Fee-for-Service Pharmacy Provider Notice #216
**** March 2016 PDL Changes ****

December 19, 2016

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 May 9, 2016.

The Kentucky Medicaid FFS Pharmacy & Therapeutics Advisory Committee (Committee) met on March 17, 2016. 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 26, 2016, 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):
Antipsoriatics, Topical	calcipotriene salicylic acid 6% gel, shampoo urea cream		Enstilar® MD	Aluvea® Bensal HP® BP® 50% calcipotriene/betamethasone Calcitrene™ calcitriol ointment Carb-O-Philic® Cem-Urea® Dovonex® Keralyt® Latrix® Realo® Remeven® Salacyn® cream, lotion salicylic acid 3%, 6% cream, lotion salicylic acid 26% liquid salicylic acid 27.5% combo pkg, kit, liquid, lotion salicylic acid 28.5% Salex® combo pkg, kit, shampoo Sorilux™ Taclonex® ointment, suspension Taclonex® Scalp

AE – Age Edit; CC – Clinical Criteria; MD – Medications with Maximum Duration; QL – Quantity Limit; ST – Step Therapy

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):
				Tazorac® Umecta® emulsion, foam, kit, suspension Umecta PD® emulsion, suspension Uramaxin® Uramaxin® GT Urea emulsion, foam, gel, kit, lotion, nail film suspension, suspension Urevaz® Vectical™ X-Viate®
COPD Agents	albuterol-ipratropium inhalation solution QL Atrovent® HFA QL Combivent® Respimat® QL ipratropium inhalation solution QL Spiriva Handihaler® QL		Seebri™ Neohaler® QL Utibron™ Neohaler® QL	Anoro™ Ellipta™ CC, QL Daliresp™ QL Incruse™ Ellipta® QL Spiriva® Respimat® QL Stiolto™ Respimat® QL Tudorza™ Pressair™ QL
GI Motility, Chronic	Amitiza® CC Linzess® CC		Viberzi® QL	alosetron CC Lotronex® CC Movantik®
Hypoglycemics, Alpha-glucosidase inhibitors	acarbose Glyset®			Precose®

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Hypoglycemics, Incretin Mimetics & Enhancers: Amylin Analogues	N/A			Symlin® ST
Hypoglycemics, Incretin Mimetics & Enhancers: DPP-4	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
Hypoglycemics, Incretin Mimetics & Enhancers: GLP-1	Byetta™ ST	Bydureon® ST		Tanzeum™ Trulicity™ Victoza®
Hypoglycemics, Insulins & Related	Humalog® Vial Humalog® Mix Vial/Pen Humulin® N Vial Humulin® R Vial Humulin® 70/30 Vial Lantus® Vial Levemir® Vial/Pen Novolog® Vial/Pen/Cartridge Novolog® Mix Vial/Pen	Humulin® R 500 Vial Lantus® Solostar Pen	Tresiba®	Afrezza® Apidra™ Vial/Pen Humalog® KwikPen Humalog® Pen/Cartridge Humulin® Pen Humulin® 70/30 Pen Novolin® Vial Novolin® 70/30 Vial Toujeo®
Hypoglycemics, Meglitinides	repaglinide Starlix®			nateglinide PrandiMet™ Prandin®
Hypoglycemics, Metformins	glyburide/metformin metformin metformin XR			Fortamet™ glipizide/metformin Glucophage® Glucophage XR® Glumetza™ Metaglip™ metformin ER (Generic Fortamet™) Riomet™
Hypoglycemics, SGLTs	Invokana® ST	Invokamet™ ST		Farxiga™ Jardiance® Synjardy® Xigduo™ XR
Hypoglycemics, Sulfonylureas	chlorpropamide glimepiride glipizide glipizide extended-release glyburide			Amaryl® Diabeta® Glucotrol® Glucotrol XL® Glynase PresTab®

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	glyburide micronized tolazamide tolbutamide			Micronase®
Hypoglycemics, TZDs	pioglitazone QL			Actos® QL ACTOplus Met® QL ActoPlus Met® XR QL Avandamet® QL Avandia® QL Avandaryl® QL DuetAct™ QL pioglitazone/glimepiride QL pioglitazone/metformin QL

New Products to Market

The following product (s) will become **non preferred** and require prior authorization (PA):

Drugs Requiring PA:	Criteria:
Belbuca™	**Belbuca™** will be approved if ALL of the following criteria are met: • Indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. • 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; or – Contraindication to preferred drugs. • Patient has inability to take oral medication; **OR** • Patient has a documented clinical trial with a combination of three preferred LONG acting opiate analgesics agents. • Patient is 18 years or older. Quantity Limit = 2 buccal films per day.
Vivlodex™	**Vivlodex™** will be approved if ALL of the following criteria are met: • Indicated for management of osteoarthritis (OA) pain. • Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; or – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure of no less than 30 days with TWO preferred drugs in the class? Document the details.

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	• Meloxicam tablet is covered without PA; clinical reason as to why meloxicam tablet cannot be used. Quantity Limit = 1 capsule per day.
Ninlaro™	**Ninlaro™** will be approved if ALL of the following criteria are met: • Indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.
Uptravi®	**Uptravi®** will be approved if ALL of the following criteria are met: • Indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. • Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; or – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure with ONE preferred drug in the class in the last 6 months? Document the details. Quantity Limit = 2 tablets per day for Uptravi 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,000 mcg, 1,200 mcg, 1,400 mcg, and 1,600 mcg tablets.
Enstilar®	**Enstilar®** will be approved if ALL of the following criteria are met: • Indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older. • Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; or – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure with ONE preferred drug in the class? Document the details. • Patient is 18 years or older.
Seebri™ Neohaler®	**Seebri™ Neohaler®** will be approved if ALL of the following criteria are met: • Indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). • Ensure diagnosis is for COPD (not indicated for use in asthma) • Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; or – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure with **ONE** preferred drug in the same class? If so, document the details and approve. • Seebri Neohaler is not indicated for use in children. The safety and efficacy

	of Seebri Neohaler in pediatric patients have not been established. Quantity Limit = 2 inhalations per day (1 inhaler per month)
Utibron™ Neohaler®	**Utibron™ Neohaler®** will be approved if ALL of the following criteria are met: • Indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). • Ensure diagnosis is COPD (not indicated for use in asthma) • 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; or – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure with ONE preferred drug in the same class? If so, document the details and approve. • Utibron Neohaler is not indicated for use in children. The safety and efficacy of Utibron Neohaler in pediatric patients have not been established. Limitations of Use: Not indicated for the relief of acute bronchospasm or for the treatment of asthma. Quantity Limit = 2 inhalations per day (1 inhaler per month)
Viberzi®	**Viberzi®** will be approved if ALL of the following criteria are met: • Indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D). • Must have tried and failed at least 2 antidiarrheal agents Quantity Limit = 2 tablets per day
Tresiba®	**Tresiba®** will be approved if ALL of the following criteria are met: • Indicated to improve glycemic control in adults with diabetes mellitus. • Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; or – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure with ONE preferred drug in the same class? Document the details. • Insulin Pens – Physical reasons such as dexterity problems/vision impairment; – Must be self-administered; and – NOT just for convenience. Limitations of Use: Not recommended for treating diabetic ketoacidosis.

Prior Authorization Criteria

The clinical criteria for the following drugs and drug classes were reviewed and finalized by the Department pursuant to the November P&T meeting agenda:

- COPD Agents
- Hypoglycemics

To review the complete summary of the final preferred drug list (PDL) selections and new products to market updates and changes, please refer to the "Commissioner's Final Decisions from March 17, 2016" 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,

Harris Taylor, CPhT

Harris Taylor, CPhT
Provider Relations Manager
kyproviders@magellanhealth.com

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 am – 4:30 pm	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 am – 5:00 pm	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.