Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations

March 15, 2018

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **March 15, 2018** meeting.

Although the Committee met on March 15, 2018, 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	**New Product to Market: Trelegy Ellipta** Non-prefer in the PDL class: *COPD Agents* **Length of Authorization:** 1 year Trelegy Ellipta is a combination of fluticasone furoate (an inhaled corticosteroid), umeclidinium (an anticholinergic), and vilanterol (a long-acting beta$_2$-adrenergic agonist). It is indicated for the long-term, once-daily, maintenance treatment of chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema. It is not indicated for the relief of acute bronchospasm or the treatment of asthma. **Criteria for Approval:** • Diagnosis of chronic obstructive pulmonary disease (COPD); AND • Failure of at least a 2-week trial with 2 different dual combination products (e.g., inhaled corticosteroid plus long-acting beta-agonist, long-acting beta-agonist plus long-acting muscarinic antagonist). **Age Limit:** ≥ 18 years **Quantity Limit:** 1 inhalation per day (1 inhaler per 30 days)	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote
2	**New Product to Market: Verzenio™** Prefer with Clinical Criteria in the PDL class: *Oral Oncology Agents, Breast Cancer* **Length of Authorization:** 1 year Verzenio™ (abemaciclib) is a cyclin-dependent kinase 4 and 6 inhibitor. It is indicated, in combination with fulvestrant, for the treatment of women with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy; and as monotherapy for the treatment of adult patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting. **Criteria for Approval**: • Diagnosis of advanced or metastatic breast cancer that is: o Hormone receptor (HR)-positive; AND o Human epidermal growth factor receptor 2 (HER2)-negative; AND **Renewal Criteria:** • Documentation of lack of disease progression or decrease in tumor size. **Age Limit**: ≥ 18 years **Quantity Limit**: 2 tablets per day	**Passed** 6 For 0 Against
3	**New Product to Market: Calquence®** Non-prefer in the PDL class: *Oral Oncology Agents, Hematologic Cancer* **Length of Authorization:** 6 months Calquence® (acalabrutinib), an irreversible Bruton's tyrosine kinase inhibitor, is indicated for the treatment of adult patients with mantle cell lymphoma who have received at least 1 prior therapy. **Criteria for Approval**: • Diagnosis of advanced mantle cell lymphoma (MCL); AND • Using acalabrutinib as a single agent; AND • Trial and failure of at least 1 prior therapy for mantle cell lymphoma; AND • Naïve to treatment with a Bruton's tyrosine kinase (BTK) inhibitor (acalabrutinib or ibrutinib). Note: does not apply to renewal authorizations. **Renewal Criteria:** • Patient continues to meet initial review criteria; AND • Documentation of disease stabilization or decrease in size or spread of tumor(s). **Age Limit**: ≥ 18 years **Quantity Limit**: 2 capsules per day	**Passed** 6 For 0 Against
4	**New Product to Market: Vyzulta™** Non-prefer in the PDL class: *Ophthalmic Prostaglandin Agonists* **Length of Authorization:** 1 year Vyzulta™ (latanoprostene bunod) is a prostaglandin analogue approved for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension. **Criteria for Approval**: • Diagnosis of open-angle glaucoma or ocular hypertension; AND	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote
	• At least 1-month trial of at least 1 preferred prostaglandin analog (e.g., latanoprost). **Age Limit**: ≥ 17 years **Quantity Limit**: 1 bottle per 30 days	
5	**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 will require PA. • For any new chemical entity in the *Antibiotics: GI* class, require PA until reviewed by the P&T Committee.	**Passed** 6 For 0 Against
6	**Antibiotics: Vaginal** • 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: Vaginal* class, require PA until reviewed by the P&T Committee.	**Passed** 6 For 0 Against
7	**Antifungals: Oral** • 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 *Antifungals: Oral* class, require PA until reviewed by the P&T Committee.	**Passed** 6 For 0 Against
8	**COPD Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 nebulizer product and 1 other 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 *COPD Agents* class, require PA until reviewed by the P&T Committee.	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote
9	**Antibiotics: Quinolones** • 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: Quinolones* class, require PA until reviewed by the P&T Committee. **New agent in the class: Baxdela™** Non-prefer in this class. **Length of Authorization:** Date of Service (up to 14 days) Baxdela™ (delafloxacin) a fluoroquinolone antibacterial indicated in adults for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible bacteria. **Criteria for Approval**: • Failure of at least a 3-day trial to 1 preferred medication; OR • Infection is caused by an organism resistant to medications not requiring prior approval (must submit culture and sensitivity information); OR • Patient is completing a course of therapy which was initiated in the hospital. **Age Limit**: ≥ 18 years **Quantity Limit**: 2 tablets per day	**Passed** 6 For 0 Against

10	**GI Motility 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 *GI Motility Agents* class, require PA until reviewed by the P&T Committee.
	
	New agent in the class: Symproic®
	Non-prefer in this class.
	Length of Authorization: 1 year
	Symproic® (naldemedine tosylate), an opioid antagonist, is indicated for the treatment of opioid-induced constipation in adults with chronic non-cancer pain.
	Criteria for Approval:
	• Diagnosis of opioid-induced constipation related to chronic non-cancer pain; AND
	• Patient has been using opioids for at least 150 days within past 180 days; AND
	• Trial and failure of at least 1 preferred GI Motility agent; AND
	• Patient does NOT have any the following conditions:
	  ○ Known or suspected gastrointestinal obstruction
	  ○ Pregnancy
		Passed
		6 For
		0 Against

	Description of Recommendation	P & T Vote
	○ Severe hepatic impairment (Child-Pugh Class C) **Age Limit**: ≥18 years **Quantity Limit**: 1 tablet per day	
11	**Hypoglycemics, Incretin Mimetics/Enhancers** **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 Committee **Diabetes: DPP-4 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 *Diabetes: DPP-4 Inhibitors* class, require PA until reviewed by the P&T Committee. **Diabetes: GLP-1 Receptor 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 *Diabetes: GLP-1 Receptor Agonists* class, require PA until reviewed by the P&T Committee. **New agent in the class: Ozempic®** Non-prefer in this class. **Length of Authorization**: 1 year Ozempic® (semaglutide) is a glucagon-like peptide 1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. **Criteria for Approval:** • Diagnosis of type 2 diabetes mellitus; AND • Trial and failure of, or contraindication to, metformin; AND • Trial (≥ 3 months) and failure of a preferred GLP-1 receptor agonist. **Age Limit**: ≥18 years **Quantity Limits**: 1 package per 28 days - 0.25 or 0.5 mg pens: 1 pen per 28 days - 1 mg pens: 2 pens per 28 days	**Passed** 6 For 0 Against
12	**Diabetes: SGLT2 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	**Passed** 5 For 0 Against 1 Abstain

	Description of Recommendation	P & T Vote
	require PA. • For any new chemical entity in the *Diabetes: SGLT2 Inhibitors* class, require PA until reviewed by the P&T Committee.	

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
13	• Absorbable Sulfonamides • Antibiotics, Inhaled • Antipsoriatics, Topical • Cephalosporins and Related Antibiotics • Hypoglycemics, Alpha-Glucosidase Inhibitors • Hypoglycemics, Insulins & Related • Hypoglycemics, Meglitinides • Hypoglycemics, Metformins • Hypoglycemics, Sulfonylureas • Hypoglycemics, Thiazolidinediones (TZDs) • Oxazolidinones • Penicillins	**Passed** 6 For 0 Against

Consent Agenda: Brand/Generic Switches Only

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

	Therapeutic Classes	P & T Vote
14	• Ketolides/Macrolides	**Passed** 6 For 0 Against

Consent Agenda: Formulation Movements Only

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

	Therapeutic Classes	P & T Vote
15	• Tetracyclines	**Passed** 6 For 0 Against