Fee-for-Service Pharmacy Provider Notice #215
**** January 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 April 18, 2016.

The Kentucky Medicaid FFS Pharmacy & Therapeutics Advisory Committee (Committee) met on January 21, 2016. The Committee did not attain the necessary quorum; however, the expertise, vote, and recommendations of the Committee members in attendance were captured within the Committee's unofficial recommendations delivered for review. DMS, through its Commissioner, reviewed the recommendations and in consultation rendered its final decisions.

On January 19, 2017 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):
Cephalosporins 1st Generation	cefadroxil capsule cephalexin			cefadroxil tablet, suspension Duricef® Keflex®
Cephalosporins, 2nd Generation	cefuroxime axetil			Ceclor® Ceclor CD® cefaclor cefaclor CD cefprozil Ceftin® Cefzil®
Cephalosporins, 3rd Generation	cefdinir cefpodoxime Suprax® suspension			Cedax® cefditoren pivoxil cefixime suspension ceftibuten Omnicef® Spectracef® Suprax® capsules, chewable tablets, tablets Vantin®
Antibiotics, GI	Alinia® tablets			Alinia® suspension

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):
	metronidazole tablets paromomycin vancomycin Xifaxan® CC, QL			Dificid® Flagyl® Flagyl® ER metronidazole capsules neomycin Tindamax® tinidazole Vancocin®
Ketolides	Ketek® CC, QL, MD			
Macrolides	azithromycin clarithromycin	erythromycin base capsule DR E.E.S. 200mg/5ml suspension	erythromycin base tablets	Biaxin® Biaxin XL® clarithromycin ER E.E.S. 400 tab EryPed Ery-tab PCE® Zithromax® Zmax®
Oxazolidinones	linezolid CC, QL tablet		linezolid QL suspension	Sivextro™ QL Zyvox® QL
Penicillins	amoxicillin amoxicillin/clavulanate tablets, suspension ampicillin dicloxacillin penicillin V			amoxicillin ER amoxicillin/clavulanate chewable tablets amoxicillin/clavulanate ER Augmentin® Augmentin XR® Moxatag™
Fluoroquinolones	ciprofloxacin tablets levofloxacin tablets			Avelox® ciprofloxacin ER ciprofloxacin suspension Cipro® Cipro XR® Factive® Levaquin® levofloxacin solution moxifloxacin Noroxin® ofloxacin

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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):
Tetracyclines	demeclocycline doxycycline hyclate doxycycline monohydrate 50 mg, 75 mg, 100 mg capsules, tablets, suspension minocycline capsules tetracycline			Adoxa® Adoxa® Pak Alodox® Convenience Pak Avidoxy® Doryx® Doxy® doxycycline hyclate DR tablets doxycycline IR-DR doxycycline monohydrate 150 mg capsules, pack Dynacin® Minocin® minocycline tablets minocycline ER Monodox® Monodoxyne NL® Morgidox® Ocudox® Oracea™ Oraxyl® Solodyn® Vibramycin®
Antibiotics, Vaginal	Cleocin® Ovules metronidazole vaginal 0.75% gel			Cleoncin® cream clindamycin vaginal 2% cream Clindesse® MetroGel Vaginal® Nuvessa® Vandazole®
Antifungals, Oral	clotrimazole fluconazole flucytosine griseofulvin suspension griseofulvin ultramicrosize Noxafil® nystatin terbinafine voriconazole			Ancobon® Cresemba® Diflucan® griseofulvin microsize Gris-PEG® itraconazole CC ketoconazole Lamisil® Mycelex Troche® Nizoral® Onmel™ Oravig™ Sporanox® Terbinex™ Vfend®
Sulfonamides, Folate Antagonists	trimethoprim/sulfamethoxazole tablet trimethoprim	Sulfatrim®	trimethoprim/sulfamethoxazole susp	Bactrim® Bactrim DS® Primsol® Septra DS® Sulfadiazine

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New Products to Market

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

Drugs Requiring PA:	Criteria:
Orkambi®	**Orkambi®** will be approved if ALL of the following criteria are met: ▪ Age ≥ 12 years; **AND** ▪ Diagnosis of cystic fibrosis homozygous for the F508del mutation in the CFTR gene confirmed by an FDA-cleared CF mutation test; **AND** ▪ Baseline ophthalmic examinations if patient is 12 to 18 years of age. ▪ For continuation of therapy if ALL of the following criteria are met: ▪ Stable or improved FEV_1; **AND** – Serum ALT or AST ≤5 x upper limit of normal (ULN), or ALT or AST ≤3 x ULN with bilirubin ≤2 x ULN.
Durlaza ER®	**Durlaza ER®** will be approved if ALL of the following criteria are met: ▪ Indicated to reduce the risk of death and myocardial infarction (MI) in patients with chronic coronary artery disease, such as patients with a history of MI or unstable angina pectoris or with chronic stable angina and to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack. ▪ 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 ▪ Has the patient had a therapeutic trial and treatment failure with **ONE** preferred drug? Document the details. ▪ Aspirin is covered without PA; clinical reason as to why aspirin cannot be used. Quantity Limit = 1 tablet per day
Odomzo®	**Odomzo®** will be approved if ALL of the following criteria are met: ▪ Indicated for use in basal cell carcinoma (BCC) that has recurred after surgery or radiation therapy or in those with basal cell carcinoma who are not candidates for surgery or radiation therapy. ▪ Verify patient is **NOT** pregnant. Use is contraindicated in pregnancy. ▪ Obtain serum creatine kinase level and perform renal function tests prior to initiation of therapy for all patients. ▪ Minimum age restriction of 18 years of age Maximum Quantity Limit = 1 per day
Lonsurf®	**Lonsurf®** will be approved if ALL of the following criteria are met: Approve Lonsurf® if the patient has metastatic colorectal cancer and has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and anti-VEGF biological therapy, and if RAS wild-type, then with an anti-EGFR therapy.

	Safety and efficacy of Lonsurf® have not been established in pediatric patients.
Aristada ER™	**Aristada ER™** will be non-preferred in the *Antipsychotics* class with the following PA criteria: Non-preferred Injectable Antipsychotics will be approved after a 2-week trial of ONE preferred Antipsychotic (oral or parenteral) at an appropriate dose. **For a non-approvable diagnosis, an injectable antipsychotic may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.
Varubi™	**Varubi™** will be approved if ALL of the following criteria are met: ▪ Indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. ▪ Varubi™ does NOT require treatment failure with preferred drugs when used for moderately or highly emetogenic chemotherapy. Approval may be granted if either of the bullet points below apply: ▪ May be approved for use in patients receiving highly or moderately emetogenic chemotherapy in addition to dexamethasone and a 5-HT3 antagonist. ▪ This includes patients on the following: AC combination (Doxorubicin or Epirubicin w/Cyclophosphamide), Aldesleukin, Amifostine, Arsenic trioxide, Azacitidine, Bendamustine, Busulfan, Carmustine, Carboplatin, Cisplatin, Clofarabine, Cyclophosphamide, Cytarabine, Dacarbazine, Dactinomycin, Daunorubicin, Doxorubicin, Epirubicin, Etoposide, Hexamethylmelamine, Idarubicin, Ifosfamide, Imatinib, Interferon alfa, Irinotecan, Mechlorethamine, Melphalan, Methotrexate, Oxaliplatin, Procarbazine, Streptozotocin, Temozolomide. ▪ May be approved for other uses restricted to patients receiving other chemotherapy who have failed maximum doses of ondansetron combined with dexamethasone. Safety and efficacy of Varubi™ have not been established in pediatric patients.
Prestalia®	**Prestalia®** will be approved if ALL of the following criteria are met: ▪ Indicated for the treatment of hypertension to lower blood pressure: ▪ In patients not adequately controlled with monotherapy. ▪ As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. ▪ Is there any reason that the patient cannot be switched to a preferred medication? Document the details and approve. Acceptable reasons include: ▪ Adverse reaction to preferred drugs ▪ Allergy to preferred drugs ▪ Contraindication to preferred drugs ▪ Has the patient had a therapeutic trial and treatment failure of single ingredient perindopril and amlodipine due to non-compliance within the last 12 months? Document the details and approve.

	▪ Do not administer Prestalia® to a pregnant female because it may cause fetal harm. ▪ When pregnancy is detected, patient must discontinue Prestalia® as soon as possible. ▪ The concomitant use of Prestalia® with aliskiren is contraindicated in patients with diabetes. ▪ Safety and effectiveness of Prestalia® in pediatric patients have not been established. Maximum Quantity Limit = 1 per day

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:

- Xifaxan®
- Ketek®
- Oxazolidnones
- Itraconazole

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 January 21, 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.