# 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 15, 2018** meeting of the Pharmacy and Therapeutics Advisory Committee.

| Single Agent Reviews | Options for Consideration |
|---|---|
| New Product to Market:<br>**Trelegy Ellipta** | Non-prefer in the PDL class: *COPD Agents (Glucocorticoids, Inhaled)*<br>**Length of Authorization:** 1 year<br>• 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. Trelegy Ellipta is available as 100 mcg/62.5 mcg/25 mcg powder for inhalation in the Ellipta device, which delivers 30 inhalations in 60 blisters.<br>**Criteria for Approval**:<br>• Diagnosis of chronic obstructive pulmonary disease (COPD); AND<br>• 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).<br>**Age Limit**: ≥ 18 years<br>**Quantity Limit**: 1 inhalation per day (1 inhaler per 30 days) |

| Single Agent Reviews | Options for Consideration |
|---|---|
| New Product to Market: **Verzenio™** | Non-prefer in the PDL class: *Oral Oncology Agents, Breast Cancer (Oncology, Oral – Breast Cancer)*<br>**Length of Authorization:** 1 year<br>• 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. Verzenio™ is available as 50, 100, 150, and 200 mg oral tablets.<br>**Criteria for Approval**:<br>• Diagnosis of advanced or metastatic breast cancer that is:<br>  ○ Hormone receptor (HR)-positive; AND<br>  ○ Human epidermal growth factor receptor 2 (HER2)-negative; AND<br>• Using with fulvestrant to treat progression following endocrine therapy; OR<br>• If metastatic, using as monotherapy to treat progression following endocrine therapy and chemotherapy.<br>**Renewal Criteria:**<br>• Patient continues to meet initial review criteria; AND<br>• Documentation of lack of disease progression or decrease in tumor size.<br>**Age Limit**: ≥ 18 years<br>**Quantity Limit**: 2 tablets per day |
| New Product to Market: **Calquence®** | Non-prefer in the PDL class: *Oral Oncology Agents, Hematologic Cancer (Oncology, Oral – Hematologic)*<br>**Length of Authorization:** 6 months<br>• 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. It is available as 100 mg oral capsules.<br>• This indication was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.<br>**Criteria for Approval**:<br>• Diagnosis of advanced mantle cell lymphoma (MCL); AND<br>• Using acalabrutinib as a single agent; AND<br>• Trial and failure of at least 1 prior therapy for mantle cell lymphoma; AND<br>• Naïve to treatment with a Bruton's tyrosine kinase (BTK) inhibitor (acalabrutinib or ibrutinib). Note: does not apply to renewal authorizations.<br>**Renewal Criteria:**<br>• Patient continues to meet initial review criteria; AND<br>• Documentation of disease stabilization or decrease in size or spread of tumor(s).<br>**Age Limit**: ≥ 18 years<br>**Quantity Limit**: 2 capsules per day |

| Single Agent Reviews | Options for Consideration |
|---|---|
| New Product to Market: **Vyzulta™** | Non-prefer in the PDL class: *Ophthalmic Prostaglandin Agonists (Ophthalmics, Glaucoma Agents)*<br>**Length of Authorization:** 1 year<br>• Vyzulta™ (latanoprostene bunod) is a prostaglandin analogue approved for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension. It is available in 5 mL bottles of 0.024% solution for ophthalmic administration.<br>**Criteria for Approval**:<br>• Diagnosis of open-angle glaucoma or ocular hypertension; AND<br>• At least 1-month trial of at least 1 preferred prostaglandin analog (e.g., latanoprost).<br>**Age Limit**: ≥ 17 years<br>**Quantity Limit**: 1 bottle per 30 days |

*Note: The following new agents will be reviewed along with their respective classes.*

- Baxdela™ – Fluoroquinolones, Oral
- Symproic® – GI Motility, Chronic
- Ozempic® – Hypoglycemics, Incretin Mimetics/Enhancers

| Full Class Reviews | Options for Consideration |
|---|---|
| **Antibiotics, GI**<br><br>**(Antibiotics: GI)** | **Antibiotics: GI**<br>• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.<br>• Agents not selected as preferred will be considered non-preferred and will require PA.<br>• For any new chemical entity in the *Antibiotics: GI* class, require PA until reviewed by the P&T Committee. |
| **Antibiotics, Vaginal**<br><br>**(Antibiotics: Vaginal)** | **Antibiotics: Vaginal**<br>• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.<br>• Agents not selected as preferred will be considered non-preferred and will require PA.<br>• For any new chemical entity in the *Antibiotics: Vaginal* class, require PA until reviewed by the P&T Committee. |
| **Antifungals, Oral**<br><br>**(Antifungals: Oral)** | **Antifungals: Oral**<br>• DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities should be preferred.<br>• Agents not selected as preferred will be considered non-preferred and will require PA.<br>• For any new chemical entity in the *Antfungals: Oral* class, require PA until reviewed by the P&T Committee. |
| **COPD Agents** | **COPD Agents**<br>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 nebulizer product and 1 other product should be preferred.<br>• Agents not selected as preferred will be considered non-preferred and will require PA.<br>• For any new chemical entity in the *COPD Agents* class, require PA until reviewed by the P&T Committee. |

| Full Class Reviews | Options for Consideration |
|---|---|
| **Fluoroquinolones, Oral**<br><br>**(Antibiotics: Quinolones)** | **Antibiotics: Quinolones**<br>• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred<br>• Agents not selected as preferred will be considered non-preferred and will require PA.<br>• For any new chemical entity in the *Antibiotics: Quinolones* class, require PA until reviewed by the P&T Committee.<br><br>**New agent in the class: Baxdela™**<br>Non-prefer in this class.<br>**Length of Authorization:** Date of Service (up to 14 days)<br>• Baxdela™ (delafloxacin) a fluoroquinolone antibacterial indicated in adults for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible bacteria. It is available as an IV infusion in 300 mg single-dose vials as well as 450 mg oral tablets.<br>**Criteria for Approval**:<br>• Failure of at least a 3-day trial to 1 preferred medication; OR<br>• Infection is caused by an organism resistant to medications not requiring prior approval (must submit culture and sensitivity information); OR<br>• Patient is completing a course of therapy which was initiated in the hospital.<br>**Age Limit**: ≥ 18 years<br>**Quantity Limit**: 2 tablets per day |
| **GI Motility, Chronic**<br><br>**(GI Motility Agents)** | **GI Motility Agents**<br>• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.<br>• Agents not selected as preferred will be considered non-preferred and will require PA.<br>• For any new chemical entity in the *GI Motility Agents* class, require PA until reviewed by the P&T Committee.<br><br>**New agent in the class: Symproic®**<br>Non-prefer in this class.<br>**Length of Authorization**: 1 year<br>• Symproic® (naldemedine tosylate), an opioid antagonist, is indicated for the treatment of opioid-induced constipation in adults with chronic non-cancer pain. It is available as 0.2 mg oral tablets.<br>**Criteria for Approval:**<br>• Diagnosis of opioid-induced constipation related to chronic non-cancer pain; AND<br>• Patient has been using opioids for at least 150 days within past 180 days; AND<br>• Trial and failure of at least 1 preferred GI Motility agent; AND<br>• Patient does NOT have any the following conditions:<br>  ○ Known or suspected gastrointestinal obstruction<br>  ○ Pregnancy<br>  ○ Severe hepatic impairment (Child-Pugh Class C)<br>**Age Limit**: ≥18 years<br>**Quantity Limit**: 1 tablet per day |

| Full Class Reviews | Options for Consideration |
|---|---|
| **Hypoglycemics, Incretin Mimetics/Enhancers**<br><br>**(Diabetes: Amylin Analogue, Diabetes: DPP-4 Inhibitors; Diabetes: GLP-1 Receptor Agonists)** | **Diabetes: Amylin Analogue**<br>• DMS to select preferred agent(s) based on economic evaluation.<br>• Agents not selected as preferred will be considered non-preferred and will require PA.<br>• For any new chemical entity in the *Diabetes: Amylin Analogue* class, require PA until reviewed by the P&T Committee<br><br>**Diabetes: DPP-4 Inhibitors**<br>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.<br>• Agents not selected as preferred will be considered non-preferred and will require PA.<br>• For any new chemical entity in the *Diabetes: DPP-4 Inhibitors* class, require PA until reviewed by the P&T Committee.<br><br>**Diabetes: GLP-1 Receptor Agonists**<br>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.<br>• Agents not selected as preferred will be considered non-preferred and will require PA.<br>• For any new chemical entity in the *Diabetes: GLP-1 Receptor Agonists* class, require PA until reviewed by the P&T Committee.<br><br>**New agent in the class: Ozempic®**<br>Non-prefer in this class.<br>**Length of Authorization**: 1 year<br>• 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. It is available in prefilled pen syringes containing 2 mg/1.5 mL solution for subcutaneous injection. One version of the pen delivers doses of 0.25 mg or 0.5 mg per injection and the other version delivers doses of 1 mg per injection.<br>**Criteria for Approval:**<br>• Diagnosis of type 2 diabetes mellitus; AND<br>• Trial and failure of, or contraindication to, metformin; AND<br>• Trial (≥ 3 months) and failure of a preferred GLP-1 receptor agonist.<br>**Age Limit**: ≥18 years<br>**Quantity Limits**: 1 package per 28 days<br>- 0.25 or 0.5 mg pens: 1 pen per 28 days<br>- 1 mg pens: 2 pens/28 days |
| **Hypoglycemics, SGLT2 Inhibitors**<br><br>**(Diabetes: SGLT2 Inhibitors)** | **Diabetes: SGLT2 Inhibitors**<br>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entities should be preferred.<br>• Agents not selected as preferred will be considered non-preferred and will require PA.<br>• For any new chemical entity in the *Diabetes: SGLT2 Inhibitors* class, require PA until reviewed by the P&T Committee. |

| Consent Agenda | Options for Consideration |
|---|---|
| A. 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 | Hypoglycemics, Meglitinides |
| Antibiotics, Inhaled | Hypoglycemics, Metformins |
| Antipsoriatics, Topical | Hypoglycemics, Sulfonylureas |
| Cephalosporins and Related Antibiotics | Hypoglycemics, Thiazolidinediones (TZDs) |
| Hypoglycemics, Alpha-Glucosidase Inhibitors | Oxazolidinones |
| Hypoglycemics, Insulins & Related | Penicillins |
| B. The following therapeutic classes have **recommended brand/generic switches** and may be voted on as a group: | |
| Ketolides/Macrolides | |
| C. The following therapeutic classes have **recommended specific formulation movements** and may be voted on as a group under a consent agenda: | |
| Tetracyclines | |