

**** Fee-For-Service Pharmacy Provider Notice #226 – March 2018 PDL Changes ****

June 05, 2018

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 25, 2018.

The Kentucky Medicaid FFS Pharmacy and Therapeutics Advisory Committee (Committee) met on March 15, 2018. The Committee did not 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 July 9, 2018, the following changes will be effective:

Existing Drug Classes

Drug Class	The following products will remain <i>preferred</i> products:	The following products will become <i>preferred</i> products:	The following products will become <i>non-preferred</i> products and require prior authorization (PA):	The following products will remain <i>non-preferred</i> products and require prior authorization (PA):
Antibiotics: GI	metronidazole tablets vancomycin Xifaxan [®] CC, QL		<i>Alinia[®] tablets</i> <i>paromomycin</i>	<i>Alinia[®] suspension</i> <i>Difucid[®]</i> <i>Flagyl[®]</i> <i>metronidazole capsules</i> <i>neomycin</i> <i>Tindamax[®]</i> <i>tinidazole</i> <i>Vancocin[®]</i>
Antibiotics: Vaginal	Cleocin [®] Ovules	Clindesse [®] Vandazole [®]	<i>metronidazole vaginal</i> <i>0.75% gel</i>	<i>Cleocin[®] cream</i> <i>clindamycin vaginal 2% cream</i> <i>MetroGel Vaginal[®]</i> <i>Nuversa[®]</i>
Antifungals: Oral	clotrimazole fluconazole griseofulvin suspension nystatin suspension, tablets terbinafine		<i>flucytosine</i> <i>griseofulvin microsize</i> <i>griseofulvin</i> <i>ultramicrosize</i> <i>Noxafil[®]</i>	<i>Ancobon[®]</i> <i>Cresemba[®]</i> <i>Diflucan[®]</i> <i>Gris-PEG[®]</i> <i>itraconazole^{CC}</i> <i>ketconazole</i> <i>Lamisil[®]</i> <i>nystatin powder</i> <i>Onmel[™]</i> <i>Oravig[™]</i> <i>Sporanox[®]</i> <i>Vfend[®]</i> <i>voriconazole</i>

Drug Class	The following products will remain <i>preferred</i> products:	The following products will become <i>preferred</i> products:	The following products will become <i>non-preferred</i> products and require prior authorization (PA):	The following products will remain <i>non-preferred</i> products and require prior authorization (PA):
COPD Agents	albuterol-ipratropium inhalation solution ^{QL} Atrovent [®] HFA ^{QL} Combivent [®] Respimat [®] ^{QL} ipratropium inhalation solution ^{QL} Spiriva Handihaler [®] ^{QL}	Bevespi Aerosphere [™] ^{QL} Stiolto [™] Respimat [®] ^{QL}	<i>Trelegy Ellipta</i> ^{CC, QL}	Anoro [®] Ellipta [®] ^{QL} Daliresp [™] ^{CC, QL} Incruse [™] Ellipta [®] ^{QL} Seebri [™] Neohaler [®] ^{CC, QL} Spiriva [®] Respimat [®] ^{QL} Tudorza [™] Pressair [™] ^{QL} Utibron [™] Neohaler [®] ^{CC}
GI Motility Agents	Amitiza [®] ^{CC, QL} Linzess [®] ^{CC, QL} Movantik [®] ^{CC, QL}		<i>Symproic</i> [®] ^{CC, QL}	alosetron ^{CC, QL} Lotronex [®] ^{CC, QL} Relistor [®] Trulance [™] ^{CC, QL} Viberzi [®] ^{CC, QL}
Hypoglycemics, Incretin Mimetics/Enhancers:				
Diabetes: Amylin Analogue	N/A			Symlin [®] ST
Diabetes: DPP-4 Inhibitors	Janumet [™] ^{ST, QL} Janumet XR [™] ^{ST, QL} Januvia [™] ^{ST, QL} Jentadueto [™] ^{ST, QL} Tradjenta [™] ^{ST, QL}	Glyxambi [®] ^{CC, QL}		alogliptin ^{QL} alogliptin/metformin ^{QL} alogliptin/pioglitazone ^{QL} Kazano [®] ^{QL} Kombiglyze [™] ^{XR} ^{QL} Nesina [®] ^{QL} Onglyza [™] ^{QL} Oseni [®] ^{QL} Qtern [®] ^{QL}
Diabetes: GLP-1 Receptor Agonists	Byetta [™] ^{ST, QL} Bydureon [®] pen, vial ^{ST, QL}	Victoza [®] ^{ST, QL}	Bydureon [®] BCise [™] Ozempic [®] ^{CC, QL}	Adlyxin [™] ^{CC, QL} Soliqua [™] ^{CC, QL} Trulicity [™] Xultophy [®] ^{CC, QL}
Diabetes: SGLT2 Inhibitors	Invokana [®] ^{ST, QL}	Jardiance [®] ^{ST, QL} Synjardy [®] ^{ST, QL}	Invokamet [™] ^{QL}	Farxiga [™] ^{QL} Invokamet [®] ^{XR} ^{QL} Synjardy [®] ^{XR} ^{QL} Xigduo [™] ^{XR} ^{QL}

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Brand/Generic Switch: Antibiotics: Macrolides	azithromycin clarithromycin erythromycin base capsules DR	E.E.S. 200 suspension	<i>erythromycin ethylsuccinate 200mg susp.</i>	<i>clarithromycin ER E.E.S 400 tablets EryPed Ery-tab erythromycin base tablets PCE® Zithromax® Zmax®</i>
Formulation Movement: Antibiotics: Tetracyclines	demeclocycline doxycycline hyclate doxycycline monohydrate 50 mg, 100 mg capsules doxycycline monohydrate tablets, suspension minocycline capsules		<i>doxycycline monohydrate 75 mg capsules</i>	<i>Adoxa® Doryx® doxycycline hyclate DR capsules doxycycline hyclate DR tablets doxycycline IR-DR doxycycline monohydrate 150 mg capsules, pack Minocin® minocycline tablets minocycline ER Morgidox® Oracea™ Solodyn® tetracycline Vibramycin® Ximino™</i>

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.

- Absorbable Sulfonamides
- Antibiotics, Inhaled
- Antipsoriatics, Topical
- Cephalosporins and Related Antibiotics
- Hypoglycemics, Alpha-Glucosidase Inhibitors
- Hypoglycemics, Insulins & Related
- Hypoglycemics, Meglitinides
- Hypoglycemics, Metformins
- Hypoglycemics, Sulfonylureas
- Hypoglycemics, Thiazolidinediones (TZDs)
- Oxazolidinones
- Penicillins

New Products to Market

Drugs Requiring PA	Criteria
Trelegy Ellipta	<p>Non-prefer in the PDL class: <i>COPD Agents</i></p> <p>Length of Authorization: 1 year</p> <p>Trelegy Ellipta is a combination of fluticasone furoate (an inhaled corticosteroid), umeclidinium (an anticholinergic), and vilanterol (a long-acting beta₂-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.</p> <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • Diagnosis of chronic obstructive pulmonary disease (COPD); AND • 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). <p>Age Limit: ≥ 18 years</p> <p>Quantity Limit: 1 inhalation per day (1 inhaler per 30 days)</p>
Verzenio™	<p>Preferred with Clinical Criteria in the PDL class: <i>Oral Oncology Agents, Breast Cancer</i></p> <p>Length of Authorization: 1 year</p> <p>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.</p> <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • Diagnosis of advanced or metastatic breast cancer that is: <ul style="list-style-type: none"> ○ Hormone receptor (HR)-positive; AND ○ Human epidermal growth factor receptor 2 (HER2)-negative; AND • Using with fulvestrant to treat progression following endocrine therapy; OR • If metastatic, using as monotherapy to treat progression following endocrine therapy and chemotherapy. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> • Documentation of lack of disease progression or decrease in tumor size. <p>Age Limit: ≥ 18 years</p> <p>Quantity Limit: 2 tablets per day</p>

Drugs Requiring PA	Criteria
<p>Calquence®</p>	<p>Non-prefer in the PDL class: <i>Oral Oncology Agents, Hematologic Cancer</i></p> <p>Length of Authorization: 6 months</p> <p>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.</p> <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • Diagnosis of advanced mantle cell lymphoma (MCL); AND • Using acalabrutinib as a single agent; AND • Trial and failure of at least 1 prior therapy for mantle cell lymphoma; AND • Naïve to treatment with a Bruton's tyrosine kinase (BTK) inhibitor (acalabrutinib or ibrutinib). Note: does not apply to renewal authorizations. <p>Renewal Criteria:</p> <ul style="list-style-type: none"> • Patient continues to meet initial review criteria; AND • Documentation of disease stabilization or decrease in size or spread of tumor(s). <p>Age Limit: ≥ 18 years</p> <p>Quantity Limit: 2 capsules per day</p>
<p>Vyzulta™</p>	<p>Non-prefer in the PDL class: <i>Ophthalmic Prostaglandin Agonists</i></p> <p>Length of Authorization: 1 year</p> <p>Vyzulta™ (latanoprostene bunod) is a prostaglandin analogue approved for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.</p> <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • Diagnosis of open-angle glaucoma or ocular hypertension; AND • At least 1-month trial of at least 1 preferred prostaglandin analog (e.g., latanoprost). <p>Age Limit: ≥ 17 years</p> <p>Quantity Limit: 1 bottle per 30 days</p>



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 15, 2018” 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,

Jade Range, CPhT

Jade Range, CPhT

Contracts 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 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.