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 **March 19, 2020** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
New Product to Market: **Aklief®**	Non-prefer in the PDL class: *Topical Acne Agents (Acne Agents, Topical)* **Length of Authorization:** 1 year Aklief® (trifarotene) is a retinoid indicated for the topical treatment of acne vulgaris in patients 9 years of age and older. **Criteria for Approval**: • Diagnosis of acne vulgaris; AND • Trial and failure of, or contraindication to, all preferred agents. **Age Limit**: ≥ 9 years
New Product to Market: **Nayzilam®**	Non-prefer in the PDL class: *Anticonvulsants: First Generation (Anticonvulsants)* **Length of Authorization:** 1 year • Nayzilam® (midazolam) nasal spray, a benzodiazepine, is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (e.g., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients ≥ 12 years old with epilepsy. **Criteria for Approval**: • Prescribed by, or in consultation with, a neurologist or epilepsy specialist; AND • Diagnosis of intermittent, stereotypic episodes of frequent seizure activity; AND • Patient is on a stable antiepileptic drug regimen; AND • Prescriber attestation that patient or caregiver has been counseled on proper identification of a seizure cluster; AND • Prescriber attestation that patient or caregiver has been counseled on proper administration and when to seek emergency medical treatment. **Renewal Criteria:** • Prescriber attestation of efficacy (e.g., decreased length of seizure episodes). **Age Limit**: ≥ 12 years **Quantity Limit**: 5 boxes (10 nasal spray units)/30 days
New Product to Market: **Nourianz™**	Non-prefer in the PDL class: *Parkinson's Disease (Antiparkinson's Agents)* **Length of Authorization:** 1 year • Nourianz™ (istradefylline) is an adenosine A2A receptor antagonist approved as adjunctive treatment to levodopa/carbidopa (LD/CD) in adults with Parkinson's disease (PD) experiencing "off" episodes. **Criteria for Approval**: • Diagnosis of Parkinson's disease (PD); AND • Receiving PD therapy with carbidopa/levodopa; AND

Single Agent Reviews	Options for Consideration

	• Experiencing "off" episodes with carbidopa/levodopa; AND
	• Trial and failure of at least 2 adjunctive therapies, such as:
	  ○ Dopamine agonists (e.g., pramipexole, ropinirole);
	  ○ Monoamine oxidase-B inhibitors (e.g., selegiline)
	  ○ Catechol-O-methyltransferase inhibitors (e.g., entacapone); AND
	• NONE of the following contraindications:
	  ○ Severe hepatic impairment (Child-Pugh C); OR
	  ○ End-stage renal disease, including dialysis; OR
	  ○ Pregnant; OR
	  ○ Major psychiatric disorder.
	Renewal Criteria:
	• Patient has clinically meaningful response to treatment (e.g., patient shows a reductions in time of "off" episodes.)
	Age Limit: ≥ 18 years
	Quantity Limit: 1 per day

New Product to Market: **Reblozyl®**	Non-prefer in the PDL class: *Erythropoiesis Stimulating Proteins* **Length of Authorization:** 1 year • Reblozyl® (luspatercept-aamt) is indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions. **Criteria for Approval:** • Diagnosis of beta thalassemia requiring regular red blood cell (RBC) transfusions. **Renewal Criteria:** • Attestation of a reduction in transfusion burden or other clinical benefit. **Age Limit:** ≥ 18 years
New Product to Market: **Brukinsa™**	Non-prefer in the PDL class: *Oral Oncology, Hematologic (Oncology, Oral – Hematologic)* **Length of Authorization:** 1 year • Brukinsa™ (zanubrutinib) is a small molecule Bruton's tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. **Criteria for Approval:** • Diagnosis of mantle cell lymphoma; AND • Patient has received ≥ 1 prior therapy; AND • Patient has NOT received prior treatment with another BTK-inhibitor (e.g., ibrutinib, acalabrutinib); AND • Drug will be used as monotherapy. **Renewal Criteria:** • 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: **Wakix®**	Non-prefer in the PDL class: *Narcolepsy Agents (Stimulants and Related Agents)* **Length of Authorization:** 1 year • Wakix® (pitolisant) a histamine-3 (H3) receptor antagonist/inverse agonist, is indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy. **Criteria for Approval:** • Diagnosis of excessive daytime sleepiness associated with narcolepsy; AND • Prescriber is a neurologist, sleep medicine, or other specialist in the treatment of narcolepsy; AND • Trial and failure/intolerance of, contraindication to, a preferred agent (e.g., modafanil); trial can be waived if member has a history of substance abuse. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day

Full Class Reviews	Options for Consideration
Antibiotics, GI **(Antibiotics: GI)**	**Antibiotics: GI** • 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 *Antibiotics: GI* class, require PA until reviewed by the P&T Advisory Committee.
Antivirals, Oral **(Antivirals: Herpes; Antivirals: Influenza)**	**Antivirals: Herpes** • 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 *Antivirals: Herpes* class, require PA until reviewed by the P&T Advisory Committee. **Antivirals: Influenza** • 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 *Antivirals: Influenza* class, require PA until reviewed by the P&T Advisory Committee.
Cephalosporins and Related Antibiotics **(Antibiotics: Cephalosporins 1st Generation; Antibiotics: Cephalosporins 2nd Generation; Antibiotics: Cephalosporins 3rd Generation)**	**Antibiotics: Cephalosporins 1st Generation** • 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 *Antibiotics: Cephalosporins 1st Generation* class, require PA until reviewed by the P&T Advisory Committee. **Antibiotics: Cephalosporins 2nd Generation** • 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 *Antibiotics: Cephalosporins 2nd Generation* class, require PA until reviewed by the P&T Advisory Committee. **Antibiotics: Cephalosporins 3rd Generation** • 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 *Antibiotics: Cephalosporins 3rd Generation* class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
Glucocorticoids, Inhaled **(Beta Agonists: Combination Products; Inhaled Corticosteroids)**	**Beta Agonists: Combination Products** • 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 require PA. • For any new chemical entity in the *Beta Agonists: Combination Products* class, require PA until reviewed by the P&T Advisory Committee. **Inhaled Corticosteroids** • 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 *Inhaled Corticosteroids* class, require PA until reviewed by the P&T Advisory Committee.
Hepatitis C Agents **(Hepatitis C: Direct-Acting Antiviral Agents; Hepatitis C: Interferons; Hepatitis C: Ribavirins)**	**Hepatitis C: Direct-Acting Antiviral Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 first-line treatment regimen should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Hepatitis C: Direct-Acting Antiviral Agents* class, require PA until reviewed by the P&T Advisory Committee. **Class Criteria review:** *Current criteria:* • Prescriber restrictions (specialist or KHAMP training) apply for all requests. • HCV genotype testing is required for all cases. *Recommended criteria*: • No prescriber restrictions for PA requests that fall under simplified treatment (adult, treatment-naïve, and no cirrhosis) and the request is for 8 weeks of Mavyret (glecaprevir/pibrentasvir). • HCV genotype testing is no longer required for PA approval when Mavyret is requested. • A gastroenterologist, hepatologist, infectious disease, or transplant specialist must prescribe under any of the following patient circumstances: o Prior hepatitis C treatment o Cirrhosis o End-stage renal disease (i.e., eGFR <30 mL/min/m^2) o HIV or HBsAg positive o Current pregnancy o Known or suspected hepatocellular carcinoma o Prior liver transplantation **Hepatitis C: Interferons** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and require PA.

Full Class Reviews	Options for Consideration
	• For any new chemical entity in the *Hepatitis C: Interferons* class, require PA until reviewed by the P&T Advisory Committee. **Hepatitis C: Ribavirins** • DMS to select preferred agent(s) based on economic evaluation; however, at least generic ribavirin tablets should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Hepatitis C: Ribavirins* class, require PA until reviewed by the P&T Advisory Committee.

HIV/AIDS
 	
(Antiretrovirals: HIV/AIDS)
	Antiretrovirals: HIV/AIDS
	• DMS to select preferred agent(s) based on economic evaluation; however, all first-line treatment regimens should be preferred.
	• Agents not selected as preferred will be considered non-preferred and will require PA.
	• For any new chemical entity in the *Antiretrovirals: HIV/AIDS* class, require PA until reviewed by the P&T Advisory Committee.
	
	Clinical Criteria Review: Descovy (emtricitabine/tenofovir alafenamide)
	
	Current criteria: Prior authorization (PA) is not required.
	
	Recommended criteria:
	• Approve for 1 year when used for treatment of HIV-1 infection; OR
	• Approve for 3 months when used for pre-exposure prophylaxis (PrEP) and ALL of the following are true:
	  ○ Prescriber submits PA request; AND
	  ○ Member is NOT a recipient of vaginal sex (not FDA-approved in this population); AND
	  ○ Negative HIV-1 test immediately prior to initiating Descovy and at least every 3 months.

Hypoglycemics, Incretin Mimetics/ Enhancers **(Diabetes: Amylin Analogue; Diabetes: DPP-4 Inhibitors; Diabetes: GLP-1 Receptor Agonists)**	**Diabetes: Amylin Analogue** • 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 *Diabetes: Amylin Analogue* class, require PA until reviewed by the P&T Advisory Committee. **Diabetes: DPP-4 Inhibitors** • 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 *Diabetes: DPP-4 Inhibitors* class, require PA until reviewed by the P&T Advisory Committee. **Diabetes: GLP-1 Receptor Agonists**

Full Class Reviews	Options for Consideration
	• 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 *Diabetes: GLP-1 Receptor Agonists* class, require PA until reviewed by the P&T Advisory Committee. **Clinical Criteria Review:** Soliqua (insulin glargine/lixisenatide) and Xultophy (insulin degludec/liraglutide) *Current criteria:* Requires trial of the specific GLP-1 agonist in the requested formulation. For example, a patient must try and fail Adlyxin (lixisenatide) in order to access Soliqua. *Recommended criteria*: • Trial and failure (e.g., A1c not at goal) of any GLP-1 agonist alone or in combination with other agents; AND • Trial and failure of any basal (long-acting) insulin alone or in combination with other agents; AND • Not to be used in combination with another GLP-1 agonist (e.g., semaglutide).
Hypoglycemics, Insulin and Related Agents **(Diabetes: Injectable Insulins)**	**Diabetes: Injectable Insulins** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 insulin of each type (short, intermediate, long) should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Diabetes: Injectable Insulins* class, require PA until reviewed by the P&T Advisory Committee.
Pleuromutulins **(Antibiotics: Pleuromutulins)**	**Antibiotics: Pleuromutulins** • 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 *Antibiotics: Pleuromutulins* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class:** Xenleta (lefamulin) Non-prefer in this PDL class. **Length of Authorization:** Date of service only • Xenleta™ (lefamulin), a pleuromutilin antibacterial, is indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by susceptible microorganisms. **Criteria for Approval:** • Diagnosis of community-acquired bacterial pneumonia (CABP) thought to be caused by a susceptible organism*; AND • Patient is not a candidate or has failed treatment with ≥ 2 preferred first-line options for CABP; AND • If continuing an inpatient/hospital treatment course, prescriber attests that it would be clinically inappropriate to deescalate therapy or use alternative

Full Class Reviews	Options for Consideration
	therapy based on susceptibility results or lack of susceptibility results in conjunction with clinical picture; AND • Oral treatment duration will not exceed 5 days. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day and 10 tablets per fill *Susceptible organisms include: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae.*

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:	
• Absorbable Sulfonamides • Antibiotics, Inhaled • Antibiotics, Vaginal • Antifungals, Oral • Antihistamines, Minimally Sedating • Bronchodilators, Beta Agonist • COPD Agents • Epinephrine, Self-Injected • Fluoroquinolones, Oral • Hepatitis B Agents • Hypoglycemics, Alpha-Glucosidase Inhibitors	• Hypoglycemics, Meglitinides • Hypoglycemics, Metformins • Hypoglycemics, SGLT2 • Hypoglycemics, Sulfonylureas • Hypoglycemics, Thiazolidinediones (TZD) • Intranasal Rhinitis Agents • Leukotriene Modifiers • Macrolides • Oxazolidenediones • Penicillins • Tetracyclines