Fee-for-Service Pharmacy Provider Notice #199
**** March 2015 P&T Changes ****

May 8, 2015

Please be advised that the Department for Medicaid Services is making changes to the Kentucky Medicaid Fee-For-Service Pharmacy Preferred Drug List (PDL) based on the Kentucky Medicaid Fee-For-Service Pharmacy & Therapeutics Advisory Committee meeting of March 19, 2015 as adopted by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services by order dated April 7, 2015.

On June 10, 2015, 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):
Apolipoprotein B Synthesis Inhibitors*	Kynamro™			Juxtapid™
Oral Anti-Emetics: 5-HT3 Antagonists	ondansetron			Aloxi® Anzemet® granisetron Granisol™ Kytril® Sancuso® Zofran® Zuplenz®
Oral Anti-Emetics: NK1 antagonist	Emend®		Akynzeo®	
Oral Anti-Emetics: Δ-9-THC Derivatives*	dronabinol			Cesamet® Marinol®
Anti-Emetics: Other	meclizine prochlorperazine promethazine (all except 50 mg suppositories) Transderm-Scop® trimethobenzamide	metoclopramide	Compazine® Compro® Metozolv® ODT Reglan®	Antivert® Diclegis® * metoclopramide ODT Phenadoz® Phenergan® promethazine 50 mg suppositories Tigan® Univert®

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):
Antispasmodics / Anticholinergics	dicyclomine glycopyrrolate hyoscyamine methscopolamine propantheline		Donnatal® Glycate® Hyomax® Hyosyne® Levbid® Levsin® Oscimin SR® Pro-Banthine® Symax®	Anaspaz® Bentyl® Cantil® chlordiazepoxide/ clidinium Cuvposa® Librax® Pamine® Pamine Forte® Robinul® Robinul Forte®
Ulcerative Colitis	Apriso™ balsalazide Canasa® mesalamine enemas/ suppositories sulfasalazine sulfasalazine EC	Delzicol®	Uceris®	Asacol® HD Azulfidine® Azulfidine EN-tabs® Colazal® Dipentum® Giazo Lialda™ mesalamine rectal kit Pentasa® Rowasa® sfRowasa®
Antidiarrheals	diphenoxylate with atropine loperamide		opium	Fulyzaq®* Lomotil® Motofen® Paregoric
Laxatives and Cathartics	lactulose solution PEG-3350 / electrolytes solution for reconstitution PEG 3350 powder Moviprep®		Entereg®	Colyte® with flavor packets Constulose® Enulose® GaviLyte-C® GaviLyte-G® GaviLyte-N® Generlac® GlycoLax® Golytely® powder pack/solution for reconstitution Halflytely-Bisacodyl Bowel Kit® Kristalose® packet Miralax® Powder Nulytely® with Flavor Packs solution for reconstitution Osmoprep® Tablets PEG-3350/Flavor

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):
				Packs Solution for Reconstitution PEG 3350 Powder Pack PEG-Prep Kit® Prepopik™ Powder Pack Relistor® * Suclear™ Suprep® TriLyte® Visicol®

New Products to Market

The following product (s) will require prior authorization (PA):

New Drugs Requiring PA:	Criteria:
Jardiance®	Empagliflozin (Jardiance®) will only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.
Invokamet™	Invokamet™ (canagliflozin/metformin) will only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.
Xigduo XR™	Xigduo XR™ (dapagliflozin/metformin ER) will only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.
Rasuvo™	Rasuvo™ (methotrexate) will only be approved for the following diagnoses: ➢ Rheumatoid arthritis (RA) after trial and failure of: o NSAID; and o Corticosteroid; and o Oral methotrexate; OR ➢ Polyarticular juvenile idiopathic arthritis (pJIA) after trial and failure of: o NSAID; and o Corticosteroid; and o Oral methotrexate; OR ➢ Psoriasis after trial and failure of: o Topical agent for the treatment of psoriasis (e.g., emollients, corticosteroids, retinoids, vitamin D analogs, and/or topical tacrolimus, pimecrolimus); AND o Oral methotrexate.
Zydelig®	Zydelig® will be placed preferred; however, it will only be approved for one of the following diagnoses: ➢ Chronic lymphocytic leukemia (CLL), in combination with rituximab; OR

	➢ Follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies; OR ➢ Small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.
Viekira Pak™	Viekira Pak™ will be placed preferred; however, it will only be approved if ALL of the following are true: • Age ≥18 years old; AND Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician; AND • Patient is treatment-naïve to all parts of the dasabuvir/ombitasvir/paritaprevir therapy. Limited to one course of therapy per lifetime.; AND • Patient is *not* receiving concomitant therapy with a hepatitis C protease inhibitor (e.g., telaprevir [Incivek®], boceprevir [Victrelis®], simeprevir [Olysio®]); AND • Patient does *not* have decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]); AND • Patient has been evaluated for and *does not* have clinically significant drug interactions (i.e., antiarrhythmics, antifungals, calcium channel blockers, corticosteroids, diuretics, immunosuppressants, narcotic analgesics, sedative/hypnotics, HMG-CoA Reductase Inhibitors, proton pump inhibitors, HIV Antivirals, long acting beta-agonists); AND • Patient does *not* have a diagnosis of HCV genotypes 2, 3, 4, 5, or 6; AND • Patient has not actively participated in illicit substance abuse or alcohol abuse for 6 months prior to or during therapy attested by the prescribing physician(s) AND using one of the following confirmation tests administered both randomly and periodically throughout treatment: ➢ Patient has been evaluated for current substance abuse and alcohol with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or National Institute on Drug Abuse's (NIDA's) drug screening tool; OR o Acceptable alcohol consumption tests include: Serum gamma-glutamyl transpeptidase (GGT), mean corpuscular volume (MCV), carbohydrate-deficient transferrin (CDT), and urine ethylglucuronide (EtG) tests. Results must be documented in the patient's medical record to include, results of testing, and date tested; AND o Urine toxicology screen results for substance abuse are acceptable in lieu of the actual laboratory drug screen report. Results must be documented in the patient's medical record to include substances tested, results of testing, and date tested; AND ➢ If patient has a prior history of substance or alcohol abuse, the patient has completed or is participating in a recovery program, or receiving substance or alcohol abuse counseling services, or seeing an addiction specialist as part of HCV treatment; AND • Baseline HCV-RNA is submitted. HCV RNA levels will be required at treatment weeks 4, and 12 for renewals; AND • Have documentation of Disease Severity **AND/OR** Highest Risk for Disease Progression, defined as: ➢ Disease Severity (patient **MUST** have one of the following): o Liver biopsy showing Metavir score of F2-F4; **OR** o Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa; **OR**

… continued Viekira Pak	o Evidence of any **TWO** of the following: ▪ Fibrotest (FibroSure) score of ≥ 0.49 ▪ Fibrosis-4 index (FIB-4) > 3.25 ▪ Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5 ▪ Cirrhotic features on imaging ▪ Physical exam consistent with cirrhosis; **AND/OR** ➢ Documentation showing patient at the highest risk for severe complications (patient **MUST** have one of the following): o Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4); **OR** o Essential mixed cryoglobulinemia with end organ manifestations (including arthralgias, palpable purpura, peripheral neuropathy, central nervous system vasculitis); **OR** o Proteinuria; **OR** o Nephrotic Syndrome; **OR** o Membranoproliferative glomerulonephritis; AND • One of the following diagnoses: ➢ For diagnosis of chronic HCV with genotype 1a, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: o Patient **does not** have cirrhosis; AND o Patient has concurrent (or planning to start) therapy with ribavirin when starting dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration o Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ▪ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ▪ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND ▪ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). ➢ For diagnosis of chronic HCV with genotype 1a, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: o Patient **has** cirrhosis (Metavir F4); AND o Patient is treatment naïve or treatment experienced with prior relapse or partial response; AND o Patient has concurrent (or planning to start) therapy with ribavirin when starting dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration o Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ▪ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ▪ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND ▪ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). ➢ For diagnosis of chronic HCV with genotype 1a approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: o Patient **has** cirrhosis (Metavir F4); AND

… continued Viekira Pak	o Treatment experienced with prior null response o Patient has concurrent (or planning to start) therapy with ribavirin when starting dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration o Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ▪ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ▪ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND ▪ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). o Approve for an additional 8 weeks (24 weeks total) of therapy (Authorization #3) IF patient meets ALL of the following criteria: ▪ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ▪ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND ▪ HCV RNA levels are < 25 IU/mL at treatment week 12 (TW12) ➢ For diagnosis of chronic HCV with genotype 1b, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: o Patient **does not** have cirrhosis; AND o Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ▪ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ▪ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND ▪ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). ➢ For diagnosis of chronic HCV with genotype 1b, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: o Patient **has** cirrhosis (Metavir F4); AND o Patient has concurrent (or planning to start) therapy with ribavirin when starting dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration o Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ▪ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ▪ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND ▪ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4).

Non preferred Drugs

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

Drugs Requiring PA:	Criteria:
Auryxia™	Auryxia™ will be placed non preferred in the PDL class titled Phosphate Binders.
Aptiom®	Aptiom® will be placed non preferred in the PDL class titled Anticonvulsants: Carbamazepine Derivatives.
Striverdi® Respimat®	Striverdi® Respimat® will be placed non preferred with similar quantity limits in the PDL class titled Long-Acting Beta Agonists.
Incruse™ Ellipta®	Incruse™ Ellipta® will be placed non preferred with similar quantity limits in the PDL class titled COPD Agents.
Arnuity™ Ellipta®	Arnuity™ Ellipta® will be placed non preferred with similar quantity limits in the PDL class titled Inhaled Corticosteroids.
Zykadia™	Zykadia™ will be placed non preferred with similar quantity limits in the PDL class titled Oral Oncology, Lung Cancer.
Lynparza™	Lynparza™ will be placed non preferred; however, it will be approved once the following criteria are met. ➢ Initial approval criteria include: • Patient must be at least 18 years of age; **AND** • Patient's disease must be advanced (i.e. Stage II or greater disease in which the cancer has spread to other areas of the pelvis or beyond); **AND** • Patient must have germline BRCA (gBRCA) mutated disease (as detected by an FDA-approved test i.e. BRACAnalysis CDx™); **AND** • Must be used as a single agent; **AND** • Patient must have received treatment with three or more prior lines of chemotherapy; **AND** • Patient has an ECOG performance status of 0-1. ➢ Renewal criteria include: • Patient continues to meet initial review criteria; **AND** • Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND** • Absence of unacceptable toxicity from the drug (e.g. anemia, nausea, fatigue, vomiting, diarrhea, dysgeusia, dyspepsia, headache, decreased appetite, upper respiratory tract infection, cough, arthralgia, myalgia, back pain, dermatitis, rash, abdominal discomfort); **AND** • Patient has not developed myelodysplastic syndrome/acute myeloid leukemia (MDS/AML); **AND** • Patient has not developed pneumonitis.
Akynzeo®	Akynzeo® will be placed non preferred with appropriate quantity limits in the PDL class titled Oral Anti-Emetics: NK-1 Antagonists.
Kerydin™	Kerydin™ will only be approved for a diagnosis of toenail onychomycosis after trial and failure of one other agent indicated for the treatment of onychomycosis.

Soolantra®	Soolantra® will be placed non preferred in the PDL class titled Topical Rosacea Agents.
Harvoni®	Harvoni® will be placed non preferred; however, it will only be approved if ALL of the following are true: • Patient has tried and failed, unless contraindicated, one preferred product. • Age ≥18 years old; AND • Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician; AND • Patient is treatment-naïve to ledipasvir and/or sofosbuvir. Limited to one course of therapy per lifetime.; AND • Patient is *not* receiving concomitant therapy with a hepatitis C protease inhibitor (e.g., telaprevir [Incivek®], boceprevir [Victrelis®], simeprevir [Olysio®]); AND • Patient does *not* have decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]); AND • Patient has been evaluated for and *does not* have clinically significant drug interactions (i.e., certain acid reducing agents, antiarrhythmics, HIV Antiretroviral medications, anticonvulsants, antimycobacterials, herbal supplements, HMG-CoA Reductase Inhibitors); AND • Patient does *not* have severe renal impairment (eGFR <30 mL/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis; AND • Patient does *not* have a diagnosis of HCV genotypes 2, 3, 4, 5, or 6; AND • Patient has not actively participated in illicit substance abuse or alcohol abuse for 6 months prior to or during therapy attested by the prescribing physician(s) AND using one of the following confirmation tests administered both randomly and periodically throughout treatment: ➢ Patient has been evaluated for current substance abuse and alcohol with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or National Institute on Drug Abuse's (NIDA's) drug screening tool; OR ➢ Acceptable alcohol consumption tests include: Serum gamma-glutamyl transpeptidase (GGT), mean corpuscular volume (MCV), carbohydrate-deficient transferrin (CDT), and urine ethylglucuronide (EtG) tests. Results must be documented in the patient's medical record to include, results of testing, and date tested; AND ➢ Urine toxicology screen results for substance abuse are acceptable in lieu of the actual laboratory drug screen report. Results must be documented in the patient's medical record to include substances tested, results of testing, and date tested; AND • If patient has a prior history of substance or alcohol abuse, the patient has completed or is participating in a recovery program, or receiving substance or alcohol abuse counseling services, or seeing an addiction specialist as part of HCV treatment; AND • Baseline HCV-RNA is submitted. HCV RNA levels will be required at treatment weeks 4, and 12 for renewals; AND • Have documentation of Disease Severity **AND/OR** Highest Risk for Disease Progression, defined as: ➢ Disease Severity (patient **MUST** have one of the following): o Liver biopsy showing Metavir score of F2-F4; **OR** o Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa; **OR** o Evidence of any **TWO** of the following: ▪ Fibrotest (FibroSure) score of ≥ 0.49

… continued Harvoni	▪ Fibrosis-4 index (FIB-4) > 3.25 ▪ Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5 ▪ Cirrhotic features on imaging ▪ Physical exam consistent with cirrhosis; **AND/OR** o Documentation showing patient at the highest risk for severe complications (patient **MUST** have one of the following): ▪ Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4); **OR** ▪ Essential mixed cryoglobulinemia with end organ manifestations (including arthralgias, palpable purpura, peripheral neuropathy, central nervous system vasculitis); **OR** ▪ Proteinuria; **OR** ▪ Nephrotic Syndrome; **OR** ▪ Membranoproliferative glomerulonephritis; AND • One of the following diagnoses: ➢ For diagnosis of chronic HCV with genotype 1, approve for 8 weeks of therapy IF patient meets ALL of the following criteria: o Treatment-naïve; AND o Have documented baseline HCV RNA of less than 6 million IU/mL; AND o Without cirrhosis (Metavir F4). ➢ For diagnosis of chronic HCV with genotype 1: o Approve for an initial 8 weeks of therapy IF patient meets ONE of the following criteria: ▪ Treatment-naïve with cirrhosis (Metavir F4); OR ▪ Treatment-naïve without cirrhosis and baseline HCV RNA greater than 6 million IU/mL; OR ▪ Treatment experienced without cirrhosis (Metavir F4). o Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ▪ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ▪ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND ▪ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). ➢ For diagnosis of chronic HCV with genotype 1: o Approve for and initial 8 weeks of therapy for treatment experienced patients with cirrhosis (Metavir F4). o Approve for an additional 8 weeks (16 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ▪ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ▪ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND ▪ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4) o Approve for an additional 8 weeks (24 weeks total) of therapy (Authorization #3) IF patient meets ALL of the following criteria: ▪ The patient has been compliant with drug therapy regimen

	(per pharmacy paid claims history); AND ▪ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND ▪ HCV RNA levels are < 25 IU/mL at treatment week 12 (TW12)

Prior Authorization Criteria

The clinical criteria for the following drugs and drug classes were reviewed during the March P&T meeting:

- ❖ Apolipoprotein B Synthesis Inhibitors
- ❖ Δ-9-THC Derivatives
- ❖ Doxylamine/pyridoxine (Diclegis®)
- ❖ Crofelemer (Fulyzaq®)
- ❖ Methylnaltrexone (Relistor®)
- ❖ Omalizumab (Xolair®)

To review the complete summary of the final preferred drug list (PDL) selections, new products to market, and clinical review criteria updates and changes, from the March P&T meeting, please refer to the "Commissioner's Final Decisions from March 19, 2015" 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.