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 **November 15, 2018** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
New Product to Market: **Lucemyra™**	Non-prefer in the PDL class: *Opiate Dependence Treatments* **Length of Authorization:** 5 days • Lucemyra™ (lofexidine) is a central alpha-2 adrenergic agonist indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults. **Criteria for Approval**: • Medication is being used to mitigate opioid withdrawal symptoms and facilitate abrupt discontinuation of opioids; AND • Patient is NOT pregnant or breastfeeding; AND • Patient does NOT have a prolonged QT interval (> 450 msec for males, > 470 msec for females); AND • If patient is currently taking methadone, prescriber attestation that a baseline electrocardiogram (ECG) has been performed; AND • Patient has tried and failed, had a contraindication to, or experienced an adverse reaction/intolerance to buprenorphine OR methadone; AND • Patient has tried and failed, had a contraindication to, or experienced an adverse reaction/intolerance to clonidine; AND • Prescriber to provide verbal attestation of a comprehensive treatment plan between provider and patient; AND • Prescriber to provide verbal attestation that the patient is capable of and instructed how to self-monitor for hypotension, orthostasis, bradycardia, and associated symptoms; AND • Prescriber to provide verbal attestation that patient is NOT receiving prescribed concurrent opioid medication based on current medication list/orders, medical records, patient history and verified by KASPER query; AND • Prescriber to provide verbal attestation that the patient has been provided with a tapering schedule and instructions on when to contact their healthcare provider for further guidance. **Age Limit**: ≥ 18 years **Quantity Limit**: 48 tablets with 1 refill (96 tabs per treatment course; 1 course per year)

Single Agent Reviews	Options for Consideration
New Product to Market: **Tibsovo®**	Prefer with clinical criteria in the PDL class: *Oncology, Oral – Hematologic Cancer (Oral Oncology, Hematologic Cancer)* **Length of Authorization:** 1 year • Tibsovo (ivosidenib) is an isocitrate dehydrogenase-1 (IDH1) indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by the Abbott RealTime™ IDH1 FDA-approved companion diagnostic. **Criteria for Approval**: • Diagnosis acute myeloid leukemia; AND • Documentation showing susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test; AND • Must be used as single agent; AND • Patient has relapsed or refractory disease; OR • Patient is not a candidate for intensive remission induction therapy; OR • Patient declines intensive therapy. **Renewal Criteria** • Patient continues to meet the above conditions; AND • Evidence of tumor response or lack of disease progression. **Age Limit**: ≥ 18 years **Quantity Limit**: 2 tablets per day
New Product to Market: **Braftovi™**	Prefer with clinical criteria in the PDL class: *Oncology, Oral – Skin (Oral Oncology, Skin Cancer)* **Length of Authorization:** 1 year • Braftovi™ (encorafenib) is a kinase inhibitor indicated, in combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test. **Criteria for Approval:** • Diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test; AND • Used in combination with binimetinib. **Renewal Criteria:** • Meet initial approval criteria; AND • Evidence of tumor response or lack of disease progression. **Age Limit**: ≥ 18 years **Quantity Limit**: 75 mg: 6 per day; 50 mg: 4 per day
New Product to Market: **Mektovi®**	Prefer with clinical criteria in the PDL class: *Oncology, Oral – Skin (Oral Oncology, Skin Cancer)* **Length of Authorization:** 1 year • Mektovi® (binimetinib) is a kinase inhibitor indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test. **Criteria for Approval:** • Diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test; AND • Used in combination with encorafenib. **Renewal Criteria:** • Meet initial approval criteria; AND • Evidence of tumor response or lack of disease progression. **Age Limit**: ≥ 18 years **Quantity Limit**: 6 per day

Single Agent Reviews	Options for Consideration
New Product to Market: **Doptelet®**	Non-prefer in the PDL class: *Thrombopoiesis Stimulating Agents* **Length of Authorization:** Date of Service; 1 fill per procedure • Doptelet® (avatrombopag), a thrombopoietin (TPO) receptor agonist, is indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure. **Criteria for Approval**: • Diagnosis of chronic liver disease; AND • Documentation of platelet count < 50 x 10^9/L; AND • Dosed per FDA-approved labeling (10 tablets per 5 days for platelets ≥ 40 x 10^9/L or 15 tablets per 5 days for platelets < 40 x 10^9/L); AND • Confirmation of a scheduled invasive procedure occurring 5 to 8 days following the last dose of avatrombopag. **Age Limit**: ≥18 years **Quantity Limit**: 15 tablets per fill
New Product to Market: **Mulpleta®**	Non-prefer in the PDL class: *Thrombopoiesis Stimulating Agents* **Length of Authorization:** Date of Service; 1 fill per procedure • Mulpleta® (lusutrombopag), a thrombopoietin (TPO) receptor agonist, is indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure. **Criteria for Approval**: • Diagnosis of chronic liver disease (CLD); AND • Documentation of platelet count < 50 x 10^9/L; AND • Dosed per FDA-approved labeling (10 tablets per 5 days for platelets ≥ 40 x 10^9/L or 15 tablets per 5 days for platelets < 40 x 10^9/L); AND • NOT have severe hepatic impairment (Child-Pugh class C), absence of hepatopetal blood flow, a prothrombotic condition other than CLD or a history of splenectomy, partial splenic embolization, or thrombosis; AND • Confirmation of a scheduled invasive procedure occurring 2 to 8 days following the last dose of lusutrombopag. **Age Limit**: ≥18 years **Quantity Limit**: 7 tablets per fill

Criteria Review	Options for Consideration

Movement Disorders:
 	
Austedo® (deutetrabenazine)
	Austedo® (deutetrabenazine) is a vesicular monoamine transporter 2 (VMAT2) inhibitor approved for the treatment of chorea associated with Huntington's disease and the treatment of tardive dyskinesia.
	
	Current criteria: Trial and failure of a preferred agent.
	
	Recommended criteria:
	Length of Authorization: 1 year
	Criteria for Approval:
	• Patient is not concurrently using monoamine oxidase (MAO) inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc within 14 days) **OR** reserpine (within 20 days) **OR** another VMAT2 inhibitor (e.g., tetrabenazine, valbenazine); **AND**
	• Patient is not pregnant; **AND**
	• Patient does not have hepatic impairment (e.g., Child-Pugh A-C); **AND**
	• Patient meets the following criteria for either Huntington's chorea *or* tardive dyskinesia:
	
	Huntington's Chorea
	• Patient is diagnosed with chorea related to Huntington's disease; **AND**
	• Trial and failure of 1 preferred product (e.g., tetrabenazine); **AND**
	• Patient is able to swallow; **AND**
	• Patient does not have the following conditions:
	  ○ History of, or current, untreated or inadequately treated depression; **OR**
	  ○ Suicidal ideation.
	
	Tardive Dyskinesia
	• Diagnosis of tardive dyskinesia; **AND**
	• Patient is able to swallow; **AND**
	• Documentation that AIMS test has been completed (e.g., score or copy of AIMS assessment); **AND**
	• Prescribed by or in consultation with a neurologist or psychiatrist (or other mental health provider), provided patient has reasonable access; **AND**
	• Documentation or claims history of current or former chronic patient use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.).
	
	Renewal Criteria:
	• Patient continues to meet criteria defined for initial approval; **AND**
	• Documentation of improvement in symptoms associated with respective condition (e.g., tardive dyskinesia or Huntington's chorea).
	
	Age Limit: ≥ 18 years
	Quantity Limit: 4 per day

Criteria Review	Options for Consideration
Movement Disorders: **Ingrezza™ (valbenazine)**	Ingrezza™ (valbenazine) is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia (TD). Tardive dyskinesia is a side effect that can be seen in patients on long treatments of antipsychotic medications and medications used for gastrointestinal disease. Current criteria: Trial and failure of a preferred agent. Recommended criteria: **Length of Authorization**: 1 year **Criteria for Approval**: • Diagnosis of tardive dyskinesia; AND • Documentation that AIMS test has been completed (e.g., score or copy of AIMS assessment); AND • Prescribed by or in consultation with a neurologist or psychiatrist (or other mental health provider), provided patient has reasonable access; AND • Documentation or claims history of current or former chronic use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.); AND • NO concurrent use of MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.). **Renewal Criteria:** • Patient continues to meet criteria defined for initial approval; AND • Attestation or documentation of improvement in TD symptoms. **Age Limit**: ≥ 18 years **Quantity Limit**: 1 per day

Full Class Reviews	Options for Consideration
Acne Agents, Topical **(Topical Acne Agents)**	**Topical Acne Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 5 products unique chemical entities or combinations should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Topical Acne Agents* class, require PA until reviewed by the P&T Advisory Committee.
Anticholinergics/ Antispasmodics	**Anticholinergics/ Antispasmodics** • 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 will require PA. • For any new chemical entity in the *Anticholinergics/Antispasmodics* class, require PA until reviewed by the P&T Advisory Committee.
Antiemetics & Antivertigo Agents **(Anti-Emetics: Other, Oral Anti-Emetics: 5-HT3**	**Anti-Emetics: Other** • 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 will require PA. • For any new chemical entity in the *Anti-Emetics: Other* class, require PA until reviewed by the P&T Committee.

Full Class Reviews	Options for Consideration
Antagonists, Oral Anti-Emetics: Delta-9-THC Derivatives, Oral Anti-Emetics: NK-1 Antagonists)	**Oral Anti-Emetics: 5-HT3 Antagonists** • 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 *Oral Anti-Emetics: 5-HT3 Antagonists* class, require PA until reviewed by the P&T Committee. **Oral Anti-Emetics: Delta-9-THC 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 will require PA. • For any new chemical entity in the *Oral Anti-Emetics: Delta-9-THC Derivatives* class, require PA until reviewed by the P&T Committee. **Oral Anti-Emetics: NK-1 Antagonists** • 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 *Oral Anti-Emetics: NK-1 Antagonists* class, require PA until reviewed by the P&T Committee.
Antifungals, Topical (Topical Antifungal Agents)	**Topical Antifungal Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities or combinations should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Topical Antifungal Agents* class, require PA until reviewed by the P&T Committee.
Antiparasitics, Topical **(Topical Antiparasitic Agents)**	**Topical Antiparasitic Agents** • 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 will require PA. • For any new chemical entity in the *Topical Antiparasitic Agents* class, require PA until reviewed by the P&T Committee.
Bile Salts	**Bile Salts** • DMS to select preferred agent(s) based on economic evaluation; however, at least generic ursodiol capsules and tablets should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Bile Salts* class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration

Cytokine and CAM Antagonists
 	
(Immunomodulators)
	Immunomodulators
	• 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 will require PA.
	• For any new chemical entity in the *Immunomodulators* class, require PA until reviewed by the P&T Advisory Committee.
	
	<u>New agent in the class:</u> Ilumya™
	Non-prefer in the PDL class: *Cytokine and CAM Antagonists (Immunomodulators)*
	Length of Authorization: 1 year
	• Ilumya™ (tildrakizumab-asmn), a high affinity, humanized IgG1 kappa monoclonal antibody that targets the p19 subunit of interleukin 23 (IL-23), is indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PSO) 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 2 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
	• NOT to be used in combination with a TNF inhibitor, anakinra, abatacept, apremilast or other biologic response modifier.
	Renewal Criteria:
	• Patient continues to meet criteria identified above; AND
	• Ongoing monitoring for TB; AND
	• Disease response 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: 1 syringe per fill

Full Class Reviews	Options for Consideration
Multiple Sclerosis Agents	**Multiple Sclerosis Agents** • 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 will require PA. • For any new chemical entity in the *Multiple Sclerosis Agents* class, require PA until reviewed by the P&T Advisory Committee. **Criteria review:** Gilenya™ (fingolimod) *Current criteria and PDL status:* Preferred with clinical PA • Requires a step through an injectable agent (e.g., Avonex®, Betaseron®, Copaxone®, Rebif®). *Recommended PDL status*: Preferred • Clinical step edit is removed and Gilenya is available without a PA.
Ophthalmics for Allergic Conjunctivitis **(Ophthalmic Antihistamines)**	**Ophthalmic Antihistamines** • 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 *Ophthalmic Antihistamines* class, require PA until reviewed by the P&T Advisory Committee.
Ophthalmic Antibiotics **(Ophthalmic Antibiotics, Non-Quinolones; Ophthalmic Antifungals; Ophthalmic Macrolides; Ophthalmic Quinolones)**	**Ophthalmic Antibiotics, Non-Quinolones** • DMS to select preferred agent(s) based on economic evaluation; however, at least 5 unique chemical entities or combinations should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Ophthalmic Antibiotics, Non-Quinolones* class, require PA until reviewed by the P&T Committee. **Ophthalmic Antifungals** • 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 *Ophthalmic Antifungals* class, require PA until reviewed by the P&T Committee. **Ophthalmic Macrolides** • 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 *Ophthalmic Macrolides* class, require PA until reviewed by the P&T Committee. **Ophthalmic Quinolones** • 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 will require PA. • For any new chemical entity in the *Ophthalmic Quinolones* class, require PA until reviewed by the P&T Committee.

Full Class Reviews	Options for Consideration
Otic Antibiotics	**Otic Antibiotics** • DMS to select preferred agent(s) based on economic evaluation; however, at least 3 unique chemical entities or combinations should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Otic Antibiotics* class, require PA until reviewed by the P&T Committee.
Steroids, Topical (Low Potency)	**Steroids, Topical (Low Potency)** • 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 will require PA. • For any new chemical entity in the *Steroids, Topical (Low Potency)* class, require PA until reviewed by the P&T 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:	
Acne Agents, Oral	Ophthlamic Immunomodulators
Anti-Ulcer Protectants	Ophthalmics, Antibiotic-Steroid Combinations
Antibiotics, Topical	Ophthalmics, Anti-inflammatories
Antidiarrheals	Ophthalmics, Antivirals
Antipsoriatics, Oral	Ophthalmics, Glaucoma Agents
Antipsoriatics, Topical	Ophthalmics, Mydriatic
Antivirals, Topical	Ophthalmics, Vasoconstrictors
GI Motility, Chronic	Otic Anti-Infectives and Anesthetics
H. Pylori Treatment	Otics, Anti-Inflammatory
Histamine II Receptor Blockers	Proton Pump Inhibitors
Immunomodulators, Atopic Dermatitis	Rosacea Agents, Topical
Immunosuppressives, Oral	Steroids, Topical (Medium, High, Very High)
Laxatives and Cathartics	Ulcerative Colitis Agents