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 **May 16, 2019** meeting of the Pharmacy and Therapeutics Advisory Committee.

<table>
<tr><th>Single Agent Reviews</th><th>Options for Consideration</th></tr>
<tr><td>New Product to Market:
Motegrity™</td><td>Non-prefer in the PDL class: GI Motility Agents
Length of Authorization: 1 year
• Motegrity (prucalopride) is a serotonin-4 (5-HT4) receptor agonist indicated for the treatment of chronic idiopathic constipation (CIC) in adults.
Criteria for Approval:
• Diagnosis of chronic idiopathic constipation (CIC); AND
• Trial and failure of, or contraindication to, at least 1 preferred agent in the class.
Age Limit: ≥ 18 years
Quantity Limit: 1 per day</td></tr>
<tr><td>New Product to Market:
Nuzyra™</td><td>Non-prefer in the PDL class: Antibiotics: Tetracyclines (Tetracyclines)
Length of Authorization: Date of service only
• Nuzyra™ (omadacycline) is a tetracycline class antibacterial indicated for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) or acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible microorganisms*.

<table>
<tr><th>*Susceptible organisms - CABP</th><th>*Susceptible organisms - ABSSSI</th></tr>
<tr><td>• Chlamydophila pneumoniae
• Haemophilus influenza
• Haemophilus parainfluenzae
• Klebsiella pneumoniae
• Legionella pneumophila
• Mycoplasma pneumoniae
• Staphylococcus aureus (methicillin-susceptible isolates; MSSA)
• Streptococcus pneumoniae</td><td>• Enterobacter cloacae
• Enterococcus faecalis
• Klebsiella pneumoniae
• Staphylococcus aureus (methicillin-susceptible and -resistant isolates; MSSA and MRSA)
• Staphylococcus lugdunensis
• Streptococcus anginosus group (includes S. anginosus, S. intermedius, and S. constellatus)
• Streptococcus pyogenes</td></tr>
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Criteria for Approval:
• Diagnosis of community-acquired bacterial pneumonia (CABP) OR acute bacterial skin and skin structure infection (ABSSSI) caused by susceptible microorganism(s); AND
• If of childbearing potential, patient is NOT pregnant; AND
• Infection is caused by an organism resistant to medications not requiring prior approval (must submit culture and sensitivity information); OR
• Patient is not a candidate or has failed treatment with ≥ 2 preferred antibiotics from 2 different classes; AND</td></tr>
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Single Agent Reviews	Options for Consideration
	• Patient has NOT failed a tetracycline unless susceptibility results demonstrate that pathogen is NOT susceptible to other tetracyclines but is susceptible to omadacycline; AND • If continuing an inpatient/hospital treatment course, prescriber attests that it would be clinically inappropriate to deescalate therapy or use alternative therapy based on susceptibility results or lack of susceptibility results in conjunction with clinical picture; AND • Total treatment duration will not exceed 14 days per course. **Renewal Criteria** • Not eligible for continued therapy beyond 14 days. **Age Limit**: ≥ 18 years **Quantity Limit**: 2 per day; override by call center for loading dose
New Product to Market: **Seysara™**	Non-prefer in the PDL class: *Antibiotics: Tetracyclines* **Length of Authorization:** 3 months • Seysara™ (sarecycline), a tetracycline, is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients ≥ 9 years of age. • Limitations of use: The efficacy and safety of sarecycline beyond 12 weeks and 12 months, respectively, have not been established. It has not been evaluated in the treatment of infections and should only be used as indicated to reduce the development of drug-resistant bacteria and maintain the efficacy of other antibacterial drugs. **Criteria for Approval**: • Diagnosis of non-nodular moderate to severe acne vulgaris; AND • If female, member is NOT pregnant; AND • Trial and failure of (or contraindication to) ≥ 2 preferred topical agents for acne vulgaris, including 2 differing mechanisms of action (e.g., benzoyl peroxide, antibiotic, retinoid); AND • Patient has a contraindication to ≥ 1 preferred oral tetracycline for acne vulgaris; AND • Will be used in combination with a topical agent (e.g., benzoyl peroxide or a topical retinoid); AND • Patient has not had a failure of another tetracycline agent used for acne vulgaris. **Renewal Criteria** • Prescriber attestation of improvement; AND • Duration of use has not exceeded 12 months. **Age Limit**: ≥ 9 years **Quantity Limit**: 1 per day

Criteria Review	Options for Consideration
Opioid Class Criteria – Urine Drug Screen Requirements	In the ordinary regulation setting the standards for prescribing controlled substances, 201 KAR 9:260, the Kentucky Board of Medical Licensure ("the Board") requires that during the course of long-term prescribing or dispensing of controlled substances for the treatment of pain and related symptoms associated with a primary medical complaint, the physician shall utilize urine drug screens in a random manner at appropriate times to determine whether the patient is taking prescribed medications or taking illegal substances or medications not prescribed by the physician. The Board has developed the following intervals for urine drug screens in order to provide some guidance to physicians on this subject:

Criteria Review	Options for Consideration
	1. At least once a year if the patient is considered "low risk" based on upon the screening done by the physician and other factors. 2. At least twice a year if the patient is considered "moderate risk" based upon the screening done by the physician and other factors. 3. At least three to four times a year if considered "high risk" based on the screening done by the physician and other factors. 4. At each office visit if the patient has exhibited aberrant behavior such as multiple lost prescriptions, multiple requests for early refills, opioids from multiple providers showing up on KASPER, unauthorized dose escalation, and apparent intoxication. It is important to note that the Board does not mandate or require urine drug screens prior to acute prescribing. Source: https://kbml.ky.gov/hb1/Pages/Considerations-For-Urine-Drug-Screening.aspx Current class criteria for opioids regarding urine drug screens (UDSs): 1. Require UDS results dated within the past 30 days for ALL new chronic opioid (e.g., beyond 45 days of treatment) requests. Note: UDS is not required for acute prescribing. 2. UDS results within the past 30 days required for ALL renewal requests for chronic use of an opioid. Recommended criteria changes: 1. Require UDS results dated within the past 30 days for ALL new chronic opioid (e.g., beyond 45 days of treatment) requests UNLESS the member is in a long-term care or skilled nursing facility. Note: UDS is not required for acute prescribing. 2. If the member is NOT in a long-term care or skilled nursing facility, require prescriber to document risk assessment and provide most recent UDS results dated within: a. 1 year if considered "low risk" b. 6 months if considered "moderate risk" c. 3 months if considered "high risk"

Full Class Reviews	Options for Consideration
Oncology, Oral – Hematologic **(Oral Oncology, Hematologic Cancer)**	**Oral Oncology, Hematologic Cancer** • DMS to select preferred agent(s) based on economic evaluation; however, agents with an FDA-approved indication or guideline recommendation for use in a first-line setting should be considered for preferred status with or without clinical criteria. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Oral Oncology, Hematologic Cancer* class, require PA until reviewed by the P&T Advisory Committee.
Oncology, Oral – Lung **(Oral Oncology, Lung Cancer)**	**Oral Oncology, Lung Cancer** • DMS to select preferred agent(s) based on economic evaluation; however, agents with an FDA-approved indication or guideline recommendation for use in a first-line setting should be considered for preferred status with or without clinical criteria. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Oral Oncology, Lung Cancer* class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
Oncology, Oral – Other **(Oral Oncology Agents, Other)**	**Oral Oncology Agents, Other** • DMS to select preferred agent(s) based on economic evaluation; however, agents with an FDA-approved indication or guideline recommendation for use in a first-line setting should be considered for preferred status with or without clinical criteria. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Oral Oncology, Other* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class:** **Vitrakvi®** Prefer with clinical criteria in this class. **Length of Authorization**: 1 year • Vitrakvi® (larotrectinib) is a tropomyosin receptor kinase (TRK) inhibitor (TRKA, TRKB, and TRKC) indicated for the treatment of adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine 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 no satisfactory alternative treatments or that have progressed following treatment. **Criteria for Approval:** • 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., next generation sequencing [NGS] or fluorescence in situ hybridization [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 of tumor response or lack of disease progression. **Quantity Limit** = 100 mg: 2 per day; 25 mg: 3 per day; oral solution: 10 mL/day
Oncology, Oral – Skin **(Oral Oncology, Skin Cancer)**	**Oral Oncology, Skin Cancer** • DMS to select preferred agent(s) based on economic evaluation; however, agents with an FDA-approved indication or guideline recommendation for use in a first-line setting should be considered for preferred status with or without clinical criteria. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Oral Oncology, Skin Cancer* class, require PA until reviewed by the P&T Advisory Committee.
Opiate Dependence Treatments	**Opiate Dependence Treatments** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 buprenorphine/naloxone product should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Opiate Dependence Treatments* class, require PA until reviewed by the P&T Committee.
Phosphate Binders	**Phosphate Binders** • 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 *Phosphate Binders* 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:	
Analgesics, Narcotics Long-Acting	Growth Hormone
Analgesics, Narcotics Short-Acting	NSAIDs
Androgenic Agents	Oncology, Oral – Breast
Antihyperuricemics	Oncology, Oral – Prostate
Antineoplastic Agents, Topical	Oncology, Oral – Renal Cell
Bone Resorption Suppression and Related	Pancreatic Enzymes
Colony Stimulating Factors	Progestins for Cachexia
Erythropoiesis Stimulating Agents	Thrombopoiesis Stimulating Agents
Glucocorticoids, Oral	