



Kentucky Department for Medicaid Services Pharmacy and Therapeutics Advisory Committee Recommendations

November 21, 2019

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **November 21, 2019** meeting.

Although the Committee met on November 21, 2019, the necessary quorum was not achieved; however, the expertise, vote and recommendations of the Committee members in attendance were captured and the Committee delivered the unofficial recommendations reflected below for review. Pending is the review by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services of these recommendations and final decisions.

	Description of Recommendation	P & T Vote
1	<p>New Product to Market: Inrebic® Prefer with clinical criteria in the PDL class: <i>Oral Oncology, Hematologic Cancer</i> Length of Authorization: 1 year</p> <ul style="list-style-type: none"> 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). <p>Criteria for Approval:</p> <ul style="list-style-type: none"> 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. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> 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). <p>Age Limit: ≥ 18 years Quantity Limit: 4 per day</p>	<p>Passed 6 For 0 Against</p>
2	<p>New Product to Market: Xpovio™ Non-prefer in the PDL class: <i>Oral Oncology, Hematologic Cancer</i> Length of Authorization: 1 year</p> <ul style="list-style-type: none"> 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. 	<p>Passed 6 For 0 Against</p>

	Description of Recommendation	P & T Vote
	<p>Criteria for Approval:</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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). <p>Renewal Criteria</p> <ul style="list-style-type: none"> • 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). <p>Age Limit: ≥ 18 years Quantity Limit: 32 tablets per 28 days</p>	
3	<p>New Product to Market: Rozlytrek™ Prefer with clinical criteria in the PDL class: <i>Oral Oncology, Lung Cancer</i></p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • Diagnosis of metastatic non-small cell lung cancer (NSCLC) that is: <ul style="list-style-type: none"> ○ ALK- and EGFR-negative; AND ○ 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 	<p>Passed 6 For 0 Against</p>

	Description of Recommendation	P & T Vote
	<ul style="list-style-type: none"> ○ 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. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> • 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). <p>Age Limit: ≥ 12 years Quantity Limit: 100 mg: 5 per day; 200 mg: 3 per day</p>	
4	<p>New Product to Market: Turalio™ Prefer with clinical criteria in the PDL class: <i>Oral Oncology, Other</i></p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> • 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. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ 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. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> • 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). <p>Age Limit: ≥ 18 years Quantity Limit: 4 per day</p>	<p>Passed 6 For 0 Against</p>

	Description of Recommendation	P & T Vote
5	<p>New Product to Market: Nubeqa® Prefer with clinical criteria in the PDL class: <i>Oral Oncology, Prostate Cancer</i></p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> Nubeqa® (darolutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> 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). <p>Renewal Criteria:</p> <ul style="list-style-type: none"> 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). <p>Age Limit: ≥ 18 years Quantity Limit: 4 per day</p>	<p>Passed 6 For 0 Against</p>
6	<p>New Product to Market: Sunosi™ Non-prefer in the PDL class: <i>Narcolepsy Agents</i></p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> 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. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> 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., modafinil). <p>Age Limit: ≥ 18 years Quantity Limit: 1 per day</p>	<p>Passed 6 For 0 Against</p>
7	<p>Topical Acne Agents</p> <ul style="list-style-type: none"> 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 <i>Topical Acne Agents</i> class, require PA until reviewed by the P&T Advisory Committee. 	<p>Passed 6 For 0 Against</p>

	Description of Recommendation	P & T Vote
8	<p>Antidiarrheals</p> <ul style="list-style-type: none"> 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 <i>Antidiarrheals</i> class, require PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>6 For 0 Against</p>
9	<p>Anti-Emetics: Other</p> <ul style="list-style-type: none"> 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 <i>Anti-Emetics: Other</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Oral Anti-Emetics: 5-HT3 Antagonists</p> <ul style="list-style-type: none"> 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 <i>Oral Anti-Emetics: 5-HT3 Antagonists</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Oral Anti-Emetics: Delta-9-THC Derivatives</p> <ul style="list-style-type: none"> 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 <i>Oral Anti-Emetics: Delta-9-THC Derivatives</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Oral Anti-Emetics: NK-1 Antagonists</p> <ul style="list-style-type: none"> 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 <i>Oral Anti-Emetics: NK-1 Antagonists</i> class, require PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>6 For 0 Against</p>
10	<p>Topical Antiparasitic Agents</p> <ul style="list-style-type: none"> 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 <i>Topical Antiparasitic Agents</i> class, require PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>6 For 0 Against</p>

	Description of Recommendation	P & T Vote
11	<p>Immunomodulators</p> <ul style="list-style-type: none"> 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 <i>Immunomodulators</i> class, require PA until reviewed by the P&T Advisory Committee. <p><u>New agent in the class: Rinvoq™</u> Non-prefer in this PDL class.</p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> 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. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> 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. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> 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. <p>Age Limit: ≥ 18 years Quantity Limit: 1 per day</p>	<p>Passed 6 For 0 Against</p>
12	<p>Multiple Sclerosis Agents</p> <ul style="list-style-type: none"> 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 <i>Multiple Sclerosis Agents</i> class, require PA until reviewed by the P&T Advisory Committee. <p><u>Class Criteria review:</u> <i>Current criteria:</i> Preferred agents do not require a prior authorization.</p>	<p>Passed 6 For 0 Against</p>

	Description of Recommendation	P & T Vote
	<p><i>Recommended criteria:</i> Preferred agents require a diagnosis code of multiple sclerosis (ICD-10 = G35) or a history of use of another MS agent. This requirement can be fulfilled automatically by drug history lookback, and/or medical diagnosis lookback/submission.</p>	
13	<p>Ophthalmic Beta Blockers</p> <ul style="list-style-type: none"> 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 <i>Ophthalmic Beta Blockers</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Ophthalmic Carbonic Anhydrase Inhibitors</p> <ul style="list-style-type: none"> 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 <i>Ophthalmic Carbonic Anhydrase Inhibitors</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Ophthalmic Combinations for Glaucoma</p> <ul style="list-style-type: none"> 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 <i>Ophthalmic Combinations for Glaucoma</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Ophthalmic Glaucoma Direct Acting Miotics</p> <ul style="list-style-type: none"> 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 <i>Ophthalmic Glaucoma Direct Acting Miotics</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Ophthalmic Prostaglandin Agonists</p> <ul style="list-style-type: none"> 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 <i>Ophthalmic Prostaglandin Agonists</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Ophthalmic Sympathomimetics</p> <ul style="list-style-type: none"> 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. 	<p>Passed</p> <p>6 For 0 Against</p>

	Description of Recommendation	P & T Vote
	<ul style="list-style-type: none"> For any new chemical entity in the <i>Ophthalmic Sympathomimetics</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Ophthalmics, Glaucoma Agents (Other)</p> <ul style="list-style-type: none"> 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 <i>Ophthalmics, Glaucoma Agents (Other)</i> class, require PA until reviewed by the P&T Advisory Committee. <p><u>Class Criteria review – Ophthalmics, Glaucoma Agents (Other):</u> <i>Current criteria:</i> Preferred agents do not require a prior authorization (PA). <i>Recommended criteria:</i> 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.</p>	
14	<p>Otic Antibiotics</p> <ul style="list-style-type: none"> 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 <i>Otic Antibiotics</i> class, require PA until reviewed by the P&T Advisory Committee. 	<p>Passed 6 For 0 Against</p>
15	<p>Proton Pump Inhibitors</p> <ul style="list-style-type: none"> 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 <i>Proton Pump Inhibitors</i> class, require PA until reviewed by the P&T Advisory Committee. 	<p>Passed 6 For 0 Against</p>
16	<p>Spinal Muscular Atrophy</p> <ul style="list-style-type: none"> 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 <i>Spinal Muscular Atrophy</i> class, require PA until reviewed by the P&T Advisory Committee. <p><u>New agent in the class: Zolgensma®</u> Non-prefer this PDL class.</p> <p>Length of Authorization: Date of service; once per lifetime</p> <ul style="list-style-type: none"> 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. 	<p>Passed 6 For 0 Against</p>

	Description of Recommendation	P & T Vote
	<p>Criteria for Approval:</p> <ul style="list-style-type: none"> • Prescribed by, or in consultation with, a pediatric neurologist or other specialist in the diagnosis and treatment of spinal muscular atrophy (SMA); AND • Diagnosis of SMA confirmed by either bi-allelic deletion or dysfunctional point mutation of the SMN1 gene; AND • Must have SMA phenotype 1 confirmed by: <ul style="list-style-type: none"> ○ 1 or 2 copies of the SMN2 gene; OR ○ 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 $\leq 1:50$ (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. 	
17	<p>Ulcerative Colitis Agents</p> <ul style="list-style-type: none"> • 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 <i>Ulcerative Colitis Agents</i> class, require PA until reviewed by the P&T Advisory Committee. 	<p>Passed 6 For 0 Against</p>

Consent Agenda

For the following therapeutic classes, the P&T Committee had no recommended changes to the currently posted Preferred Drug List (PDL) status.

	Therapeutic Classes	P & T Vote
18	<ul style="list-style-type: none"> • 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 	<p>Passed 6 For 0 Against</p>

	Therapeutic Classes	P & T Vote
	<ul style="list-style-type: none"> • 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) 	