

Fee-for-Service Pharmacy Provider Notice #211
**** November 2015 PDL Changes ****

April 29, 2016

Please be advised that the Department for Medicaid Services 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 March 16, 2016.

The Kentucky Medicaid FFS Pharmacy & Therapeutics Advisory Committee was scheduled to meet on November 19, 2015. The Committee did not attain the necessary quorum; however, the proposed Committee recommendations were submitted to the Department for Medicaid Services for consideration, and final decisions were made.

On June 2, 2016, 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, Breast Cancer	anastrozole ^{QL} exemestane ^{QL} letrozole ^{QL} tamoxifen citrate ^{QL}	Ibrance ^{QL}	Arimidex ^{QL} Aromasin ^{QL} Fareston ^{QL} Faslodex ^{QL} Femara ^{QL}	
Antimigraine Agents, triptans	rizatriptan ODT ^{QL} sumatriptan ^{QL}	rizatriptan ^{QL} Relpax ^{TM QL}		almotriptan ^{QL} Alsuma ^{TM QL} Amerge ^{QL} Axert ^{QL} Cambia ^{TM QL} Frova ^{TM QL} Imitrex ^{QL} Maxalt ^{QL} Maxalt-MLT ^{QL} naratriptan ^{QL} Sumavel ^{TM Dosepro} ^{TM QL} Treximet ^{TM QL} Zecuity ^{QL} zolmitriptan ^{QL} zolmitriptan ODT ^{QL} Zomig ^{QL} Zomig-ZMT ^{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):
AntiParkinson's Agents	amantadine syrup, tablets, benzotropine carbidopa Comtan [®] levodopa/carbidopa levodopa/carbidopa CR levodopa/carbidopa ODT selegiline tablets trihexyphenidyl	amantadine capsules		Azilect [®] Duopa [™] entacapone levodopa/carbidopa/entacapone Lodosyn [®] Parcopa [™] Rytary [™] selegiline capsules Sinemet [®] Sinemet [®] CR Stalevo [®] Tasmar [®] tolcapone Zelapar [™]
Sedative Hypnotics	flurazepam ^{QL} temazepam 15 mg, 30 mg ^{QL} triazolam ^{QL} zolpidem ^{QL}		estazolam ^{QL}	Ambien ^{® QL} Ambien CR ^{® QL} Belsomra ^{® QL} Doral ^{® QL} Edluar ^{® CC, QL} eszopiclone ^{QL} Halcion ^{® QL} Hetlioz ^{® CC, QL} Intermezzo ^{® QL} Lunesta ^{™ QL} Restoril ^{® QL} Rozerem ^{® CC, QL} temazepam 22.5 mg, 7.5 mg ^{QL} Silenor ^{® QL} Somnote [®] Sonata ^{® QL} zaleplon ^{QL} zolpidem ER ^{QL} Zolpimist ^{™ QL}
Skeletal Muscle Relaxants	baclofen ^{QL} chlorzoxazone ^{QL} cyclobenzaprine ^{QL} methocarbamol ^{QL} orphenadrine ^{QL} orphenadrine compound ^{QL} orphenadrine compound forte ^{QL} tizanidine tablets ^{QL}		dantrolene ^{QL}	Amrix ^{® QL, MD} carisoprodol ^{QL, MD} carisoprodol compound ^{QL, MD} cyclobenzaprine ER ^{QL, MD} Dantrium ^{® QL} Fexmid ^{® QL, MD} Flexeril ^{® QL, MD} Lorzone ^{® QL} metaxalone ^{QL} methocarbamol/aspirin ^{QL} Parafon Forte DSC ^{® QL} Robaxin ^{® QL} Skelaxin ^{® QL} Soma ^{® QL, MD}

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):
				tizanidine capsules ^{QL} Zanaflex ^{QL}
Tobacco Cessation	bupropion SR ^{QL} Chantix ^{QL} nicotine buccal/gum/lozenge ^{QL} nicotine transdermal system ^{QL}			Commit ^{QL} Habitrol ^{QL} Nicoderm ^{QL} Nicoderm CQ ^{QL} Nicorelief ^{QL} Nicorette ^{QL} Nicotrol ^{QL} Inhaler ^{QL} Nicotrol ^{QL} NS ^{QL} Nicotrol ^{QL} Patch ^{QL} Prostep ^{QL} Zyban ^{QL}
Analgesic Narcotics, short-acting	butalbital/APAP/caffeine ^{CC} codeine/APAP ^{MD} dihydrocodeine bitartrate/APAP/caffeine hydrocodone/APAP ^{MD} hydrocodone/ibuprofen hydromorphone liquid, tablets meperidine morphine IR oxycodone oxycodone/APAP ^{MD} tramadol			All branded short-acting narcotics and narcotic combinations butalbital/APAP/caffeine/ codeine ^{CC} butalbital compound/codeine ^{CC} codeine Capital [®] Demerol [®] dihydrocodeine bitartrate/ASA/caffeine Dilaudid [®] Endodan [®] Hycet [®] hydromorphone suppositories Ibudone [™] levorphanol Magesic H [®] Maxidone [®] Norco [®] Nucynta [™] Opana [®] Oxaydo [®] oxycodone/ASA ^{MD} oxycodone/ibuprofen oxymorphone IR Primlev [®] Reprexain [™] Rybix [™] ODT Synalgos DC [®] tramadol APAP Trezix [®] Ultracet [®] Ultram [®] Vanatol [™] LQ ^{CC} Xartemis [™] XR

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):
				Xodol [®] Xolox [®] Zamicet [™] Zolvit [™]
Analgesic Narcotics, Long-acting	fentanyl transdermal 12, 25, 50, 75, 100 mcg ^{CC, QL} Kadian ^{® QL} morphine sulfate SA (Generic for MS Contin [®]) QL			Avinza ^{™ QL} Butrans ^{™ CC, QL} ConZip ^{™ QL} Dolophine [®] Duragesic ^{® CC, QL} Embeda ^{™ QL} Exalgo ^{™ QL} fentanyl transdermal 37.5, 62.5, 87.5 mcg ^{CC, QL} hydromorphone ER ^{QL} Hysingla ^{™ ER QL} Ionsys ^{® CC, QL} morphine sulfate SA (Generic Kadian [®] , Avinza [™]) QL MS Contin ^{® QL} Nucynta ^{® ER CC, QL} Opana ER ^{® QL} Oramorph ^{® SR QL} oxycodone ER/SR ^{QL} OxyContin ^{® QL} oxymorphone ER ^{QL} Ryzolt ^{™ QL} tramadol ER ^{QL} Ultram ^{® ER QL} Zohydro ER ^{™ CC, QL}
Fentanyl Buccal	N/A			Abstral ^{® CC, QL} Actiq ^{® CC, QL} fentanyl citrate lollipop ^{CC, QL} Fentora ^{® CC, QL} Lazanda ^{® CC, QL} Onsolis ^{™ CC, QL} Subsys ^{® CC, QL}
NSAIDs	celecoxib ^{QL} flurbiprofen ibuprofen indomethacin ketoprofen ketorolac tromethamine QL meloxicam tablets naproxen tablets piroxicam sulindac	diclofenac sodium	diclofenac potassium etodolac naproxen sodium	Anaprox [®] Anaprox ^{® DS} Ansaid [®] Arthrotec [®] Cataflam [®] Celebrex ^{® QL} Clinoril [®] Daypro [®] Dermacin RX Lexitral PharmaPak [®] diclofenac/misoprostol diclofenac topical diclofenac SR

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):
				diflunisal Duexis [®] CC etodolac SR Feldene [®] fenoprofen Flector [®] CC Indocin [®] indomethacin ER ketoprofen ER meclufenamate mefenamic acid meloxicam suspension Mobic [®] nabumetone Nalfon [®] Naprelan [®] EC naproxen suspension naproxen CR naproxen EC oxaprozin Pennsaid [®] CC Pennsaid [®] Pump ^{CC} Ponstel [®] Sprix [™] CC Tivorbex [®] tolmetin Vimovo [™] QL Voltaren [®] Gel ^{CC} Voltaren [®] XR Zipsor [™] Zorvolex [™]

New Products to Market

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

Drugs Requiring PA:	Criteria:
Rexulti [®]	Rexulti[®] will be placed non-preferred with similar quantity limits in the PDL class titled Second-Generation Antipsychotics.
Daklinza [™]	Daklinza[™] will be Preferred in the Hep C agents class with the following PA criteria: <ul style="list-style-type: none"> ▪ Approve daclatasvir (Daklinza[™]) if ALL of the following are true: <ul style="list-style-type: none"> – Age > 18 years; AND – Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist; AND – Patient is treatment-naïve to all daclatasvir therapy. Limited to one course of therapy per lifetime.; AND

	<ul style="list-style-type: none"> – Patient is NOT taking any of the following contraindicated medications: phenytoin, carbamazepine, rifampin, and St. John’s wort; 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 a diagnosis of HCV genotypes 1, 2, 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: <ul style="list-style-type: none"> ▪ 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, within the past 6 month, 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 level will be required at treatment week 4 for renewal; AND ▪ Have documentation of Disease Severity AND/OR Highest Risk for Disease Progression, defined as: <ul style="list-style-type: none"> – Disease Severity (patient MUST have one of the following): <ul style="list-style-type: none"> ▪ Liver biopsy showing Metavir score of F2-F4; OR ▪ Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa; OR ▪ Evidence of any TWO of the following: <ul style="list-style-type: none"> • 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): <ul style="list-style-type: none"> ▪ 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
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	<ul style="list-style-type: none"> ▪ Membranoproliferative glomerulonephritis; AND ▪ One of the following diagnoses: <ul style="list-style-type: none"> – For a diagnosis of chronic HCV genotype 3 without cirrhosis (Metavir F2-F3) approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: <ul style="list-style-type: none"> ▪ Used in combination with sofosbuvir 400mg daily; and ▪ Approve initially: <ul style="list-style-type: none"> • A dose of 90 mg daily will be approved if the patient is taking a moderate CYP3A inducer (e.g., bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, rifapentine). • A dose of 30 mg daily will be approved if the patient is taking a strong CYP3A inhibitor (e.g., atazanavir/ritonavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, posaconazole, saquinavir, telithromycin, voriconazole). ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: <ul style="list-style-type: none"> • The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND • If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, 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 a diagnosis of chronic HCV genotype 3 with cirrhosis (Metavir F4) approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: <ul style="list-style-type: none"> ▪ Used in combination with sofosbuvir 400mg daily; and ▪ Treatment-naïve versus experienced: <ul style="list-style-type: none"> • Treatment-naïve patients must try and fail therapy sofosbuvir + ribavirin + pegylated interferon for 12 weeks OR sofosbuvir + ribavirin for 24 weeks.; or • Treatment-experienced patients must have tried and failed sofosbuvir + ribavirin + pegylated interferon OR be interferon ineligible; and ▪ Approve initially: <ul style="list-style-type: none"> • A dose of 90 mg daily will be approved if the patient is taking a moderate CYP3A inducer (e.g., bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, rifapentine). • A dose of 30 mg daily will be approved if the patient is taking a strong CYP3A inhibitor (e.g., atazanavir/ritonavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, posaconazole, saquinavir, telithromycin, voriconazole). ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: <ul style="list-style-type: none"> • The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND • If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, the patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested
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	<p>by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND</p> <ul style="list-style-type: none"> • HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4).
<p>Technivie™</p>	<p>Technivie™ will be preferred in the PDL class titled Hep C agents with the following PA criteria:</p> <ul style="list-style-type: none"> ▪ Approved if ALL of the following criteria are met: <ul style="list-style-type: none"> – Age > 18 years; AND – Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist; AND – Patient is NOT taking any of the following contraindicated medications: alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine, dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol-containing medications such as combined oral contraceptives, St. John’s wort, lovastatin, simvastatin, pimozide, efavirenz, and sildenafil (when dosed as Revatio® for the treatment of pulmonary arterial hypertension), triazolam, and orally administered midazolam; 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 a diagnosis of HCV genotypes 1, 2, 3, 5, or 6; AND ▪ Patient does NOT have a cirrhosis; 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: <ul style="list-style-type: none"> – 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 <ul style="list-style-type: none"> ▪ 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, within the past 6 month, 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 level will be required at treatment week 4 for renewal; AND ▪ Have documentation of Disease Severity AND/OR Highest Risk for Disease Progression, defined as: <ul style="list-style-type: none"> – Disease Severity (patient MUST have one of the following): <ul style="list-style-type: none"> ▪ Liver biopsy showing Metavir score of F2-F3; OR ▪ Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa; OR ▪ Evidence of any TWO of the following:

	<ul style="list-style-type: none"> • Fibrotest (FibroSure) score of ≥ 0.49 • Fibrosis-4 index (FIB-4) > 3.25 • Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5; AND/OR <ul style="list-style-type: none"> – Documentation showing patient at the highest risk for severe complications (patient MUST have one of the following): <ul style="list-style-type: none"> ▪ 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 ▪ Diagnosis of chronic HCV genotype 4 without cirrhosis (without Metavir F4) approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: <ul style="list-style-type: none"> – Used in combination with weight-based ribavirin (unless patient is treatment-naïve and cannot tolerate ribavirin). – Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: <ul style="list-style-type: none"> ▪ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ▪ If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, 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). ▪ Of Note: Ombitasvir/ paritaprevir/ ritonavir (Technivie™) will be limited to one course of therapy per lifetime.
<p>Praluent®</p>	<p>Praluent® will be non-preferred in the PCSK9 Inhibitors class with the following PA criteria:</p> <ul style="list-style-type: none"> ▪ Approve alirocumab (Praluent®) if ALL of the following criteria are met: <ul style="list-style-type: none"> – For initial therapy (initial 3 months): <ul style="list-style-type: none"> ▪ Patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) as confirmed by genotyping or by clinical criteria (“definite FH” using either the Simon Broome or WHO/Dutch Lipid Network criteria); AND ▪ Patient age ≥ 18 years; AND ▪ Request is from or in consultation with a specialist (including cardiologists, lipidologists, or endocrinologists); AND ▪ Patient has tried and failed highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) AND ezetimibe for at least three continuous months with failure to reach target LDL-C (70 mg/dL for patients with clinical ASCVD and 100 mg/dL for patients with HeFH and no history of clinical ASCVD). – If the patient failed to reach target LDL-C (<70 mg/dL for patients with clinical ASCVD and <100 mg/dL for patients with HeFH and no history of clinical ASCVD), adherence to maximally-tolerated statin and ezetimibe has been verified using pharmacy claims data and the patient is determined to be compliant for at least three consecutive months prior to the lipid panel

	<p>demonstrating suboptimal reduction; or</p> <ul style="list-style-type: none"> – If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms. <ul style="list-style-type: none"> ▪ Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following: <ul style="list-style-type: none"> • Muscle symptoms resolve after discontinuation of statin; and • Muscle symptoms occurred when rechallenged at a lower dose of the same statin; and • Muscle symptoms occurred after switching to an alternative statin; and • Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); or ▪ The patient has been diagnosed with statin-induced rhabdomyolysis <ul style="list-style-type: none"> • The diagnosis should be supported by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually >5,000 IU/L or five times the upper limit of normal); AND – Maximally-tolerated statin will continue to be used; AND – Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor; AND – Request is being made for the lowest approved dose to adequately treat the patient. Requests for an escalated dose must contain a lipid panel documenting suboptimal reduction in LDL-C after at least 4 weeks of the lower dose. ▪ For continuation of therapy: <ul style="list-style-type: none"> – Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating therapy; AND – Continued adherence to maximally-tolerated statin dose established prior to the original approval.
<p>Repatha™</p>	<p>Repatha™ will be non-preferred in the PCSK9 Inhibitors class with the following PA criteria:</p> <ul style="list-style-type: none"> ▪ Approve evolocumab (Repatha™) if ALL of the following criteria are met: <ul style="list-style-type: none"> – For initial therapy (initial 3 months): <ul style="list-style-type: none"> ▪ Patient has a diagnosis of: <ul style="list-style-type: none"> • Atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) as confirmed by genotyping or by clinical criteria (“definite FH” using either the Simon Broome or WHO/Dutch Lipid Network criteria); or • Homozygous familial hypercholesterolemia (HoFH) as confirmed by either: <ul style="list-style-type: none"> – Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality; or – A history of an untreated LDL-C concentration > 500 mg/dL and triglycerides <300 mg/dL and both parents with documented untreated TC >250 mg/dL; AND

	<ul style="list-style-type: none"> ▪ Patient age \geq 18 years if diagnosis is atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) or \geq 13 years if diagnosed with homozygous familial hypercholesterolemia (HoFH); AND ▪ Request is from or in consultation with a specialist (including cardiologists, lipidologists, or endocrinologists); AND ▪ Patient has tried and failed highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) AND ezetimibe for at least three continuous months with failure to reach target LDL-C (70 mg/dL for patients with clinical ASCVD and 100 mg/dL for patients with HeFH and no history of clinical ASCVD). ▪ If the patient failed to reach target LDL-C ($<$70 mg/dL for patients with clinical ASCVD and $<$100 mg/dL for patients with HeFH or HoFH and no history of clinical ASCVD), adherence to maximally-tolerated statin and ezetimibe has been verified using pharmacy claims data and the patient is determined to be compliant for at least three consecutive months prior to the lipid panel demonstrating suboptimal reduction; or ▪ If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms. <ul style="list-style-type: none"> • Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following: <ul style="list-style-type: none"> – Muscle symptoms resolve after discontinuation of statin; and – Muscle symptoms occurred when rechallenged at a lower dose of the same statin; and – Muscle symptoms occurred after switching to an alternative statin; and – Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); or ▪ The patient has been diagnosed with statin-induced rhabdomyolysis <ul style="list-style-type: none"> – The diagnosis should be supported by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually $>$5,000 IU/L or five times the upper limit of normal); AND – Maximally-tolerated statin will continue to be used; AND – Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor. ▪ For continuation of therapy: <ul style="list-style-type: none"> – Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating therapy; AND – Continued adherence to maximally-tolerated statin dose established prior to the original approval.
Synjardy [®]	Synjardy [®] will be non-preferred in the SGLT2 Inhibitors class

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:

- ❖ Zolpidem Sublingual / Oral Spray (Edluar[®] / Intermezzo[®] / Zolpimist[™])
- ❖ Tasimelteon (Hetlioz[®])
- ❖ Dantrolene
- ❖ Buprenorphine Transdermal (Butrans[™])
- ❖ Fentanyl Transdermal
- ❖ Hydrocodone Extended-Release
- ❖ Methadone
- ❖ Tapentadol Extended-Release (Nucynta[®] ER)
- ❖ Fentanyl Buccal Products
- ❖ Combination Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
- ❖ Topical Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

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 November 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.