) block, sick sinus syndrome, or sinoatrial block (unless treated with a functioning pacemaker) o Current systemic or clinically significant local infection o Moderate to severe hepatic impairment (Child-Pugh B or C) o Use of any other antineoplastic, immunosuppressive or immunomodulating drugs to treat other conditions 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 Monitoring of respiratory function in patients with baseline respiratory conditions (e.g., pulmonary fibrosis, asthma, chronic obstructive pulmonary disease); 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 weeks prior to beginning therapy. **Renewal Criteria** o Continue to meet initial approval criteria; AND

Single Agent Reviews	Options for Consideration
	○ Documentation of response to therapy (e.g., progress note). **Age Limit**: ≥ 18 years **Quantity Limit**: 4-day Starter Pack: 1 pack/14 days, maintenance: 1 tablet (20 mg)/day
New Product to Market: **Lumakras™** Oral tablet 120mg	Non-PDL drug class agent requiring PA – *Oral Oncology* **Length of Authorization:** 1 year • Sotorasib (Lumakras) is rat sarcoma proto-oncogene guanosine triphosphatase (RAS GTPase) inhibitor indicated for the treatment of adult patients with Kirsten rat sarcoma viral oncogene homologue (KRAS) G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by a United States (US) Food and Drug Administration (FDA)-approved test, who have received at least 1 prior systemic therapy. **Criteria for Approval:** **Initial Approval Criteria** • Patient is ≥ 18 years of age; AND • Patient has locally advanced, metastatic, or recurrent (excluding locoregional) disease; AND • Patient has presence of Kirsten rat sarcoma viral oncogene homologue (KRAS) G12C-mutation(s) in tumor or plasma specimens as detected by a United States (US) Food & Drug Administration (FDA) or Clinical Laboratory Improvement Amendments (CLIA)-compliant test (Note: if no mutation is detected in a plasma specimen, tumor tissue should be tested); AND • Sotorasib will be used as a single agent; AND • Sotorasib will be used as subsequent therapy after prior treatment with an immune checkpoint inhibitor and/or platinum-based chemotherapy; AND • Patient does not have active brain metastases. **Renewal Criteria** • Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in above criteria; • Absence of unacceptable toxicity from the drug (e.g., interstitial lung disease, hepatotoxicity); AND • Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread. **Age Limit**: ≥ 18 years of age **Quantity Limit**: 240 tablets per 30 days (960 mg daily)
New Product to Market: **Fotivda™** Oral capsule 0.89mg, 1.34mg	Non-PDL drug class agent requiring PA – *Oral Oncology* **Length of Authorization:** 1 year

Single Agent Reviews	Options for Consideration
	• Tivozanib (Fotivda) is a kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following ≥ 2 prior systemic therapies. **Criteria for Approval:** **Initial Approval Criteria** • Patient is ≥ 18 years of age; AND • Patient has a diagnosis of renal cell carcinoma (RCC); AND • Patient has relapsed or refractory advanced disease with clear cell histology; AND • Patient has progressed after ≥ 2 prior systemic therapies; AND • Patient's blood pressure is controlled prior to initiation of treatment (note: do NOT administer if systolic >150 mmHg or diastolic > 100 mmHg); AND • Patient must NOT have had a surgical procedure within the preceding 24 days or have a surgical wound that has NOT fully healed; AND • Patient does NOT have unstable or untreated central nervous system (CNS) metastases; AND • Tivozanib will be used as a single agent; AND • For females of childbearing potential, a pregnancy test is performed before starting therapy; AND • Prescriber attestation to monitor for standard of practice tests for this condition and/or drug therapy (e.g., blood pressure, proteinuria, thyroid function). **Renewal Criteria** • Patient must continue to meet the above criteria (not including prerequisite therapy); AND • Patient has disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; AND • Patient has NOT experienced any treatment-restricting adverse effects (e.g., severe hypertension, cardiac ischemia, cardiac failure, arterial thromboembolic events, venous thromboembolic events, hemorrhage, severe proteinuria, thyroid dysfunction, impaired would healing, reversible posterior leukoencephalopathy syndrome [RPLS], tartrazine hypersensitivity). **Age Limit**: ≥ 18 years of age **Quantity Limit**: 0.89 mg capsule: 21 capsules every 28 days 1.34 mg capsule: 21 capsules every 28 days (Maximum dose: 1.34 mg daily for 21 days of a 28-day cycle)
New Product to Market: **Truseltiq™** Oral capsule 25 mg, 100 mg	Non-PDL drug class agent requiring PA – *Oral Oncology* **Length of Authorization:** 6 months initial, 6 months renewal • Infigratinib (Truseltiq) is a kinase inhibitor indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion

Single Agent Reviews	Options for Consideration
	or other rearrangement as detected by a Food and Drug Administration (FDA)- approved test. **Criteria for Approval:** **Initial Approval Criteria** • Patient must have cholangiocarcinoma that is unresectable, locally advanced or metastatic; AND • Patient has a susceptible gene mutation rearrangement or fusion in the fibroblast growth factor receptor 2 (FGFR2) gene, as determined by an FDA-approved or CLIA-compliant test; AND • Infigratinib will be used as a single agent; AND • Patient has received at least 1 line of prior therapy which contained gemcitabine; AND • Patient has received a comprehensive ophthalmic examination including optical coherence tomography at baseline and will be repeated periodically (months 1, 3, and every 3 months thereafter) throughout therapy; AND • Patient's serum phosphate level is measured at baseline and periodically throughout therapy; AND • Therapy will NOT be used concomitantly with other selective FGFR inhibitors (e.g., erdafitinib, pemigatinib); AND • Female patients of reproductive potential have had a negative pregnancy test prior to infigratinib therapy; AND • Female patients of reproductive potential and male patients with partners of reproductive potential should use effective contraception during therapy and for 1 month following the last dose. **Renewal Criteria** • Patient must continue to meet the above criteria; AND • Patient must have disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; AND • Patient has NOT experienced any treatment-restricting adverse effects (e.g., retinal pigment epithelial detachment [RPED], severe hyperphosphatemia); AND • Patient's serum phosphate level is ≤ 7.5 mg/dL. **Age Limit**: ≥ 18 years of age **Quantity Limit**: 25 mg capsule: 63 capsules every 28 days 100 mg capsule: 21 capsules every 28 days (Maximum dose: 125 mg daily for 21 days of a 28-day cycle)
Gemtesa™ Oral tablet 75 mg	Non-prefer in the PDL class: *Bladder relaxants* **Length of Authorization:** 1 year • Vibegron (Gemtesa), a selective ß3-adrenergic receptor agonist, is indicated for the treatment of overactive bladder (OAB) in adults who have symptoms of urge urinary incontinence, urgency, and urinary frequency. **Criteria for Approval:**

Single Agent Reviews	Options for Consideration
	Initial Approval Criteria • Patient is ≥ 18 years of age; AND • Patient has a diagnosis of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; AND • Patient must not have hypersensitivity to vibegron or any component of the product; AND • Patient must have an adequate trial and failure of behavioral therapy (bladder training, bladder control strategies, pelvic floor muscle training, and fluid management); AND • Patient has tried and failed at least one month, or has an intolerance, or contraindication to at least two preferred medications. • Patient has tried and failed at least one month of treatment with Myrbetriq. **Renewal Criteria** • Patient has not experienced urinary retention; AND • Patient has experienced disease response as indicated by a reduction in the daily number of micturitions and the average daily number of urge urinary incontinence (UUI) episodes. **Age Limit**: ≥ 18 years of age **Quantity Limit**: 30 tablets per 30 days

Full Class Reviews	Options for Consideration
Antidepressants, Other **Antidepressants, SNRIs**	**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. **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.
Antidepressants, SSRIs	**Antidepressants: SSRIs** • 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: SSRIs class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
Movement Disorders	**Movement Disorders** • 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 Movement Disorders class, require PA until reviewed by the P&T Advisory Committee.
Stimulants and Related Agents **Narcolepsy Agents**	**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. **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.

Consent Agenda	Options for Consideration
For the following therapeutic classes, there are **no recommended changes to the Preferred Drug List (PDL) status**; these may be voted on as a group:	
• Alzheimer's Agents • Angiotensin Modulator Combinations • Angiotensin Receptor Blockers • Antianginal & Anti-Ischemic • Antiarrhythmics Oral • Anticoagulants • Anticonvulsants • Antidepressants, Tricyclic • Antiparkinson's Agents • Antipsychotics • Anxiolytics	• Beta Blockers • Bladder Relaxant Preparations • BPH Treatments • Calcium Channel Blockers • Lipotropics, Other • Lipotropics, Statins • Opiate Dependence Treatments • PAH Agents - Oral and Inhaled • Platelet Aggregation Inhibitors • Sedative Hypnotics • Smoking Cessation