** Fee-For-Service Pharmacy Provider Notice #223 – March 2017 PDL Changes **

December 14, 2017

Please be advised that the Department for Medicaid Services (DMS) is making changes to the Kentucky Medicaid Fee-For-Service (FFS) Pharmacy Preferred Drug List (PDL) based on recommendations and guidance as adopted by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services by order dated March 16, 2017.

The Kentucky Medicaid FFS Pharmacy and Therapeutics Advisory Committee (Committee) met on March 16, 2017. The Committee did attain the necessary quorum; the expertise, vote, and recommendations of the Committee members in attendance were captured within the Committee's official recommendations delivered for review. DMS, through its Commissioner, reviewed the recommendations and in consultation rendered its final decisions.

On January 15, 2018, the following changes will be effective:

Existing Drug Classes

Drug Class	The following products will remain *preferred* products:	The following products will become *preferred* products:	The following products will become *non-preferred* products and require prior authorization (PA):	The following products will remain *non-preferred* products and require prior authorization (PA):
Anticoagulants	Eliquis® enoxaparin Jantoven® Pradaxa® warfarin Xarelto®		*fondaparinux* *Fragmin®* *Note: grandfathering is allowed for patients established on therapy before the change	*Arixtra™* *Coumadin®* *Innohep®* *Lovenox®* *Savaysa™*
Antifungals, Oral	clotrimazole fluconazole flucytosine griseofulvin suspension griseofulvin ultramicrosize Noxafil® nystatin suspension, tablet terbinafine	griseofulvin microsize	*nystatin powder* *voriconazole*	*Ancobon®* *Cresemba®* *Diflucan®* *Gris-PEG®* *itraconazole* CC *ketoconazole* *Lamisil®* *Mycelex Troche®* *Nizoral®* *Onmel™* *Oravig™* *Sporanox®* *Terbinex™* *Vfend®*

Drug Class	The following products will remain *preferred* products:	The following products will become *preferred* products:	The following products will become *non-preferred* products and require prior authorization (PA):	The following products will remain *non-preferred* products and require prior authorization (PA):
Cephalosporins; 1st, 2nd, 3rd Generation	**1st:** cefadroxil capsule cephalexin **2nd:** cefuroxime axetil **3rd:** cefdinir cefpodoxime tablet Suprax® suspension		*cefpodoxime suspension*	***1st:*** *cefadroxil tablet, suspension* *Duricef®* *Keflex®* ***2nd:*** *Ceclor®* *Ceclor CD®* *cefaclor* *cefaclor CD* *cefprozil* *Ceftin®* *Cefzil®* ***3rd:*** *Cedax®* *cefditoren pivoxil* *cefixime suspension* *ceftibuten* *Omnicef®* *Spectracef®* *Suprax® capsules, chewable tablets, tablets* *Vantin®*
GI Motility Agents	Amitiza® CC Linzess® CC	Movantik®		*alosetron CC* *Lotronex® CC* *Relistor® oral QL* *Viberzi® QL*
Amylin Analogs	N/A			*Symlin® ST*
DPP-4 Inhibitors	Janumet™ ST, QL Janumet XR™ ST, QL Januvia™ ST, QL Jentadueto™ ST, QL Tradjenta™ ST, QL			*Glyxambi® QL* *Kazano® QL* *Kombiglyze™ XR QL* *Nesina® QL* *Onglyza™ QL* *Oseni® QL*
GLP-1 Receptor Agonists	Byetta™ ST Bydureon® ST		*Adlyxin™ QL* *Soliqua™ QL* *Xultophy® QL*	*Tanzeum™* *Trulicity™* *Victoza®*

Drug Class	The following products will remain *preferred* products:	The following products will become *preferred* products:	The following products will become *non-preferred* products and require prior authorization (PA):	The following products will remain *non-preferred* products and require prior authorization (PA):
Injectable Insulins	Humalog® Vial Humalog® Mix Vial Humulin® N Vial Humulin® R Vial Humulin® R 500 Vial Humulin® 70/30 Vial Lantus® Vial Lantus® Solostar Pen Levemir® Vial/Pen Novolog® Vial/Pen/Cartridge Novolog® Mix Vial/Pen		*Humalog® Mix Pen*	*Afrezza®* *Apidra™ Vial/Pen* *Humalog® KwikPen* *Humalog® Pen/Cartridge* *Humulin® Pen* *Humulin® 70/30 Pen* *Novolin® Vial* *Novolin® 70/30 Vial* *Toujeo®* *Tresiba®*
SGLT2 Inhibitors	Invokana® ST Invokamet™ ST		*Invokamet® XR QL*	*Farxiga™* *Jardiance®* *Synjardy®* *Xigduo™ XR*
Sulfonylureas	glimepiride glipizide glipizide extended-release glyburide glyburide micronized		*chlorpropamide* *tolazamide* *tolbutamide*	*Amaryl®* *Diabeta®* *Glucotrol®* *Glucotrol XL®* *Glynase PresTab®* *Micronase®*
Tetracyclines	demeclocycline doxycycline hyclate doxycycline monohydrate 50 mg, 75 mg capsules, tablets, suspension minocycline capsules	Doxycycline monohydrate 100 mg capsules	*tetracycline*	*Adoxa®* *Adoxa® Pak* *Alodox® Convenience Pak* *Avidoxy®* *Doryx®* *Doxy®* *doxycycline hyclate DR capsules* *doxycycline hyclate DR tablets* *doxycycline IR-DR* *Doxycycline monohydrate capsules BRAND prod* *doxycycline monohydrate 150 mg capsules, pack* *Dynacin®* *Minocin®* *minocycline tablets* *minocycline ER* *Monodox®* *Mondoxyne NL®* *Morgidox®* *Ocudox®* *Oracea™* *Oraxyl®* *Solodyn®* *Vibramycin®*

Orkambi Criteria Change

Although not on the PDL, Orkambi criteria was reviewed and the following changes made:

- Age ≥ 6 years
- Quantity Limit = 112 tablets per 28 days
    - 6 – 11 years: 100 mg / 125 mg tablets
    - ≥ 12 years: 200 mg / 125 mg tablets

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

The therapeutic classes in the table below were reviewed; no changes were made to the currently posted status for agents in these classes.

- 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

New Products to Market

Drugs Requiring PA	Criteria
DermacinRx® Therazole Pak™	Non-prefer in the PDL class: *Topical Antifungal Agents* **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)
Vemlidy®	Non-prefer in PDL class: *Anti-infectives: Hepatitis B* **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.

Drugs Requiring PA	Criteria
Rubraca™	Non-prefer in the PDL class: *Oral Oncology, 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)
BromSite™	Non-prefer in the PDL class: *Ophthalmic NSAIDs* **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 – Contraindication to preferred drugs **Age Limit =** ≥ 18 years

Drugs Requiring PA	Criteria
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 – 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
Adlyxin™	Non-prefer in PDL class: *GLP-1 Receptor Agonists* **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; AND • Trial and failure of a preferred GLP-1 receptor agonist. **Age Limit** = ≥ 18 years **Quantity Limit** = 2 pens per 28 days

Drugs Requiring PA	Criteria
Soliqua™	Non-prefer in PDL class: *GLP-1 Receptor Agonists* **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™) 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
Xultophy®	Non-prefer in PDL class: *GLP-1 Receptor Agonists* **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

To review the complete summary of the final PDL selections and new products to market updates and changes, please refer to the "Commissioner's Final Decisions from March 16, 2017" posted on the provider web portal at: https://kyportal.magellanhealth.com (by clicking the Resources/Documents/Committees/P&T tabs).

Thank you for helping Kentucky Medicaid members maintain access to prescription coverage by selecting drugs on the preferred drug list whenever possible. Please contact Magellan Medicaid Administration at kyproviders@magellanhealth.com for any additional information or questions you may have.

Sincerely,

Noah L Greenberg

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Kentucky Medicaid Fee-for-Service Pharmacy Program's Contact Information		
Clinical Support Center	1-800-477-3071 Sunday – Saturday 24 hours a day	Please contact the Clinical Support Center to request a prior authorization (PA) or to check the status of a request. **NOTE: The only drugs that are now required to be submitted via fax are Brand Medically Necessary, Buprenorphine products, Synagis®, and Zyvox®.**
Pharmacy Support Center	1-800-432-7005 Sunday – Saturday 24 hours a day	Please contact the Pharmacy Support Center when claims assistance is required. Timely filing, lock-in, and early refill (ER) overrides can be obtained through this Call Center.
Provider Services	1-877-838-5085 Monday – Friday 8:00 a.m. – 4:30 p.m.	Please contact Provider Services if you have questions about enrollment or when updating your license or bank information.
Member Services	1-800-635-2570 Monday – Friday 8:00 a.m. – 5:00 p.m.	Please contact Member Services if you are a member or if you as the provider have questions regarding the member's benefits or eligibility coverage dates.