** Fee-For-Service Pharmacy Provider Notice #236 – May 2019 PDL Changes **

July 19, 2019

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 June 4, 2019.

The Kentucky Medicaid FFS Pharmacy and Therapeutics Advisory Committee (Committee) met on May 16, 2019. The Committee necessary quorum was attained and the expertise, vote, and recommendations of the Committee were captured within the Committee's official recommendations. DMS, through its Commissioner, reviewed the recommendations and in consultation rendered its final decisions.

On August 19, 2019, 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):
Oral Oncology, Hematologic Cancer	Alkeran® Daurismo™ *CC, QL* Gleevec® QL hydroxyurea Imbruvica® *CC, QL* Jakafi® *CC, QL* Leukeran® mercaptopurine Revlimid® Rydapt® *CC, QL* Sprycel® QL Tibsovo® *CC, QL* Thalomid® Zolinza® QL Zydelig® *CC, QL*	Tasigna® *CC, QL*	*Purixan®*	*Bosulif® QL* *Calquence® CC, QL* *Copiktra™ CC, QL* *Farydak® QL* *Hydrea®* *Iclusig® QL* *Idhifa® CC, QL* *imatinib QL* *melphalan* *Ninlaro®* *Pomalyst®* *Venclexta™ QL* *Xospata® CC, QL*
Oral Oncology, Lung Cancer	Hycamtin® Iressa® QL Tarceva® QL Vizimpro® *CC, QL* Xalkori® *CC, QL*	Alecensa® *CC, QL* Tagrisso™ *CC, QL*		*Alunbrig™ CC, QL* *Gilotrif™ CC, QL* *Lorbrena® CC, QL* *Zykadia™ QL*
Oral Oncology, Other	Cometriq™ QL temozolomide	Vitrakvi® CC, QL Lynparza™ *CC, QL*		*Caprelsa® QL* *Lonsurf® CC* *Rubraca™ CC, QL* *Stivarga® CC, QL* *Temodar®* *Zejula™ CC, QL*

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):
Oral Onocology, Skin Cancer	Braftovi™ *CC, QL* Erivedge™ *CC, QL* Mekinist™ *CC, QL* Mektovi® *CC, QL* Odomzo® *CC, QL* Tafinlar® *CC, QL*	Cotellic™ *CC, QL* Zelboraf™ CC, QL		
Opiate Dependence Treatments	naltrexone Suboxone® film *AE, QL* Vivitrol®	buprenorphine/ naloxone SL tablets *AE, QL*		*Bunavail® CC, QL* *buprenorphine CC, QL* *buprenorphine/naloxone SL films CC, QL* *Lucemyra™ CC, QL* *Probuphine® CC, QL* *Sublocade™ CC, QL* *Zubsolv® CC, QL*
Phosphate Binders	calcium acetate MagneBind® 400 RX Phoslyra™ Renagel® Renvela™ tablets		*Fosrenol® chewable tablets*	*Auryxia™* *Eliphos™* *Fosrenol® powder packets* *lanthanum carbonate* *PhosLo®* *sevelamer carbonate* *sevelamer hydrochloride* *Renvela™ powder packets* *Velphoro®*

Criteria Review

Opioid Class Criteria- Urine Drug Screen Requirements

In the ordinary regulation setting the standards for prescribing controlled substances, 201 KAR 9:260, the Kentucky Board of Medical Licensure ("the Board") requires that during the course of long-term prescribing or dispensing of controlled substances for the treatment of pain and related symptoms associated with a primary medical complaint, the physician shall utilize urine drug screens in a random manner at appropriate times to determine whether the patient is taking prescribed medications or taking illegal substances or medications not prescribed by the physician.

The Board has developed the following intervals for urine drug screens in order to provide some guidance to physicians on this subject:

1. At least once a year if the patient is considered "low risk" based on upon the screening done by the physician and other factors.
2. At least twice a year if the patient is considered "moderate risk" based upon the screening done by the physician and other factors.
3. At least three to four times a year if considered "high risk" based on the screening done by the physician and other factors.

4. At each office visit if the patient has exhibited aberrant behavior such as multiple lost prescriptions, multiple requests for early refills, opioids from multiple providers showing up on KASPER, unauthorized dose escalation, and apparent intoxication.

It is important to note that the Board does not mandate or require urine drug screens prior to acute prescribing.

Source: https://kbml.ky.gov/hb1/Pages/Considerations-For-Urine-Drug-Screening.aspx

Current class criteria for opioids regarding urine drug screens (UDSs):

1. Require UDS results dated within the past 30 days for ALL new chronic opioid (e.g., beyond 45 days of treatment) requests. Note: UDS is not required for acute prescribing.
2. UDS results within the past 30 days required for ALL renewal requests for chronic use of an opioid.

New criteria for opioids regarding urine drug screens (UDSs):

1. Require UDS results dated within the past 30 days for ALL new chronic opioid (e.g., beyond 45 days of treatment) requests UNLESS the member is in a long-term care or skilled nursing facility. Note: UDS is not required for acute prescribing.
2. If the member is NOT in a long-term care or skilled nursing facility, require prescriber to document risk assessment and provide most recent UDS results dated within:
    a. 1 year if considered "low risk"
    b. 6 months if considered "moderate risk"
    c. 3 months if considered "high risk"

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.

- Analgesics, Narcotics Long-Acting
- Analgesics, Narcotics Short-Acting
- Androgenic Agents
- Antihyperuricemics
- Antineoplastic Agents, Topical
- Bone Resorption Suppression and Related
- Colony Stimulating Factors
- Erythropoiesis Stimulating Agents
- Glucocorticoids, Oral
- Growth Hormone
- NSAIDs
- Oncology, Oral- Breast
- Oncology, Oral- Prostate
- Oncology, Oral- Renal Cell
- Pancreatic Enzymes
- Progestins for Cachexia
- Thrombopoiesis Stimulating Agents

New Products to Market

<table>
<tr><th>Drugs Requiring PA</th><th>Criteria for Prior Authorization</th></tr>
<tr><td>Motegrity™</td><td>Non-prefer in the PDL class: GI Motility Agents
Length of Authorization: 1 year
Motegrity (prucalopride) is a serotonin-4 (5-HT4) receptor agonist indicated for the treatment of chronic idiopathic constipation (CIC) in adults.
Criteria for Approval:
• Diagnosis of chronic idiopathic constipation (CIC); AND
• Trial and failure of, or contraindication to, at least 1 preferred agent in the class.
Age Limit: ≥ 18 years
Quantity Limit: 1 per day</td></tr>
<tr><td>Nuzyra™</td><td>Non-prefer in the PDL class: Antibiotics: Tetracyclines (Tetracyclines)
Length of Authorization: Date of service only
Nuzyra™ (omadacycline) is a tetracycline class antibacterial indicated for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) or acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible microorganisms*.
<table>
<tr><th>*Susceptible microorganisms - CABP</th><th>*Susceptible microorganisms – ABSSSI</th></tr>
<tr><td>• Chlamydophila pneumoniae
• Haemophilus influenza
• Haemophilus parainfluenzae
• Klebsiella pneumoniae
• Legionella pneumophila
• Mycoplasma pneumoniae
• Staphylococcus aureus (methicillin- susceptible isolates; MSSA)
• Streptococcus pneumoniae</td><td>• Enterobacter cloacae
• Enterococcus faecalis
• Klebsiella pneumoniae
• Staphylococcus aureus (methicillin- susceptible and -resistant isolates; MSSA and MRSA)
• Staphylococcus lugdunesis
• Streptococcus anginosus group (includes S. anginosus, S. intermedius, and S. constellatus)
• Streptococcus pyogenes</td></tr>
</table>
Criteria for Approval:
• Diagnosis of community-acquired bacterial pneumonia (CABP) OR acute bacterial skin and skin structure infection (ABSSSI) caused by susceptible microorganism(s); AND
• If of childbearing potential, patient is NOT pregnant; AND
• Infection is caused by an organism resistant to medications not requiring prior approval (must submit culture and sensitivity information); OR
• Patient is not a candidate or has failed treatment with ≥ 2 preferred antibiotics from 2 different classes; AND
• Patient has NOT failed a tetracycline unless susceptibility results demonstrate that pathogen is NOT susceptible to other tetracyclines but is susceptible to omadacycline; AND
• If continuing an inpatient/ hospital treatment course, prescriber attests that it would be clinically inappropriate to deescalate therapy or use alternative therapy based on susceptibility results or lack of susceptibility results in conjunction with clinical picture AND
• Total treatment duration will not exceed 14 days per course.</td></tr>
</table>

Drugs Requiring PA	Criteria for Prior Authorization
	Renewal Criteria • Not eligible for continued therapy beyond 14 days. **Age Limit**: ≥ 18 years **Quantity Limit**: 2 per day; override by call center for loading dose
Seysara™	Non-prefer in the PDL class: *Antibiotics: Tetracyclines (Tetracyclines)* **Length of Authorization:** 3 months Seysara™ (sarecycline), a tetracycline, is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients ≥ 9 years of age. **Limitations of use:** The efficacy and safety of sarecycline beyond 12 weeks and 12 months, respectively, have not been established. It has not been evaluated in the treatment of infections and should only be used as indicated to reduce the development of drug-resistant bacteria and maintain the efficacy of other antibacterial drugs. **Criteria for Approval**: • Diagnosis of non-nodular moderate to severe acne vulgaris; AND • Trial and failure of (or contraindication to) ≥ 2 preferred topical agents for acne vulgaris, including 2 differing mechanisms of action (e.g., benzoyl peroxide, antibiotic, retinoid); AND • Patient has contraindication to ≥ 1 preferred oral tetracycline for acne vulgaris; AND • Use of sarecycline will be in combination with topical agent (e.g., benzoyl peroxide or a topical retinoid); AND • Patient has not had a failure of another tetracycline agent used for acne vulgaris. **Renewal Criteria** • Prescriber attestation of improvement; AND • Patient continues to meet above criteria (e.g., NOT pregnant, use of topical agent); AND • Duration of use has not exceeded 12 months. **Age Limit**: ≥ 9 years **Quantity Limit**: 1 per day **NOTE: Coverage will depend on manufacturer participation in the Medicaid Drug Rebate Program. As of this notice, the product is not covered.**

Drug Class	The following generics will become *preferred* products:	The following brand products will become *non-preferred* and require prior authorization (PA):
Antibiotics: Acne	adapalene gel	*Differin® Gel*
Oral Oncology Agents	imatinib [QL]	*Gleevec®* [QL]
5-ASA Derivatives: Rectal	mesalamine suppository	*Canasa®*
Anti-Anginal and Anti-Ischemic Agents	ranolazine	*Ranexa®*

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 May 16, 2019 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,

ShaLeigh Hammons, CPhT

ShaLeigh Hammons, CPhT
Account Manager I
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.

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