** Fee-For-Service Pharmacy Provider Notice #232 – September 2018 PDL Changes **

January 3, 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 October 31, 2018.

The Kentucky Medicaid FFS Pharmacy and Therapeutics Advisory Committee (Committee) met on September 20, 2018. The Committee did not attain the necessary quorum; the expertise, vote, and recommendations of the Committee members in attendance were captured within the Committee's official recommendations delivered for review. DMS, through its Commissioner, reviewed the recommendations and in consultation rendered its final decisions.

On <u>February 4, 2019</u>, the following changes will be effective:

New Drug Classes

Drug Class	The following products will become *preferred* products:	The following products will become *non-preferred* products and require prior authorization (PA):
Antimigraine: CGRP Inhibitors	N/A	*Aimovig™* CC, QL
Ophthalmics, Glaucoma Agents (Other)	N/A	*Rhopressa* CC, QL
Movement Disorders	tetrabenazine	*Austedo®* *Ingrezza®* *Xenazine®*
Neuropathic Pain	*duloxetine DR (generic Cymbalta®)* *gabapentin capsules, solution, tablets* QL *Lyrica®* CC, QL	*Cymbalta®* *DermacinRx PHN Pak™* *duloxetine (generic Irenka™)* *Gralise™* *Horizant®* *lidocaine 5% patch* CC *Lidoderm®* *Lyrica® CR* QL *Neurontin®* QL *Savella®* CC

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):
Anticonvulsants: First Generation	Celontin® clonazepam tablets QL DiaStat® QL			*clonazepam ODT* *Depakene®* *Depakote®*

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):
	divalproex DR divalproex sprinkle ethosuximide felbamate Peganone® phenobarbital CC Phenytek® phenytoin phenytoin ER primidone CC valproic acid			*Depakote ER®* *Depakote® Sprinkle* *diazepam rectal gel QL* *Dilantin®* *divalproex ER* *Felbatol®* *Klonopin® QL* *Mysoline®* *Onfi™ CC, QL* *Zarontin®*
Anticonvulsants: Second Generation	Banzel® CC, QL Gabitril® QL gabapentin capsules, solution, tablets QL lamotrigine chewable tablets, tablets (except dose packs) levetiracetam solution, tablets QL Lyrica® CC, QL Sabril® CC topiramate QL zonisamide QL		*lamotrigine dose packs, ODT*	*Briviact® QL* *Fycompa™ QL* *Gralise™* *Keppra® tablets QL, solution* *Keppra XR® QL* *Lamictal®* *Lamictal ODT®* *Lamictal® XR™ QL* *lamotrigine ER QL* *levetiracetam ER QL* *Lyrica® CR QL* *Neurontin® QL* *Qudexy® XR QL* *tiagabine QL* *Topamax® QL* *topiramate ER QL* *Trokendi XR™ QL* *vigabatrin* *Vimpat® QL* *Zonegran® QL*
Anticonvulsants: Carbamazepine Derivatives	carbamazepine chewable, tablets carbamazepine ER capsules (generic Carbatrol®) Equetro™ oxcarbazepine QL Tegretol® suspension Tegretol® XR			*Aptiom® QL* *carbamazepine ER tablets* *carbamazepine suspension* *Carbatrol®* *Oxtellar™ XR QL* *Tegretol® tablets* *Trileptal® QL*
Dopamine Receptor Agonists	bromocriptine pramipexole ropinirole			*Mirapex®* *Mirapex® ER* *Neupro®* *Parlodel®* *pramipexole ER* *Requip®* *Requip® XL* *ropinirole ER*
Parkinson's Disease	amantadine capsules, syrup benztropine Comtan® levodopa/carbidopa levodopa/carbidopa CR levodopa/carbidopa ODT		*carbidopa*	*Azilect®* *amantadine tablets* *Duopa™* *entacapone* *Gocovri™* *levodopa/carbidopa/entacaone*

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):
	selegiline tablets trihexyphenidyl			*Lodosyn®* *Osmolex™ ER* *rasagiline* *Rytary™* *selegiline capsules* *Sinemet®* *Sinemet® CR* *Stalevo®* *Tasmar®* *tolcapone* *Xadago® QL* *Zelapar™*
Bladder Relaxants	oxybutynin QL Toviaz™ QL VESIcare® QL	oxybutynin ER QL		*darifenacin ER QL* *Detrol® QL* *Detrol® LA QL* *Ditropan® XL QL* *Enablex® QL* *flavoxate QL* *Gelnique™ CC, QL* *Myrbetriq™ QL* *Oxytrol® QL* *tolterodine QL* *tolterodine ER QL* *trospium QL* *trospium ER QL*
Pulmonary Arterial Hypertension (PAH) Agents	Letairis™ sildenafil CC Tracleer® tablets Ventavis®		*Tracleer® 32 mg tablets for suspension*	*Adcirca™* *Adempas® CC* *Opsumit®* *Orenitram ER™* *Revatio™* *Tyvaso™* *Uptravi® QL*
Platelet Aggregation Inhibitors	Aggrenox® Brilinta™ CC cilostazol clopidogrel dipyridamole	prasugrel		*aspirin/dipyridamole* *Effient™* *Plavix®* *ticlopidine* *Zontivity™ CC*
Narcolepsy Agents	Provigil® CC, QL			*armodafinil QL* *modafinil QL* *Nuvigil® QL* *Xyrem® QL*
Stimulants and Related Agents	Adderall XR® 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	Aptensio XR® (methylphenidate ER capsules) QL	*dextroamphetamine ER CC, QL* *Metadate® ER CC, QL* *methylphenidate ER tablets CC, QL* *methylphenidate ER OROS (generic Concerta®) QL*	*Adderall® QL* *Adzenys ER™* *Adzenys XR-ODT™ QL* *clonidine ER QL* *Concerta® QL* *Cotempla XR-ODT™ QL* *Daytrana® QL* *Desoxyn® QL* *Dexedrine® QL* *dexmethylphenidate ER QL* *dextroamphetamine solution 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):
	Quillivant XR® (methylphenidate ER suspension) CC, QL Vyvanse® capsules, chewable tablets CC, QL			*Dyanavel® XR* QL *Evekeo®* QL *Focalin®* QL *Intuniv®* QL *Kapvay®* QL *methamphetamine* QL *Methylin® solution* QL *methylphenidate CD (generic for Metadate CD®)* QL *methylphenidate chewable tablets* QL *methylphenidate LA (generic Ritalin LA®)* QL *methylphenidate solution* QL *mixed amphetamine salts ER* QL *Mydayis™* QL *ProCentra®* QL *QuilliChew ER™* QL *Relexxii* QL *Ritalin®* QL *Ritalin LA®* QL *Strattera®* QL *Zenzedi®* QL

Criteria Review

Compound Claims

Recommended Criteria: Claims for compounded medications ("compounds") that exceed $100 will now be subject to prior authorization (PA). Currently, compound claims will deny due to high cost at $5,000.

Exceptions: The POS system will bypass the PA for claims where the route of administration (ROA) is indicated as intravenous (IV) or intramuscular (IM) AND at least one medication billed is an antibiotic or other anti-infective agent.

Length of Authorization: 1 year
Criteria for Approval (ALL of the following conditions MUST be met):

- The compound contains ≥ 1 covered prescription ("Rx") required ingredient; AND
- ALL active ingredients in the compound product are FDA-approved, or are supported by peer-reviewed, medical literature and/or CMS-approved compendia (e.g., Micromedex) for the diagnosis in the requested route of delivery; AND
- If any ingredient in the compounded product requires PA, the member must meet the PA criteria for that ingredient; AND
- The member's drug therapy needs are unable to be met by commercially available dosage strengths and/or forms of the drug, as indicated by one of the following:
    - The FDA-approved or evidence-based dosage required for the patient's age or weight cannot be achieved with a commercially available product; OR
    - Member has documented dysphagia and/or requires use of a feeding tube and there are no suitable commercially available products within the drug class; OR
    - Member has a documented sensitivity to dyes, preservatives, or fillers in commercial products and requires a specialized preparation; OR
    - There is a current supply shortage of the commercial product; OR
    - The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness.

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 Modulator Combinations
- Angiotensin Modulators:
- Antialcoholic Preparations
- Antianginal & Anti-Ischemic
- Antiarrhythmics, Oral
- Anticoagulants
- Antidepressants, Other
- Antidepressants, SSRIs
- Antidepressants, Tricyclics
- Antimigraine Agents - Triptans
- Antipsychotics
- Anxiolytics
- Beta Blockers
- BPH Treatments
- Calcium Channel Blockers
- Lipotropics, Other
- Lipotropics, Statins
- Sedative Hypnotics
- Skeletal Muscle Relaxants
- Smoking Cessation

New Products to Market

<table>
<tr><th>Drugs Requiring PA</th><th>Criteria</th></tr>
<tr><td>Aimovig™</td><td>
Non-prefer in the PDL class: Antimigraine, Other (Antimigraine: CGRP Inhibitors)
Length of Authorization: 3 months initial; 1 year renewal
Aimovig (erenumab-aooe), a monoclonal antibody that targets the calcitonin gene-related peptide (CGRP) receptor, is indicated for the preventative treatment of migraine in adults. It is available as a 70 mg/mL solution in a single-dose prefilled syringe or auto-injector for monthly subcutaneous administration of 70 or 140 mg as one or two injections, respectively.
Criteria for Approval:
• Diagnosis of migraine with or without aura; AND
• If female of child-bearing age (18-45), negative pregnancy screening; AND
• Trial and failure (≥ 1 month) of at least 2 medications – <u>at least 1 must be level A or B recommendation</u> – listed below from the 2012 American Academy of Neurology/American Headache Society guidelines.
<table>
<tr><th>Level A</th><th>Level B</th><th colspan="2">Level C</th></tr>
<tr><td>AEDs:
-divalproex sodium
-sodium valproate
-topiramate</td><td>Antidepressants:
-amitriptyline
-venlafaxine</td><td>Alpha-agonists:
-clonidine
-guanfacine</td><td>ACE/ARB:
-lisinopril
-candesartan</td></tr>
<tr><td>Beta blockers:
-metoprolol
-propranolol
-timolol</td><td>Beta blockers:
-atenolol
-nadolol</td><td>AEDs:
-carbamazepine</td><td>Beta blockers:
-nebivolol
-pindolol</td></tr>
<tr><td></td><td>NSAIDs:
-fenoprofen
-ibuprofen
-ketoprofen
-naproxen</td><td>Antihistamines:
-cyproheptadine</td><td>NSAIDs:
-flurbiprofen
-mefenamic acid</td></tr>
</table>
AED = antiepileptic drug; ACE = angiotensin converting enzyme inhibitor;
ARB = angiotensin receptor blocker; NSAID = nonsteroidal anti-inflammatory drug

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

Age Limit: <u>≥</u> 18 years
Quantity Limit: 1 package (70 or 140 mg) per month
</td></tr>
</table>

Drugs Requiring PA	Criteria
Olumiant®	Non-prefer in the PDL class: *Cytokine and CAM Antagonists (Immunomodulators)* **Length of Authorization:** 1 year Olumiant® (baricitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. It is available as a 2 mg tablet for oral administration. **Criteria for Approval**: • Diagnosis of moderately to severely active rheumatoid arthritis (RA); AND • Trial and failure (at least 3 months) of at least 1 oral disease-modifying antirheumatic drug (DMARD) such as methotrexate, azathioprine, hydroxychloroquine, leflunomide, etc.; AND • Trial and failure of (at least 3 months), or contraindication to, a preferred immunomodulator (i.e., Enbrel® or Humira®). • Negative tuberculosis (TB) screening prior to initiating treatment; AND • Olumiant® will not be used with a TNFα inhibitor (e.g., Enbrel®, Humira®) or other biologic DMARD (e.g., Actemra®, Orencia®) **Age Limit**: ≥ 18 years **Quantity Limit**: 1 tablet per day
Rhopressa™	Non-prefer in the PDL class: *Ophthalmics, Glaucoma Agents (Other)* **Length of Authorization:** 1 year Rhopressa™ (netarsudil) is indicated to reduce intraocular pressure (IOP) in patients with ocular hypertension (OHT) or open-angle glaucoma (OAG). It is a Rho kinase (ROCK) inhibitor theorized to reduce IOP through the trabecular mesh network; however, the exact mechanism is unknown. **Criteria for Approval**: • Have a diagnosis of ocular hypertension or open-angle glaucoma AND • Have had at least a 1-month trial and failure of a prostaglandin inhibitor and/or beta-adrenergic antagonist. **Age Limit**: ≥ 18 years **Quantity Limit**: 5 mL per 30 days

Drugs Requiring PA	Criteria
Tavalisse™	Non-prefer in the PDL class: *Thrombopoiesis Stimulating Agents* **Length of Authorization:** 3 months initial; 1 year renewal Tavalisse (fostamatinib) is a kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. It is available in 100 and 150 mg tablets for oral administration. **Criteria for Approval**: • Diagnosis of chronic immune thrombocytopenia (ITP); AND • Trial and failure (e.g., not achieved a platelet count ≥ 50 x 10^9/L) of at least 1 other therapy for chronic ITP such as corticosteroids, IV immune globulin, RhO(D) immune globulin, thrombopoietin receptor antagonists, etc. **Renewal Criteria:** • Laboratory values documenting platelet response to therapy (platelet count ≥ 50 x 10^9/L). **Age Limit**: ≥ 18 years **Quantity Limit**: 2 tablets 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 September 20, 2018 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.