Kentucky Department for Medicaid Services
Drug Review and Options for Consideration

The following table lists the Agenda items scheduled, as well as the Options for Consideration, to be presented and reviewed at the **March 16, 2017** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
New Products to Market: **DermacinRx® Therazole Pak™**	Non-prefer in the PDL class: *Topical Antifungal Agents (Antifungals, Topical)* **Length of Authorization:** 1 month DermacinRx® Therazole Pak™ (clotrimazole/betamethasone dipropionate packaged with zinc oxide) is a cream formulation of an azole-antifungal and a corticosteroid indicated for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris, and tinea corporis due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, and *Trichophyton rubrum* in those ≥ 17 years of age. Available as a cream of 10 mg clotrimazole and 0.64 mg of betamethasone dipropionate. **Criteria for Approval**: • Trial and failure of two different preferred agents; OR • Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include: – Adverse reaction to preferred drugs – Allergy to preferred drugs – Contraindication to preferred drugs **Age Limit** = ≥ 17 years **Quantity Limit** = 180 grams per month (45 grams per week is the maximum usage per the package insert)

Single Agent Reviews	Options for Consideration
New Products to Market: **Vemlidy®**	Non-prefer in PDL class: *Anti-infectives: Hepatitis B (Hepatitis B Agents)* **Length of Authorization:** 6 months initial; 1 year renewal • Vemlidy® (tenofovir alafenamide fumarate [TAF]) is a nucleoside analog reverse transcriptase inhibitor indicated for the treatment of chronic hepatitis B virus infection in adults with compensated liver disease. Available as a 25 mg tablet. **Criteria for Approval**: • Diagnosis of Hepatitis B virus infection; AND • Child-Pugh score is not B or C (decompensated cirrhosis); AND • Not concurrently using any P-gp inducers (oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, or St. John's wort); AND • Not concurrently taking tenofovir disoproxil (Viread); AND • Not HIV-1 positive using TAF as monotherapy. **Age Limit =** ≥ 18 years **Quantity Limit** = 30 tablets per 30 days OR, if the patient is on carbamazepine, then 60 tablets per 30 days. *Note: Prior Authorization review and appropriate dosage to be determined by the Contact Center.
New Products to Market: **Rubraca™**	Non-prefer in the PDL class: *Oral Oncology, Other (Oncology Oral, Other)* **Length of Authorization**: 6 months; may be renewed • Rubraca™ (rucaparib) is a poly ADP-ribose polymerase (PARP) inhibitor indicated for use as single-agent therapy for treatment of adult females with advanced ovarian cancer that is associated with deleterious BRCA mutations in which patients have failed 2 or more other chemotherapies. Available as 200 mg and 300 mg tablets. **Criteria for Approval**: • Must have advanced disease; AND • Have a deleterious BRCA mutation as detected by an FDA-approved test (e.g., FoundationFocus CDxBRCA); AND • Must be used as a single agent; AND • Must have received treatment with at least 2 prior lines of chemotherapy. **Age Limit** = ≥ 18 years **Quantity Limit** = 60 tablets per 30 days (1,200 mg per day is max dose)

Single Agent Reviews	Options for Consideration
New Products to Market: **BromSite™**	Non-prefer in the PDL class: *Ophthalmic NSAIDs (Ophthalmics, Anti-inflammatories)* **Length of Authorization:** 3 weeks • BromSite™ (bromfenac 0.075%) is a nonsteroidal anti-inflammatory (NSAID) indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery. Available as a 0.075% ophthalmic solution. **Criteria for Approval**: • Cataract surgery; AND • Trial and failure of 1 preferred ophthalmic NSAID; OR • Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include: – Adverse reaction to preferred drugs; – Allergy to preferred drugs; AND – Contraindication to preferred drugs. **Age Limit =** ≥ 18 years
New Products to Market: **Yosprala™**	Non-prefer in the PDL class: *Platelet Aggregation Inhibitors* **Length of Authorization:** 1 year • Yosprala™ (aspirin/omeprazole) is a combination of aspirin (an anti-platelet) and omeprazole (a Proton Pump Inhibitor [PPI]) indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events who are at risk of developing aspirin-associated gastric ulcers. It is not interchangeable with the individual components of aspirin and omeprazole. Available as 325 mg delayed-release aspirin/40 mg immediate-release omeprazole or as 81 mg delayed-release aspirin/40 mg immediate-release omeprazole. **Criteria for Approval**: • Has the patient had a therapeutic trial and treatment failure of at least 1 preferred drug? Document the details; OR • Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include: – Adverse reaction to preferred drugs; – Allergy to preferred drugs; AND – Contraindication to preferred drugs. **Limitations of Use**: Not for use as initial dose of aspirin therapy during onset of acute coronary syndrome, acute myocardial infarction, or before percutaneous coronary intervention. It has not been shown to reduce the risk of gastrointestinal bleeding due to aspirin. **Quantity Limit:** 1 tablet per day

Full Class Reviews	Options for Consideration
	Agents in the following Therapeutic Classes are subject to status changes from what is on the current Preferred Drug List (PDL).
Anticoagulants	• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 low molecular weight heparin, 1 factor Xa inhibitor, and 2 oral anticoagulants should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Anticoagulants* class, require PA until reviewed by the P&T Advisory Committee.
Antifungals, Oral	• DMS to select preferred agent(s) based on economic evaluation; however, at least fluconazole, griseofulvin, nystatin, and terbinafine should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Antifungals, Oral* class, require PA until reviewed by the P&T Advisory Committee.
Cephalosporins & Related (Antibiotics: Cephalosporins 1st, 2nd, 3rd Generation)	**1st Generation**: • DMS to select preferred agent(s) based on economic evaluation; however, at least cephalexin should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *1st Generation Cephalosporin* class, require PA until reviewed by the P&T Advisory Committee. **2nd Generation**: • DMS to select preferred agent(s) based on economic evaluation; however, at least cefuroxime should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *2nd Generation Cephalosporin* class, require PA until reviewed by the P&T Advisory Committee. **3rd Generation**: • DMS to select preferred agent(s) based on economic evaluation; however, at least cefixime and cefpodoxime should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *3rd Generation Cephalosporin* class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
GI Motility, Chronic (GI Motility Agents)	• 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 *GI Motility, Chronic* class, require PA until reviewed by the P&T Committee.
Hypoglycemics, Incretin Mimetics & Enhancers (Diabetes: Amylin Analogs, DPP-4 Inhibitors, GLP-1 Receptor Agonists)	**Amylin Analogs**: • DMS to select preferred agent(s) based on economic evaluation. • Allow for use of pramlintide with active insulin therapy only. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Hypoglycemics, Amylin Analogues* class, require PA until reviewed by the P&T Advisory Committee. **DPP-4 Inhibitors**: • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 single entity agent should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Hypoglycemics, DPP4-Inhibitors* class, require PA until reviewed by the P&T Advisory Committee. **GLP-1 Receptor Agonists**: New addition to the class: **Adlyxin™** Non-prefer in this class. **Length of Authorization:** 1 year • Adlyxin™ (lixisenatide) is a glucagon-like peptide-1 (GLP-1) receptor agonist administered subcutaneously once daily within 1 hour of the first meal of the day, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Available as 50 mcg/ mL and 100 mcg/ mL solution in a 3 mL prefilled pen. **Criteria for Approval**: • Diagnosis of type 2 diabetes mellitus; AND • Trial and failure of metformin, document; AND • Trial and failure of a preferred GLP-1 receptor agonist. **Age Limit** = ≥ 18 years **Quantity Limit** = 2 pens per 28 days New addition to the class: **Soliqua™** Non-prefer in this class. **Length of Authorization:** 1 year • Soliqua™ (insulin glargine/lixisenatide) is a fixed-dose combination of insulin glargine (Lantus®) and the GLP-1 agonist, lixisenatide (Adlyxin™)

Full Class Reviews	Options for Consideration
	administered subcutaneously once daily within 1 hour of the first meal of the day, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not controlled with basal insulin (< 60 units) or lixisenatide. Available as 100 unit insulin glargine/ 33 mcg lixisenatide per mL solution in a 3 mL prefilled multi-dose pen. **Criteria for Approval**: • Diagnosis of type 2 diabetes mellitus; AND • Trial and failure of lixisenatide or basal insulin separately; AND • Trial and failure of preferred GLP-1 receptor agonists and preferred long-acting insulin; AND • Not used in combination with other GLP-1 agonists. **Age Limit** = ≥ 18 years **Quantity Limit** = 5 pens (1 carton) per 25 days New addition to the class: **Xultophy®** Non-prefer in this class. **Length of Authorization:** 1 year • Xultophy® (insulin degludec/liraglutide) is a fixed-dose combination of insulin degludec (Tresiba®) and the GLP-1 agonist, liraglutide (Victoza®) administered subcutaneously once daily at the same time of day, with or without food, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not controlled on basal insulin (< 50 units daily) or liraglutide (≤ to 1.8 mg daily). **Criteria for Approval**: • Diagnosis of type 2 diabetes mellitus; AND • Trial and failure of liraglutide or basal insulin; AND • Trial and failure of preferred GLP-1 receptor agonists and insulin; AND • Not used in combination with other GLP-1 agonists. **Age Limit** = ≥ 18 years **Quantity Limit** = 5 pens (1 carton) per 30 days • DMS to select preferred agent(s) based on economic evaluation; however, at least one unique chemical entity should be preferred. • Continue to require PA for all agents in this class to ensure appropriate utilization. • For any new chemical entity in the *Hypoglycemics, GLP-1 Receptor Agonists* class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
Hypoglycemics, Insulins & Related **(Diabetes: Injectable Insulins)**	• DMS to select preferred agent(s) based upon economic evaluation; however, at least 1 insulin per class should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Hypoglycemics, Insulins and Related* class, require PA until reviewed by the P&T Advisory Committee.
Hypoglycemics, SGLT2s **(Diabetes: SGLT2 Inhibitors)**	New addition to the class: **Invokamet® XR** Non-prefer in this class. **Length of Authorization**: 6 months initial; 1 year renewal • Invokamet® XR (canagliflozin/metformin) is a sodium-glucose co-transporter 2 (SGLT2) inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both canagliflozin and metformin is appropriate. Available as 50 mg/ 500 mg, 50 mg/ 1000 mg, 150 mg/ 500 mg, and 150 mg/ 1000 mg extended-release tablets. **Criteria for Approval**: • Diagnosis of type 2 diabetes mellitus; AND • Documented reason Invokamet® cannot be used (Invokamet® is preferred without PA). **Quantity Limit** = 2 extended-release tablets per day. • 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 *Hypoglycemics, SGLT2 Inhibitors* class, require PA until reviewed by the P&T Advisory Committee.
Hypoglycemics, Sulfonylureas **(Diabetes: Sulfonylureas)**	• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique second generation sulfonylureas should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Hypoglycemics, Sulfonylureas* class, require PA until reviewed by the P&T Advisory Committee.
Tetracyclines **(Antibiotics: Tetracyclines)**	• DMS to select preferred agent(s) based on economic evaluation; however, at least generic formulations of doxycycline and minocycline should be preferred. • If demeclocycline is selected as non-preferred, allow for its use in SIADH only. • 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 *Tetracyclines* class, require PA until reviewed by the P&T Advisory Committee.
Orkambi® Criteria Review	Current Criteria: **Length of Authorization**: 6 months; may be renewed **Criteria for Approval**: • Diagnosis of cystic fibrosis homozygous for the F508del mutation in the CFTR gene confirmed by an FDA-approved CF mutation test; AND • Baseline ophthalmic examinations if patient is 12 – 18 years of age. **Renewal Criteria**; • Stable or improved FEV_1; AND • Serum ALT or AST ≤ 5 times the ULN, or ALT or AST, ≤ 3 times the ULN with bilirubin ≤ 2 times the ULN. **Age Limit** = ≥ 12 years **Recommended Changes:** **Age Limit** = ≥ 6 years **Quantity Limit** = 112 tablets per 28 days. • Patient age 6 – 11 years = 2 tablets orally every 12 hours with fat-containing food. Use the lumacaftor 100 mg/ivacaftor 125 mg tablet strength. • Patient age ≥ 12 years = 2 tablets orally every 12 hours with fat-containing food. Use the lumacaftor 200 mg/ ivacaftor 125 mg tablet strength. **Renewal Criteria**: • Patient has not received a lung transplant; AND • No unacceptable toxicity from the drug; AND • Disease response as indicated by 1 or more of the following; – Decreased pulmonary exacerbations as compared to pretreatment baseline – Improvement or stabilization of lung function compared to baseline – Decrease in decline of lung function – Improvement in quality of life, weight gain, or growth

Consent Agenda	Options for Consideration	
	For the following therapeutic classes, there are **no recommended changes to the currently posted Preferred Drug List (PDL) status**.	
	• Antibiotics, GI • Antibiotics, Inhaled • Antibiotics, Vaginal • Antipsoriatics, Topical • COPD Agents • Fluoroquinolones, Oral • Hypoglycemics, Alpha-Glucosidase Inhibitors	• Hypoglycemics, Meglitinides • Hypoglycemics, Metformins • Hypoglycemics, Thiazolidinediones • Ketolides/Macrolides • Oxazolidinones • Penicillins • Sulfonamides, Folate Antagonists
	For the following therapeutic classes, there are **no recommended changes other than a brand/generic switch.**	
	N/A	