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 21, 2019** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
New Product to Market: **Inrebic®**	Prefer with clinical criteria the PDL class: *Oral Oncology, Hematologic Cancer (Oncology, Oral – Hematologic)* **Length of Authorization:** 1 year Inrebic® (fedratinib) is a Janus kinase 2 (JAK2) inhibitor indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF). **Criteria for Approval**: • Diagnosis of intermediate-2 or high-risk myelofibrosis (MF), including secondary post-polycythemia vera or post-essential thrombocythemia MF; AND • NOT to be used in combination with rituximab. **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**: 4 per day

New Product to Market: **Xpovio™**	Non-prefer in the PDL class: *Oral Oncology, Hematologic Cancer (Oncology, Oral – Hematologic)*
	Length of Authorization: 1 year
	• Xpovio™ (selinexor) is a nuclear export inhibitor indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received ≥ 4 prior therapies and whose disease is refractory to ≥ 2 proteasome inhibitors, ≥ 2 immunomodulatory agents, and an anti-CD38 monoclonal antibody.
	Criteria for Approval:
	• Diagnosis of relapsed or refractory multiple myeloma; AND
	• Patient does NOT have smoldering myeloma, central nervous system myeloma, systemic amyloid light chain amyloidosis or plasma cell leukemia; AND
	• Trial and failure (inadequate response; progression during or within 60 days of therapy) of ≥ 4 prior therapies that must include:
	  ○ 2 proteasome inhibitors (e.g., bortezomib, ixazomib, or carfilzomib); AND
	  ○ 2 immunomodulatory agents (e.g., lenalidomide, pomalidomide, thalidomide); AND
	  ○ An anti-CD38 antibody (e.g., daratumumab).

Single Agent Reviews	Options for Consideration
	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**: 32 tablets per 28 days

New Product to Market:
Rozlytrek™
	Prefer with clinical criteria in the PDL class: *Oral Oncology, Hematologic Cancer (Oncology, Oral – Hematologic)*
	Length of Authorization: 1 year
	• Rozlytrek™ (entrectinib) is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive. Patients should be selected based on the presence of ROS1 rearrangement(s) in tumor specimens. An FDA-approved test for detection of these mutations in NSCLC for selecting patients is not available; however, a companion diagnostic test is planned to be submitted to the FDA for approval.
	• Entrectinib is also indicated for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that:
	  ○ Have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation;
	  ○ Are metastatic or where surgical resection is likely to result in severe morbidity; and
	  ○ Have either progressed following treatment or have no satisfactory alternative therapy.
	• Patients should be selected for treatment of locally advanced or metastatic solid tumors based on the presence of a NTRK gene fusion. An FDA-approved test for the detection of NTRK gene fusion in solid tumors is not available; however, a companion diagnostic test is planned to be submitted to the FDA for approval.
	Criteria for Approval:
	• Diagnosis of metastatic non-small cell lung cancer (NSCLC) are ROS1-positive as determined by laboratory testing (e.g., next generation sequencing [NGS] or fluorescence in situ hybridization [FISH]); OR
	• Diagnosis of solid tumor (e.g., soft tissue sarcoma, salivary gland, infantile fibrosarcoma, thyroid, lung, or gastrointestinal stromal tumors); AND
	  ○ Tumor has a positive NTRK gene fusion status, without a known acquired resistance mutation, as determined by laboratory testing (e.g., NGS or FISH); AND
	  ○ Disease is metastatic or surgical resection is likely to result in severe morbidity; AND
	  ○ Patient has no satisfactory alternative treatments or has progressed following treatment.
	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: ≥ 12 years
	Quantity Limits: 100 mg: 5 per day; 200 mg: 3 per day

Single Agent Reviews	Options for Consideration

New Product to Market: **Turalio™**	Prefer with clinical criteria in the PDL class: *Oral Oncology, Other (Oncology, Oral – Other)*
	Length of Authorization: 1 year
	• Turalio™ (pexidartinib) is indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.
	Criteria for Approval:
	• Histologically confirmed diagnosis of tenosynovial giant cell tumor (TGCT) – also referred to as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS); AND
	  ○ NOT metastatic; AND
	  ○ Symptomatic and/or associated with severe morbidity or functional limitations; AND
	  ○ NOT amenable to improvement with surgery or patient is not a surgery candidate.
	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: 4 per day

New Product to Market: **Nubeqa®**	Prefer with clinical criteria in the PDL class: *Oral Oncology, Prostate (Oncology, Oral – Prostate)* **Length of Authorization:** 1 year • Nubeqa® (darolutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer. **Criteria for Approval:** • Diagnosis of non-metastatic castration-resistant disease (nmCRPC); AND • Patient will also receive a gonadotropin-releasing hormone (GnRH)-analog or has had a bilateral orchiectomy; AND • NOT used with another androgen receptor inhibitor (e.g., apalutamide, enzalutamide). **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:** 4 per day

Single Agent Reviews	Options for Consideration
New Product to Market: **Sunosi™**	Non-prefer in the PDL class: *Narcolepsy Agents (Stimulants and Related Agents)* **Length of Authorization:** 1 year • Sunosi™ (solriamfetol) is a dopamine and norepinephrine reuptake inhibitor (DNRI) approved for improving wakefulness in adults with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA). • Limitations of use: Solriamfetol is not indicated to treat underlying airway obstruction in OSA. In patients with OSA, the underlying airway obstruction must be treated (e.g., with continuous positive airway pressure [CPAP]) for ≥ 1 month before initiating solriamfetol for EDS. Any treatment used for the underlying airway obstruction should be continued throughout treatment with solriamfetol. Solriamfetol is a controlled substance, schedule C-IV. **Criteria for Approval:** • Diagnosis of excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA); AND • Prescriber attestation or documentation that member's blood pressure is adequately controlled (≤ 140/90 mmHg); AND • Trial and failure/intolerance of, or contraindication to, a preferred agent (e.g., modafanil). **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 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 *Topical Acne Agents* class, require PA until reviewed by the P&T Advisory Committee.
Antidiarrheals	Antidiarrheals • 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 *Antidiarrheals* class, require PA until reviewed by the P&T Advisory Committee.
Antiemetics & Antivertigo Agents (Anti-Emetics: Other, Oral Anti-Emetics: 5-HT3 Antagonists, Oral Anti-Emetics: Delta-9-THC Derivatives, Oral Anti-Emetics: NK-1 Antagonists)	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 Advisory Committee. 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 Advisory 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 Advisory 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 Advisory 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 require PA. • For any new chemical entity in the *Topical Antiparasitic Agents* 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 require PA. • For any new chemical entity in the *Immunomodulators* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class: Rinvoq™** Non-prefer in this PDL class. **Length of Authorization:** 1 year • Rinvoq™ (upadacitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate (MTX). • Use in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants, such as azathioprine and cyclosporine, is not recommended. **Criteria for Approval:** • Diagnosis of moderately to severely active rheumatoid arthritis (RA) using an objective measure/tool; AND • Trial and failure (at least 3 months) or intolerance to methotrexate (MTX); AND • Trial and failure (at least 3 months), or contraindication to, a preferred immunomodulator (e.g., Enbrel® or Humira®); AND • Used for treatment of RA as a single agent or in combination with MTX or similar non-biologic DMARD; AND • Negative tuberculosis (TB) screening and no signs of clinically significant infection prior to treatment initiation. • **Renewal Criteria:** • Meet initial approval criteria; AND • Ongoing monitoring for TB or other active infection; AND • Disease response as indicated by improvement in signs and symptoms compared to baseline objective measurements, such as the number of tender and swollen joints. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
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. **Class Criteria review:** *Current criteria:* Preferred agents do not require a prior authorization. *Recommended criteria*: Preferred agents require a diagnosis code of multiple sclerosis (ICD-10 = G35) or a history of use of another MS agent. This

Full Class Reviews	Options for Consideration
	requirement can be fulfilled automatically by drug history lookback, and/or medical diagnosis lookback/submission.
Ophthalmics, Glaucoma Agents **(Ophthalmic Beta Blockers; Ophthalmic Carbonic Anhydrase Inhibitors; Ophthalmic Combinations for Glaucoma; Ophthalmic Glaucoma Direct Acting Miotics; Ophthalmic Prostaglandin Agonists; Ophthalmic Sympathomimetics; Ophthalmics, Glaucoma Agents (Other))**	**Ophthalmic Beta Blockers** • 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 *Ophthalmic Beta Blockers* class, require PA until reviewed by the P&T Advisory Committee. **Ophthalmic Carbonic Anhydrase Inhibitors** • 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 Carbonic Anhydrase Inhibitors* class, require PA until reviewed by the P&T Advisory Committee. **Ophthalmic Combinations for Glaucoma** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique 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 Combinations for Glaucoma* class, require PA until reviewed by the P&T Advisory Committee. **Ophthalmic Glaucoma Direct Acting Miotics** • 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 Glaucoma Direct Acting Miotics* class, require PA until reviewed by the P&T Advisory Committee. **Ophthalmic Prostaglandin Agonists** • 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 Prostaglandin Agonists* class, require PA until reviewed by the P&T Advisory Committee. **Ophthalmic Sympathomimetics** • 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 Sympathomimetics* class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
	Ophthalmics, Glaucoma Agents (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 *Ophthalmics, Glaucoma Agents (Other)* class, require PA until reviewed by the P&T Advisory Committee. **Class Criteria review – Ophthalmics, Glaucoma Agents (Other):** *Current criteria:* Preferred agents do not require a prior authorization (PA). *Recommended criteria*: Preferred agents require PA consisting of a step edit through generic latanoprost. An electronic 90-day lookback for a paid pharmacy claim for latanoprost will be established to allow an automated PA.
Otic Antibiotics	**Otic Antibiotics** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 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 *Otic Antibiotics* class, require PA until reviewed by the P&T Advisory Committee.
Proton Pump Inhibitors	**Proton Pump Inhibitors** • 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 *Proton Pump Inhibitors* class, require PA until reviewed by the P&T Advisory Committee.
Spinal Muscular Atrophy	**Spinal Muscular Atrophy** • 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 *Spinal Muscular Atrophy* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class: Zolgensma®** Prefer with clinical criteria in this PDL class. **Length of Authorization:** Date of service; once per lifetime • Zolgensma® (onasemnogene abeparvovec-xioi) is an adeno-associated virus vector-based gene therapy indicated for the treatment of pediatric patients < 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. • The safety and effectiveness of repeat administration and use in patients with advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence) have not been evaluated. **Criteria for Approval:** • Diagnosis of spinal muscular atrophy (SMA) confirmed by either bi-allelic deletion or dysfunctional point mutation of the SMN1 gene; AND • Must have SMA phenotype 1 confirmed by: o 1 or 2 copies of the SMN2 gene; OR

Full Class Reviews	Options for Consideration
	○ 3 copies of the SMN2 gene WITHOUT the c.859G>C single base substitution modification in exon 7; AND • NOT have advanced SMA (e.g., permanent ventilation support; complete limb paralysis); AND • NOT have pre-existing hepatic insufficiency; AND • Baseline anti-AAV9 antibody titer of ≤ 1:50 (as measured by ELISA); AND • Must be used with systemic corticosteroids (e.g., 1 mg/kg/day oral prednisone or equivalent) as directed; AND • NOT to be used in combination with nusinersen; AND • Therapy to be administered prior to recipient's 2nd birthday.
Ulcerative Colitis Agents	**Ulcerative Colitis 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 *Ulcerative Colitis 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:	
• Acne Agents, Oral • Antibiotics, Topical • Anticholinergics/Antispasmodics • Antifungals, Topical • Antipsoriatics, Oral • Antipsoriatics, Topical • Anti-Ulcer Protectants • Antivirals, Topical • Bile Salts • GI Motility, Chronic • H. Pylori Treatment • Histamine II Receptor Blockers • Immunomodulators, Atopic Dermatitis • Immunosuppressives, Oral	• Laxatives & Cathartics • Ophthalmic Antibiotic-Steroid Combinations • Ophthalmic Antibiotics • Ophthalmics, Anti-Inflammatories • Ophthalmics, Anti-Inflammatories-Immunomodulators • Ophthalmics, Antiviral • Ophthalmics for Allergic Conjunctivitis • Ophthalmics, Mydriatic • Ophthalmics, Vasoconstrictor • Otic Anti-Infectives & Anesthetics • Otics, Anti-Inflammatory • Rosacea Agents, Topical • Steroids, Topical (High, Low, Medium, Very High)