** Fee-For-Service Pharmacy Provider Notice #238 – September 2019 PDL Changes **

November 8, 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 September 24, 2019.

The Kentucky Medicaid FFS Pharmacy and Therapeutics Advisory Committee (Committee) met on September 19, 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 December 9, 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):
Angiotensin Modulator Combinations	amlodipine/benazepril valsartan/amlodipine	amlodipine/valsartan/HCTZ	*Exforge HCT®*	*Azor™* *Exforge®* *Lotrel®* *olmesartan/amlodipine* *olmesartan/amlodipine/HCTZ* *Tarka®* *telmisartan/amlodipine* *verapamil/trandolapril*
Oral Anti-Arrhythmics	amiodarone 100, 200mg disopyramide dofetilide flecainide mexiletine propafenone quinidine sulfate quinidine sulfate ER Sorine® sotalol sotalol AF		*quinidine gluconate ER*	*amiodarone 400 mg* *Betapace®* *Betapace AF®* *Multaq®* *Norpace®* *Norpace® CR* Pacerone® propafenone SR *Rythmol SR®* *Tikosyn®*
Anticoagulants	Eliquis® enoxaparin Jantoven® Pradaxa® warfarin Xarelto®		*Bevyxxa™ CC, QL*	*Arixtra™* *Coumadin®* *fondaparinux* *Fragmin®* *Lovenox®* *Savaysa™*

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):
Anticonvulsants: Carbamazepine Derivatives	carbamazepine tablets carbamazepine ER capsules (generic Carbatrol®) carbamazepine ER tablets Equetro™ oxcarbazepine QL Tegretol® suspension			*Aptiom® QL* *carbamazepine suspension* *Carbatrol®* *Epitol®* *Oxtellar™ XR QL* *Tegretol® tablets* *Tegretol® XR* Trileptal® QL
Anticonvulsants: First Generation	Celontin® clonazepam tablets QL Diastat® QL divalproex delayed-release divalproex sprinkle ethosuximide felbamate Peganone® phenobarbital CC phenytoin IR/ER primidone CC valproate valproic acid	clobazam QL divalproex sodium ER	*Phenytek®*	*clonazepam ODT* *Depakene®* *Depakote®* *Depakote® Sprinkle* *diazepam rectal gel QL* *Dilantin®* *Felbatol®* *Klonopin® QL* *Mysoline®* *Onfi™ CC, QL* *Sympazan™ CC, QL* *Zarontin®*
Anticonvulsants: Second Generation	Banzel® CC, QL Gabitril® QL lamotrigine chewable tablets, tablets (except dose packs) levetiracetam solution, tablets QL Sabril® CC topiramate QL zonisamide QL	levetiracetam ER QL	*Diacomit™ CC, QL*	*Briviact® QL* *Epidiolex™ CC* *Fycompa™, QL* *Keppra® tablets QL, solution* *Keppra XR® QL* *Lamictal®* *Lamictal ODT®* *Lamictal® XR ™ QL* *lamotrigine dose packs* *lamotrigine ER QL* *lamotrigine ODT* *Qudexy® XR QL* *Spritam QL* *tiagabine QL* *Topamax® QL* *topiramate ER QL* *Trokendi XR™ QL* *vigabatrin* *Vimpat® QL*
Antidepressants: MAOIs	N/A			*Emsam®* *Marplan®* *Nardil®* *Phenelzine* *tranylcypromine*

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):
Antidepressants: Other	bupropion bupropion XL 150, 300 mg tablets bupropion SR trazodone		*Spravato™ CC, QL*	*Aplenzin™* *bupropion XL 450 mg tablets* *Forfivo XL™* *nefazodone* *Viibryd™* *Trintellix™* *Wellbutrin®* *Wellbutrin®* SR *Wellbutrin®* XL
Antidepressants: SNRIs	desvenlafaxine succinate ER (generic Pristiq®) venlafaxine venlafaxine ER capsules			*desvenlafaxine ER base* *desvenlafaxine fumarate ER* *Effexor XR®* *Fetzima®* *Khedezla™* *Pristiq®* venlafaxine ER tablets
Antimigraine Agents, Other	Emgality™ 120 mg/mL CC, QL		*Emgality™ 100 mg/mL CC, QL*	*Aimovig™ QL* *Ajovy™ QL*
Parkinson's Disease	amantadine capsules, syrup benztropine Comtan® levodopa/carbidopa levodopa/carbidopa CR levodopa/carbidopa ODT selegiline tablets trihexyphenidyl	amantadine tablet selegiline capsule		*Azilect®* *carbidopa* *Duopa™* *entacapone* *Gocovri™* *Inbrija™* *levodopa/carbidopa/entacaone* *Lodosyn®* *Osmolex™ ER* *rasagiline* *Rytary™* *Sinemet®* *Sinemet® CR* *Stalevo®* *Tasmar®* *tolcapone* *Xadago® QL* *Zelapar™*
First Generation Antipsychotics	amitriptyline/ perphenazine chlorpromazine fluphenazine haloperidol loxapine perphenazine thioridazine thiothixene trifluoperazine			*Adasuve®* *pimozide*

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):
Second-Generation Antipsychotics	aripiprazole tablets CC, QL clozapine tablets CC, QL Latuda® CC, QL olanzapine CC, QL quetiapine CC, QL quetiapine ER CC, QL risperidone CC, QL Saphris® CC, QL ziprasidone CC, QL		*Symbyax® CC, QL*	*Abilify® oral formulations QL* *aripiprazole ODT, oral solution* *clozapine ODT QL* *Clozaril® QL* *Fanapt™ QL* *FazaClo® QL* *Geodon® QL* *Invega® QL* *Nuplazid™ QL* *olanzapine/fluoxetine QL* *paliperidone QL* *Rexulti® QL* *Risperdal® QL* *Seroquel® QL* *Seroquel® XR 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 ER™ QL* *Aristada Initio™ QL* *Haldol® Decanoate QL* *Haldol® Lactate QL* *Perseris™* *Zyprexa® QL* *Zyprexa® Relprevv QL*
Antianxiety Agents	alprazolam IR tablets MD buspirone chlordiazepoxide MD diazepam oral solution, tablets MD lorazepam MD		*oxazepam MD*	*alprazolam ER MD* *alprazolam ODT MD* *alprazolam Intensol MD* *Ativan® MD* *clorazepate MD* *diazepam Intensol MD* *meprobamate CC* *Tranxene-T® MD* *Valium® MD* *Xanax® MD* *Xanax XR MD*
Calcium Channel Blockers (DHP)	amplodipine nifedipine ER/SA/SR			*Adalat CC®* *Afeditab™ CR* *Dynacirc®* *felodipine ER* *isradipine* *Katerzia™* *nicardipine* *nifedipine IR*

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):
				nimodipine *nisoldipine ER* *Norvasc®* *Nymalize®* *Plendil®* *Procardia®* *Procardia XL®* *Sular®*
Calcium Channel Blockers (Non-DHP)	diltiazem diltiazem ER verapamil verapamil ER (except 360 mg capsules)		*diltiazem LA*	*Calan®* *Calan® SR* *Cardizem®* *Cardizem CD®* *Cardizem LA®* *Cartia XT* *Dilt-XR* *Diltia XT®* *Matzim LA™* *Taztia XT* *Tiazac®* *verapamil ER 360 mg capsules* *verapamil ER PM* *Verelan®* *Verelan PM®*
Neuropathic Pain	duloxetine DR (generic Cymbalta®) gabapentin capsules, solution, tablets QL Lyrica® capsules CC, QL		*Lyrica oral solution CC*	*Cymbalta®* *DermacinRx PHN Pak™* *duloxetine (generic Irenka™)* *Gralise™* *Horizant®* *lidocaine 5% patch CC, QL* *Lidoderm® QL* *Lyrica® CR QL* *Neurontin® QL* *pregabalin capsules QL* *pregabalin oral solution* *Savella®* *ZTlido™*
Narcolepsy Agents	modafinil CC, QL			*armodafinil QL* *Nuvigil® QL* *Provigil® CC, QL* *Xyrem® 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):
Stimulants and Related Agents	Aptensio XR® (methylphenidate ER capsules) CC, QL atomoxetine CC, QL dexmethylphenidate CC, QL dextroamphetamine CC, QL Focalin XR® CC, QL guanfacine ER CC, QL methylphenidate tablets CC, QL mixed amphetamine salts tablets CC, QL mixed amphetamine salts ER capsules CC, QL Quillivant XR® (methylphenidate ER suspension) CC, QL Vyvanse® capsules, chewable tablets CC, QL	QuilliChew ER™ CC, QL Dyanavel® XR CC, QL		*Adderall® QL* *Adderall XR® QL* *Adhansia XR™ QL* *Adzenys ER™* *Adzenys XR-ODT™ QL* *amphetamine sulfate* *clonidine ER QL* *Concerta® QL* *Cotempla XR-ODT™ QL* *Daytrana® QL* *Desoxyn® QL* *Dexedrine® QL* *dexmethylphenidate ER QL* *dextroamphetamine ER QL* *dextroamphetamine solution QL* *Evekeo® QL* *Evekeo® ODT QL* *Focalin® QL* *Intuniv® QL* *Jornay PM™ QL* *Metadate® ER QL* *methamphetamine QL* *Methylin® solution QL* *methylphenidate CD (generic Metadate CD®) QL* *methylphenidate chewable tablets QL* *methylphenidate ER tablets QL* *methylphenidate ER OROS (generic Concerta®) QL* *methylphenidate LA (generic Ritalin LA®) QL* *methylphenidate solution QL* *Mydayis™ QL* *ProCentra® QL* *Relexxii QL* *Ritalin® QL* *Ritalin LA® QL* *Strattera® QL* *Zenzedi® QL*

Criteria Review

Clinical Criteria Review: Emaglity™ for Episodic Cluster Headache

Non-prefer for this indication/ strength in the PDL class *Antimigraine: CGRP Inhibitors*
Length of Authorization: 3 months initial; 1- year renewal
Emgality™ (galcanezumab-gnlm) is a calcitonin gene-related peptide (CGRP) antagonist indicated in adults for the preventive treatment of migraine and treatment of episodic cluster headache.
Criteria for Approval

- Diagnosis of episodic cluster headache; AND
- Prescribed by, or in consultation with, a neurologist or headache specialist; AND
- If female of childbearing potential, negative pregnancy screening.

Renewal Criteria

- Patient has an overall improvement in function with therapy; AND
- If female, of child-bearing age, continued monitoring for pregnancy.

Age Limit: ≥ 18 years
Quantity Limit: 300 mg per 30 days

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.

- Alzheimer's Agents
- Angiotensin Modulators
- Antianginal & Anti-Ischemic
- Antidepressants, SSRIs
- Antidepressants, Tricyclic
- Antimigraine Agents, Triptans
- Beta-Blockers
- Bladder Relaxant Preparations
- BPH Treatments
- Lipotropics, Other
- Lipotropics, Statins
- Movement Disorders
- PAH Agents, Oral and Inhaled
- Platelet Aggregation Inhibitors
- Sedative Hypnotics
- Skeletal Muscle Relaxants
- Smoking Cessation

New Products to Market

Drugs Requiring PA	Criteria for Prior Authorization

Evenity™	Non-prefer in the PDL class: *Bone Resorption Suppression and Related Agents*
	Length of Authorization: 1 year; no
	• Evenity™ (romosozumab-aqqg**)** is a sclerostin inhibitor indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for the fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
	• Romosozumab-aqqg carries a limitation for use in that it should only be used for a maximum of 12 monthly doses because of decreased efficacy after that time. If further treatment for osteoporosis is necessary, it is recommended to switch to another anti-resorptive agent.
	Criteria for Approval:
	• Patient is a postmenopausal female; AND
	• Diagnosis of osteoporosis; AND
	• Member has 1 or more risk factors for fracture including, but not limited to:
	  ○ History of an osteoporotic fracture as an adult
	  ○ Parental history of hip fracture
	  ○ Low BMI
	  ○ Rheumatoid arthritis
	  ○ Alcohol intake (3 or more drinks per day)
	  ○ Current smoking
	  ○ History of oral glucocorticoids ≥ 5mg/day of prednisone (or equivalent) for > 3 months; AND
	• Documented intolerance contraindication of treatment failure/ineffective response to a minimum 12-month trial on a previous therapy with:
	  ○ Bisphosphonates (oral or intravenous [IV]) such as alendronate, risedronate, or zoledronic acid; AND
	  ○ RANKL-blocking agents such as Prolia ® (denosumab); OR
	• Patient has extremely low bone mineral density (BMD) defined as a T-score < -3.5 or a T-score < -2.5 with a history of fragility fractures; AND
	• Member has NOT had a myocardia infarction or stroke within the past 12 months.
	Age Limit: ≥ 18 years
	Quantity Limit: 2 syringes per 30 days

Skyrizi™	Non-prefer in the PDL class: *Immunomodulators (Cytokines and CAM Antagonists)* **Length of Authorization:** 1 year Skyrizi™ (risankizumab-rzaa) is an interleukin-23 antagonist indicated for the treatment of moderate-to-severe plaque psoriasis (PSO) in adults who are candidates for the systemic therapy or phototherapy. **Criteria for Approval**: • Diagnosis of moderate to severe plaque psoriasis; AND • Symptoms persistent for ≥ 6 months with at least 1 of the following:

Drugs Requiring PA	Criteria for Prior Authorization
	○ Involvement of at least 10% of body surface area (BSA); OR ○ Psoriasis Area and Severity Index (PASI) score of 12 or greater; OR ○ 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: ○ Methotrexate ○ Cyclosporine ○ Oral retinoid (e.g., Soriatane®, acitretin) ○ Topical corticosteroids ○ Phototherapy/ UV light ○ Coal tar preparations; AND • Trial and failure of, or contraindication to, a preferred immunomodulator (i.e., Enbrel® or Humira®); AND • Medication will not be used in combination with any other agent in the immunomodulator class. **Renewal Criteria** • Patient continues to meet criteria identified above; AND • Ongoing monitoring for TB; AND • Disease response (e.g., progress note) as indicated by the 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**: 2 syringes per 12 weeks; call center to override loading dose
Mavenclad®	Non-prefer in the PDL class: *Multiple Sclerosis Agents* **Length of Authorization:** 35 days initial; one 35-day renewal Mavenclad® (cladribine) is a purine antimetabolite indicated for the treatment of adults with relapsing forms of multiple sclerosis (MS), to include relapsing -remitting disease and active secondary progressive disease. Due to its safety profile, use is generally recommended for patients who have an inadequate response to or are unable to tolerate an alternate drug indicated to treat MS. **Criteria for Approval**: • Prescribed by a neurologist or multiple sclerosis specialist; AND • Diagnosis of relapsing-remitting MS (RRMS) OR active secondary progressive MS (SPMS); AND • Patient has had an inadequate response to, or is unable to tolerate, at least 2 or more MS treatments; AND • Patient does NOT meet ANY of the following conditions: ○ Human immunodeficiency virus (HIV), hepatitis B or C infection, or tuberculosis (TB) infection; ○ Current cancer or malignancy; ○ Current systemic, or clinically significant local, infection;

Drugs Requiring PA	Criteria for Prior Authorization
	○ Use of any other antineoplastic, immunosuppressive or immunomodulator drugs to treat other conditions; ○ Use of cladribine in combination with other MS agents; AND • Patient has had or will have ALL of the following: ○ Screening for hepatitis B/C, HIV, and TB infections; AND ○ Testing for antibodies to the varicella zoster virus (VZV) OR have received immunization for VZV at least 4 to 6 weeks prior to beginning therapy; AND ○ Baseline MRI ≤ 3 months before initiating the first treatment course; AND ○ For women of childbearing potential, a negative pregnancy test and counseling on contraception use during therapy. **Renewal Criteria** • At least 43 weeks has/will have elapsed since the end of the first treatment course; AND • Continue to meet initial approval criteria; AND • Prescribed by a neurologist or multiple sclerosis specialist; AND • Documentation of response to therapy (e.g., progress note) **Age Limit**: ≥ 18 years **Quantity Limit**: 100 mg per cycle (2 cycles per approval)
Mayzent®	Non-prefer in the PDL class: *Multiple Sclerosis Agents* **Length of Authorization:** 1 year Mayzent® (siponimod), a sphingosine 1-phosphate (S1P) receptor modulator, is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS), and active secondary progressive disease (SPMS) in adults. **Criteria for Approval:** • Initially prescribed by a neurologist or multiple sclerosis specialist (non-specialist may renew and refill); AND • Patient has a diagnosis of a relapsing form of multiple sclerosis (MS): relapsing-remitting MS (RRMS) active secondary progressive MS (SPMS), or clinically isolated syndrome (CIS); AND • Patient has had an inadequate response to, or is unable to tolerate, 1 or more preferred MS agent; AND • Patient does NOT meet ANY of the following conditions: ○ Presence of contraindicated cardiovascular comorbidities (e.g., recent heart attach or stroke, heart failure) ○ Current systemic or clinically significant local infection; ○ Use of any other antineoplastic, immunosuppressive or immunomodulating drugs to treat other conditions; ○ Use of siponimod in combination with another MS agent; ○ Prior use of alemtuzumab; AND • Patient has had or will have ALL of the following: ○ CYP2C9 variant genotyping testing to guide dosing; AND ○ Screening for clinically significant drug interactions; AND

Drugs Requiring PA	Criteria for Prior Authorization
	○ Baseline electrocardiogram (ECG), liver function tests (LFTs) and ophthalmic evaluation; AND ○ If pre-existing non-contraindicated cardiac disease (e.g., arrhythmia), cardiology consultation and follow-up will be conducted prior to and during treatment; AND ○ Testing for antibodies to the varicella zoster virus (VZV) OR have received immunization for VZV at least 4 to 6 weeks prior to beginning therapy. **Renewal Criteria** • Continue to meet initial approval criteria; AND • Documentation of response to therapy (e.g., progress note) **Age Limit:** ≥ 18 years **Quantity Limit:** 2 mg: 1 per day; 0.25 mg: 4 per day
Piqray®	Prefer with criteria in the PDL class: *Oral Oncology- Breast (Oncology, Oral- Breast)* **Length of Authorization:** 1 year Piqray® (alpelisib), a phosphatidylinositol- 3- kinase (PI3K) inhibitor, is indicated for use in combination with fulvestrant for the treatment of me and postmenopausal women with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)- negative, PI3K-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen. **Criteria for Approval** • If female, patient is postmenopausal; AND • Diagnosis of advanced or metastatic breast cancer that is: ○ Hormone receptor- positive (HR-positive); AND ○ HER2-negative; AND ○ PIK3CA- mutation positive as detected by an FDA- approved companion diagnostic; AND ○ Progressing during, or relapsing within 12 months following, endocrine-based treatment; AND • Patient has NOT previously received any of the following therapies: ○ Chemotherapy for advanced breast cancer; OR ○ Another PI3K inhibitor (e.g., copanlisib, duvelisib); OR ○ An mTOR inhibitor (e.g., everolimus); AND • Medication will be given in combination with fulvestrant. **Renewal Criteria** • Continue to meet initial approval criteria; AND • Evidence, such as progress report, of disease response (e.g., lack of progression or decrease in tumor size and spread). **Age Limit:** ≥ 18 years **Quantity Limit:** 200 mg daily dose pack: 1 per day; 250/300 mg daily dose pack: 2 per day

Drugs Requiring PA	Criteria for Prior Authorization
Balversa™	Non-prefer in the PDL class: *Oral Oncology Agents-Other* **Length of Authorization:** 12 months Balversa™ (erdafitinib), a kinase inhibitor that binds and inhibits enzymatic activity of fibroblast growth factor receptor (FGFR) 1, FGFR2, FGFR3, FGFR4 and several other kinases, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) that has susceptible FGFR3 or FGFR2 genetic alterations and has progressed during or following ≥ 1 line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. **Criteria for Approval** • Diagnosis of locally advanced or metastatic urothelial carcinoma; AND • Susceptible point mutation in fibroblast growth factor receptor (FGFR)-3 as determined by an FDA- approved companion diagnostic; AND • Disease progressed during, or relapsed within 12 months following, platinum-based chemotherapy; AND • Medication will be used as a single agent therapy. **Renewal Criteria** • Continue to meet initial approval criteria; AND • Evidence, such as progress report, of disease response (e.g., lack of progression or decrease in tumor size and spread). **Age Limit:** ≥ 18 years **Quantity Limit:** 3, 4, and 5 mg tablets: 3, 2, and 1 per day (respectively)
Bevyxxa™	Non-prefer in the PDL class: *Anticoagulants* **Length of Authorization:** 42 days Bevyxxa™ (betrixaban) is an oral factor Xa inhibitor indicated for the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE. The safety and efficacy of betrixaban has not been established in patients with prosthetic heart valves because that population has not been studied. **Criteria for Approval** • Patient is hospitalized for an acute medical illness; AND • Intolerance, contraindication, or trial and failure of a preferred anticoagulant. **Age Limit:** ≥ 18 years **Quantity Limit:** up to 31 capsules per 30 days
Diacomit™	Non-prefer in the PDL class: *Anticonvulsants: Second Generation* **Length of Authorization:** 1 year Diacomit™ (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients ≥ 2 years of age taking clobazam. There are no clinical data to support the use of stiripentol as monotherapy in Dravet syndrome. **Criteria for Approval** • Diagnosis of Dravet syndrome; AND • Prescriber is, or has a consultative relationship with, a neurology/ epilepsy specialist; AND

Drugs Requiring PA	Criteria for Prior Authorization
	• Medication will be used in adjunct to ≥ 1 antiepileptic drug, including clobazam; AND • Trial and failure (e.g., incomplete seizure control) of at least 2 antiepileptic drugs; OR • Patient is continuing therapy (e.g., using ex-US supply). **Renewal Criteria** • Continue to meet initial approval criteria; AND • Evidence (e.g., a progress report) of effectiveness. **Age Limit:** ≥ 2 years **Quantity Limit:** 250 mg: 12 per day; 500 mg: 6 per day

Spravato™	Non-prefer in the PDL class: *Antidepressants: Other*
	Length of Authorization: 4 weeks initial; 1-year renewal
	Spravato™ (esketamine), classified as a Schedule III controlled substance, is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist approved for treatment-resistant depression (TRD) in conjunction with an oral antidepressant.
	Criteria for Approval
	• Diagnosis of major depressive disorder (MDD) and prescriber has performed baseline depression assessment using any validated rating scale; AND
	• Prescribed by, or in consultation with, a psychiatrist or psychiatric mental health nurse practitioner (PMHNP); AND
	• Trial and failure (defined as < 50% reduction in symptom severity using any validated depression rating scale) of ≥ 2 antidepressants from different classes for a duration of ≥ 6 weeks each at generally accepted doses in the current depressive episode, unless contraindicated or clinically significant adverse effects are experienced; AND
	• Trial and failure of antidepressant augmentation therapy for a duration of ≥ 6 weeks in the current depressive episode with ≥ 1 of the following, unless contraindicated or clinically significant adverse effects are experienced:
	  ○ An atypical antipsychotic; OR
	  ○ Lithium; OR
	  ○ An antidepressant from a different class; AND
	• Used in conjunction with another antidepressant medication (not to be used as monotherapy); AND
	• If female of childbearing potential, NOT pregnant or planning to become pregnant; AND
	• Prescriber attests that:
	  ○ An accessible treatment center certified in the Spravato Risk Evaluation and Mitigation Strategies (REMS) program has been identified; AND
	  ○ Dosing schedule has been reviewed with patient; AND
	  ○ Patient understands and is committed to dosing schedule and requirements (e.g., office visits, transportation).
	Renewal Criteria
	• Continue to meet initial approval criteria; AND
	• Prescriber attestation that patient has been compliant with doses/ appointments; AND

Drugs Requiring PA	Criteria for Prior Authorization
	• Attestation or documentation of disease improvement or stabilization as evidenced by improvement on a validated depression rating scale. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 kit (56 or 84 mg) per week; call center to override for twice weekly dosing

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 September 19, 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.