** Fee-For-Service Pharmacy Provider Notice #225 – November 2017 PDL Changes **

April 26, 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 December 22, 2017.

The Kentucky Medicaid FFS Pharmacy and Therapeutics Advisory Committee (Committee) met on November 16, 2017. A quorum was not achieved; however, the recommendations of the Committee were submitted for review. DMS, through its Commissioner, reviewed the recommendations and in consultation rendered its final decisions.

On May 29, 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):
Anti-Emetics: Other	meclizine metoclopramide (EXCEPT ODT) prochlorperazine promethazine (EXCEPT 50 mg suppositories) Transderm-Scop® trimethobenzamide			*Compazine®* *Compro®* *Diclegis™ CC, QL* *metoclopramide ODT* *Phenadoz®* *Phenergan®* *promethazine 50 mg suppositories* *Reglan®* *scopolamine transdermal system* *Tigan®*
Oral Anti-Emetics: 5-HT3 Antagonists	ondansetron			*Aloxi® QL* *Anzemet®* *granisetron* *Sancuso® CC, QL* *Varubi™* *Zofran®* *Zuplenz®*
Oral Anti-Emetics: Δ-9-THC Derivatives	dronabinol CC, QL		*Syndros™ CC, QL*	*Cesamet® CC, QL* *Marinol® CC, QL*
Oral Anti-Emetics: NK-1 Antagonists	Emend® capsules QL		*Emend® powder packets QL*	*Akynzeo® QL* *aprepitant 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):
First-Generation Antipsychotics	amitriptyline/perphenazine chlorpromazine fluphenazine haloperidol loxapine Orap® perphenazine thioridazine thiothixene trifluoperazine			*Adasuve®* *pimozide*
Second-Generation Antipsychotics	aripiprazole tablets CC, QL clozapine CC, QL Latuda® CC, QL olanzapine CC, QL quetiapine CC, QL risperidone CC, QL Saphris® CC, QL ziprasidone CC, QL	quetiapine ER CC, QL	*clozapine ODT CC, QL* *Fanapt™ CC, QL* *Seroquel® XR CC, QL*	*Abilify® oral formulations CC, QL* *Aripiprazole ODT, solution CC, QL* *Clozaril® QL* *FazaClo® QL* *Geodon® QL* *Invega® QL* *Nuplazid™ QL* *paliperidone QL* *Rexulti® QL* *Risperdal® QL* *Seroquel® QL* *Versacloz® QL* *Vraylar™ QL* *Zyprexa® QL*
Antipsychotics: Injectable	Abilify Maintena™ CC, QL fluphenazine decanoate CC, QL Geodon® CC, QL haloperidol decanoate CC, QL haloperidol lactate CC, QL Invega® Sustenna® CC, QL Invega Trinza™ CC, QL olanzapine CC, QL Risperdal® Consta® CC, QL			*Aristada™* *Haldol® Decanoate QL* *Haldol® lactate QL* *Zyprexa® QL* *Zyprexa® Relprevv QL*
Atypical Antipsychotic and SSRI Comb.	Symbyax® CC, QL			*olanzapine/fluoxetine QL*
Alpha Blockers for BPH	alfuzosin ER doxazosin tamsulosin terazosin			*Cardura®* *Cardura XL®* *Flomax®* *Rapaflo™* *Uroxatral®*

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5-Alpha Reductase (5AR) Inhibitors	finasteride CC	dutasteride		*Avodart®* *dutasteride/tamsulosin* *Jalyn®* *Proscar®*
Immunomodulators	Enbrel® CC QL Humira® CC, QL		*Tremfya™ CC, QL*	*Actemra® CC, QL* *Cimzia® CC, QL* *Cosentyx® CC, QL* *Entyvio™ CC, QL* *Kevzara® CC, QL* *Kineret® CC, QL* *Orencia® CC, QL* *Otezla® CC, QL* *Remicade® CC* *Siliq™ CC, QL* *Simponi™ CC, QL* *Simponi™ ARIA CC, QL* *Stelara™ CC, QL* *Taltz® CC* *Xeljanz™ CC, QL*
***H. pylori* Treatment**	Pylera® QL		*lansoprazole/amoxicillin /clarithromycin QL*	*Omeclamox-Pak™ QL* *Prevpac® QL*
Hepatitis C: Direct-Acting Antiviral Agents **Hepatitis C: Interferons** **Hepatitis C: Ribavirins**	 PEGASYS® ProClick CC, QL PEGASYS® syringe CC, QL ribavirin CC	Mavyret™ CC, QL Vosevi™ CC, QL	*Daklinza™ CC, QL* *Epclusa® CC, QL* *Technivie™ CC, QL* *Viekira XR and Pak® CC, QL*	*Harvoni® CC, QL* *Olysio™ CC, QL* *Sovaldi™ CC, QL* *Zepatier™ CC, QL* *PEGASYS® vial CC, QL* *PEGIntron™ CC, QL* *Copegus™ CC* *Moderiba™ CC* *Rebetol® CC* *Ribasphere™ CC* *Ribasphere RibaPak™ CC* *ribavirin dose pack CC*
Anticonvulsants: Second Generation	Banzel™ CC Gabitril® gabapentin capsules, solution lamotrigine IR tablets, ODT levetiracetam IR tablets, solution Lyrica® CC Sabril® CC topiramate IR zonisamide	gabapentin tablets		*Briviact® QL* *Fycompa™* *gabapentin tablets* *Gralise™* *Keppra™ tablets, solution* *Keppra XR™* *Lamictal®* *Lamictal ODT®* *Lamictal® XR* *lamotrigine ER* *levetiracetam ER* *Neurontin®* *Qudexy XR™* *tiagabine*

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				Topamax® *topiramate ER* *Trokendi XR™* *vigabatrin* *Vimpat®* *Zonegran®*
Antidepressants: SNRIs	Savella™ CC venlafaxine venlafaxine ER capsules	*duloxetine DR (generic Cymbalta®)*		*Cymbalta®* *desvenlafaxine ER base* *desvenlafaxine fumarate ER* *duloxetine (generic Irenka™)* *Effexor®* *Effexor XR®* *Fetzima™* *Irenka™* *Khedezla®* *Pristiq®* *venlafaxine ER tablets*
Oral Oncology Agents, Hematologic Cancer	Alkeran® cladribine Gleevec® QL hydroxyurea Imbruvica™ CC, QL Jakafi™ CC, QL mercaptopurine Purixan® Rydapt® CC, QL Sprycel® QL Zolinza® QL Zydelig® CC, QL		*Idhifa® CC, QL*	*Bosulif® QL* *Farydak® QL* *Hydrea®* *Iclusig™ QL* *imatinib QL* *melphalan* *Ninlaro™* *Tasigna® QL* *Venclexta® QL*
Stimulants and Related Agents	Adderall XR® CC, QL dexmethylphenidate IR CC, QL dextroamphetamine IR CC, QL dextroamphetamine ER CC, QL Focalin XR™ CC, QL guanfacine ER CC, QL Metadate ER® CC, QL Methylin® chewable tablets CC, QL methylphenidate IR tablets, capsules CC, QL methylphenidate ER/SA/SR CC, QL methylphenidate ER OROS CC, QL	atomoxetine CC, QL Vyvanse Chew CC, QL	*Cotempla XR-ODT™ QL* *Mydayis™ QL* *Strattera® QL*	*Adderall® QL* *Adzenys XR-ODT™ QL* *Aptensio XR® QL* *clonidine ER QL* *Concerta® QL* *Daytrana™ QL* *Desoxyn® QL* *Dexedrine® QL* *dexmethylphenidate ER QL* *dextroamphetamine solution QL* *Dyanavel™ XR susp QL* *Evekeo™ QL* *Focalin™ QL* *Intuniv™ QL* *Kapvay™ QL*

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	mixed amphetamine salts IR CC, QL Quillivant™ XR CC, QL Vyvanse™ CC, QL			*methamphetamine QL* *Methylin® solution QL* *methylphenidate (Generic for Metadate CD®) QL* *methylphenidate chewable (Generic for Methylin® chewable tablets) QL* *methylphenidate LA (Generic Ritalin LA®) QL* *methylphenidate solution QL* *mixed amphetamine salts ER QL* *Procentra™ QL* *QuilliChew ER™ QL* *Ritalin® QL* *Ritalin LA® QL* *Zenzedi™ QL*
Oral Anti-Arrhythmics	amiodarone 100, 200 mg disopyramide flecainide mexiletine procainamide propafenone quinidine gluconate ER quinidine sulfate quinidine sulfate ER Sorine® sotalol sotalol AF	dofetilide	*Tikosyn®*	*amiodarone 400 mg* *Betapace®* *Betapace® AF* *dofetilide* *Multaq®* *Norpace®* *Norpace® CR* *Pacerone®* *propafenone SR* *Rythmol® SR* *Sotylize®*
Familial Hypercholesterole-mia Agents	Kynamro™ CC			*Juxtapid™*
Lipotropics: Bile Acid Sequestrants	cholestyramine cholestyramine light colestipol tablets Prevalite®			*Colestid®* *colestipol granules/packets* *Questran®* *Questran Light®* *WelChol®*
Lipotropics: Cholesterol Absorption Inhibitors		ezetimibe	*Zetia®*	
Lipotropics: Fibric Acid Derivatives	gemfibrozil	fenofibrate nanocrystallized (generic Tricor®) fenofibric acid (generic Trilipix™)	*TriCor®* *Trilipix™*	*Antara™* *Fenoglide™* *fenofibrate (generic Antara™, Lipofen™, Lofibra®)* *fenofibric acid (generic Fibricor™)*

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				Fibricor™ *Lipofen™* *Lopid®* *Triglide™*
Lipotropics: Omega-3 Fatty Acids **Lipotropics: Niacin Derivatives** **Lipotropics: PCSK9 Inhibitors**	Lovaza® ST Niaspan®			*omega-3 acid ethyl esters* *Vascepa®* *Niacor®* *niacin* *niacin ER* *Praluent® CC* *Repatha™ CC*

New Sedative Hypnotic Maximum Duration Edit

Requests for long-term (more than 60 days per year) use of sedative hypnotics will be approved for 6-month periods when the following conditions are met:

- Patient has been evaluated for signs and symptoms of abuse, dependency, misuse or overuse of controlled substances including KASPER monitoring; AND
- Patient has had a trial (at least 3 weeks) of non-pharmacological therapies (e.g., stimulus control, sleep restriction, sleep hygiene measures, and relaxation therapy); AND
- Patient has a diagnosis of severe or refractory insomnia; AND/OR
- Patient has a comorbid condition (e.g., psychiatric disorder, chronic pain) which causes and/or exacerbates insomnia; AND/OR
- Patient requires use of a sedative hypnotic medication to maintain compliance with nighttime breathing apparatus (e.g., CPAP); OR
- A Clinical Pharmacist may approve the request if there is another valid medical reason why the recipient requires long-term use of the requested medication.
- Approval of requests beyond 60 days should be limited to non-benzodiazepine agents (e.g., eszopiclone, suvorexant, zaleplon, zolpidem) wherever possible due to the higher potential for abuse, dependency, and withdrawal associated with benzodiazepines. Benzodiazepine sedative hypnotics (e.g., estazolam, flurazepam, temazepam, triazolam) should only be approved for long-term use when:
    - Patient has tried and failed a non-benzodiazepine sedative hypnotic (e.g., eszopiclone, suvorexant, zaleplon, zolpidem) or is unable to use these agents due to allergy or contraindication which does not apply to benzodiazepine sedative hypnotics; AND
    - Patient meets all other above criteria for exceeding the duration limit.

Note: Each member will be allowed 60 days of sedative hypnotic use from the date the edit takes effect.

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.

- Antianginal & Anti-Ischemic
- Antibiotics, Topical
- Anticoagulants
- Bronchodilators, Beta-Agonists
- Calcium Channel Blockers
- Laxatives & Cathartics
- Oncology Oral - Other
- Ophthalmics, Allergic Conjunctivitis
- Ophthalmics, Anti-inflammatories
- Ophthalmics, Antibiotic-Steroid Combinations Ophthalmics, Antibiotics
- Ophthalmics, Antivirals
- Ophthalmics, Glaucoma
- Ophthalmics, Mydriatics
- Platelet Aggregation Inhibitors
- Proton Pump Inhibitors
- Thrombopoiesis Stimulating Proteins

New Products to Market

Drugs Requiring PA	Criteria
Nerlynx™	*Non-prefer in the PDL class: Oral Oncology Agents, Breast Cancer* ***Length of Authorization:*** *1 year* • *Nerlynx™ (neratinib) is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early stage human epidermal growth factor receptor 2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.* ***Criteria for Approval****:* • *Diagnosis of early stage, human epidermal growth factor receptor 2 (HER2)-positive breast cancer; AND* • *Previous treatment with Herceptin® (trastuzumab) within the past 2 years.* ***Age Limit****: ≥ 18 years* ***Quantity Limit****: 6 tablets per day*
Syndros™	*Non-prefer in the PDL class: Oral Anti-Emetics: Δ-9-THC Derivatives* **Length of Authorization:** 6 months • Syndros™ (dronabinol) oral solution is a cannabinoid indicated in adults for the treatment of anorexia associated with weight loss in patients with AIDS as well as nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. It is available as a 5 mg/mL oral solution in 30 mL bottles. • NOTE: The DEA has classified Syndros™ as C- II, indicating that this liquid formulation may have a higher potential for addiction, abuse and/or misuse than dronabinol capsules, which are C-III. **Criteria for Approval:** • Clinically valid reason (e.g., feeding tube, swallow study) that dronabinol capsules cannot be used; AND • No history of hypersensitivity to, or abuse of, alcohol; AND • Diagnosis of nausea and vomiting associated with cancer chemotherapy; AND • Have failed to respond adequately to at least 1 other anti-emetic therapy; OR • Diagnosis of anorexia associated with weight loss in a patient with AIDS. **Age Limit**: ≥ 18 years **Quantity Limits**: *AIDS Anorexia*: 3 mL per day *Chemotherapy Nausea and Vomiting*: 8 mL per day

Drugs Requiring PA	Criteria
Tremfya™	Non-prefer in the PDL class: *Immunomodulators* **Length of Authorization**: 1 year • Tremfya™ (guselkumab) is a monoclonal antibody that functions as an interleukin-23 (IL-23) antagonist; it is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is available as a 100 mg/mL pre-filled syringe for subcutaneous injection. **Criteria for Approval:** • Diagnosis of moderate to severe plaque psoriasis; AND • Symptoms persistent for ≥ 6 months with at least 1 of the following: o Involvement of at least 10% of body surface area (BSA); OR o Psoriasis Area and Severity Index (PASI) score of 12 or greater; OR o Incapacitation due to plaque location (i.e., head and neck, palms, soles or genitalia); AND • Negative tuberculosis (TB) screening prior to initiating treatment; AND • Trial and failure of **two** of the following therapies: o Methotrexate o Cyclosporine o Oral retinoid (e.g., Soriatane®, acitretin) o Topical corticosteroids o Phototherapy/UV light o Coal tar preparations; AND • Trial and failure of, or contraindication to, a preferred immunomodulator (i.e., Enbrel® or Humira®). **Renewal Criteria:** • Patient continues to meet criteria identified above; AND • Ongoing monitoring for TB; AND • Disease response as indicated by improvement in signs and symptoms compared to baseline, such as redness, thickness, scaliness, and/or the amount of surface area involvement. **Age Limit**: ≥18 years **Quantity Limit:** *Loading Dose*: 2 syringes per 56 days *Maintenance Dose*: 1 syringe per 56 days

Drugs Requiring PA	Criteria
Mavyret™	Prefer with Clinical Criteria in the PDL class: *Hepatitis C: Direct-Acting Antiviral Agents* **Length of Authorization**: Duration of treatment course (8, 12, or 16 weeks) • Mavyret™ (glecaprevir/pibrentasvir) is a fixed-dose combination product containing glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor (PI), and pibrentasvir, an HCV NS5A inhibitor. It is indicated for the treatment of HCV genotypes 1 to 6 in adult patients without cirrhosis or with compensated cirrhosis (Child-Pugh A). It is also indicated to treat HCV in patients who have genotype 1 and have been treated previously with regimens containing either an HCV NS5A inhibitor or an HCV NS3/4A PI, but not both. Mavyret™ is available as tablets for oral administration containing 100 mg glecaprevir and 40 mg pibrentasvir; the recommended dosing is 3 tablets once daily. **Criteria for Approval:** • Diagnosis of chronic hepatitis C virus (HCV) infection; AND • Patient does not have a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy; AND • Patient is NOT pregnant; AND • Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease provider; AND • Must be evaluated for liver disease severity and have no cirrhosis or compensated cirrhosis (Child-Pugh A); AND • Must be screened for Hepatitis B Virus (HBV) infection prior to treatment; AND • Must be prescribed for an FDA-labeled and/or AASLD-recommended treatment course regarding cirrhosis status, genotype, and prior treatment experience. • Requests for repeat treatment are subject to additional criteria. **Age Limit**: ≥ 18 years **Quantity Limit**: 3 tablets per day

Drugs Requiring PA	Criteria
Vosevi™	Prefer with Clinical Criteria in the PDL class: *Hepatitis C: Direct-Acting Antiviral Agents* **Length of Authorization**: 12 weeks • Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir), a fixed-dose combination product containing sofosbuvir, a hepatitis C virus (HCV) NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor, is indicated for the treatment of chronic HCV infection in patients without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have genotypes 1-6 infection and previously received treatment with an NS5A inhibitor, or who have genotype 1a or 3 HCV infection and have been treated previously with sofosbuvir without an NS5A inhibitor. Vosevi™ is available as a fixed-dose combination tablet containing 400 mg sofosbuvir, 100 mg velpatasvir, and 100 mg voxilaprevir; the recommended dosing is 1 tablet daily. **Criteria for Approval:** • Diagnosis of chronic hepatitis C virus (HCV) infection; AND • Patient does not have a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy; AND • Patient is NOT pregnant; AND • Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease provider; AND • Must be evaluated for liver disease severity and have no cirrhosis or compensated cirrhosis (Child-Pugh A); AND • Must be screened for Hepatitis B Virus (HBV) infection prior to treatment; AND • Patient must be evaluated for alcohol and substance abuse using a validated screening tool with appropriate follow up to address addiction as part of HCV treatment; AND • Abstinence from alcohol and illicit substances confirmed by laboratory testing; AND • Treatment-experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir); OR • Genotype 1a or 3 and treatment-experienced with sofosbuvir without an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir). **Age Limit**: ≥18 years **Quantity Limit**: 1 tablet per day

Drugs Requiring PA	Criteria
Idhifa®	*Non-prefer in the PDL class: Oral Oncology Agents, Hematologic Cancer* **Length of Authorization**: 1 year • Idhifa® (enasidenib) is an isocitrate dehydrogenase-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase-2 mutation as detected by an FDA-approved test. It is available as 50 mg and 100 mg tablets for oral administration. **Criteria for Approval**: • Diagnosis of relapsed or refractory acute myeloid leukemia (AML); AND • Presence of an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test; AND • Not pregnant. **Renewal Criteria:** • Continue to meet above criteria; AND • Clinical response or lack of disease progression. **Age Limit**: ≥18 years **Quantity Limit**: 1 tablet per day

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,

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.