** Fee-For-Service Pharmacy Provider Notice #235 – March 2019 PDL Changes **

May 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 April 4, 2019.

The Kentucky Medicaid FFS Pharmacy and Therapeutics Advisory Committee (Committee) met on March 21, 2019. 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 June 3, 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):
Antibiotics, Inhaled	Bethkis® QL Kitabis™ Pak QL			*Cayston® QL* *TOBI® QL* *TOBI Podhaler® QL* *tobramycin inhalation solution QL*
Antivirals: Herpes	acyclovir famciclovir valacyclovir			*Sitavig®* *Valtrex®* *Zovirax®*
Antivirals: Flu	Relenza® rimantadine Tamiflu® QL			*Flumadine®* *oseltamivir QL*
Antibiotics: Cephalosporins 1st Generation	cefadroxil capsules cephalexin			*cefadroxil tablets, suspension* *Daxbia™* *Keflex®*
Antibiotics: Cephalosporins 2nd Generation	cefuroxime axetil	cefaclor capsule cefprozil		*cefaclor tablets, suspension* *cefaclor CD* *Ceftin®*
Antibiotics: Cephalosporins 3rd Generation	cefdinir Suprax® suspension		*cefpodoxime*	*cefditoren pivoxil* *cefixime suspension* *ceftibuten* *Spectracef®* *Suprax® capsules, chewable tablets, tablets*

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):
COPD Agents	albuterol-ipratropium inhalation solution QL Atrovent® HFA QL Bevespi Aerosphere™ QL Combivent® Respimat® QL ipratropium inhalation solution QL Spiriva Handihaler® QL Stiolto™ Respimat® QL	Spiriva® Respimat® QL		*Anoro® Ellipta® QL* *Daliresp™ CC, QL* *Incruse® Ellipta® QL* *Lonhala™ Magnair™ CC, QL* *Seebri™ Neohaler® CC, QL* *Trelegy Ellipta CC, QL* *Tudorza® Pressair™ QL* *Utibron™ Neohaler® CC, QL*
Anti-Infectives: Hepatitis B	entecavir Epivir-HBV® solution lamivudine HBV		*Baraclude™* *Hepsera®*	*adefovir* *Epivir-HBV® tablet* *Vemlidy® CC, QL*
Antiretrovirals: HIV/AIDS	abacavir QL abacavir-lamivudine atazanvir QL Atripla® QL Biktarvy® QL Cimduo™ QL Complera® QL Delstrigo™ QL Descovy® QL Edurant® Emtriva® Evotaz™ QL Genvoya® QL Intelence® Isentress® Juluca QL Kaletra® tablet lamvidudine QL lamivudine-zidovudine lopinavir-ritonavir solution Norvir® suspension QL Norvir® tablets Odefsey® QL Pifeltro™ QL Prezcobix® QL Prezista® Selzentry® stavudine capsules QL stavudine solution Stribild® QL Sustiva® Symfi™ QL Symfi Lo™ QL Symtuza™ QL Tivicay® QL Triumeq® QL Trizivir® Truvada® CC, QL Tybost® Videx® EC QL Viread® powder packets zidovudine syrup, tablets		*Aptivus®* *Crixivan®* *didanosine DR QL* *Fuzeon®* *Invirase®* *Lexiva®* *nevirapine QL* *nevirapine ER QL* *Norvir® powder packets* *Rescriptor®* *Reyataz® powder packets* *Videx® solution* *Viracept®* *Viramune® QL* *Viramune XR® QL* *zidovudine capsules*	*abacavir-lamivudine-zidovudine* *Combivir®* *efavirenz* *Epivir® QL* *Epzicom®* *fosamprenavir* *Kaletra® solution* *ritonavir* *Retrovir®* *Reyataz®* *Zerit® capsules QL* *Ziagen® QL*

Criteria Review

Bile Salts: Ocaliva® (obeticholic acid)

Ocaliva® (obeticholic acid), a farnesoid X receptor (FXR) agonist, is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA, ursodiol) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

Current criteria: Trial and failure of 1 preferred agent.

Recommended criteria:
Length of Authorization: 1 year
Criteria for Approval:

- Diagnosis of primary biliary cholangitis (PBC); AND
- Prescriber is a gastroenterologist, hepatologist, or liver transplant specialist; AND
- Contraindication or intolerance to, or 12-month trail and failure of, ursodiol.

Age Limit: ≥ 18 years
Quantity Limit: 1 per day

Hepatitis C: Directing Acting Antivirals

Current prescriber criteria: Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease provider.

Recommended prescriber criteria: Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, infectious disease or HIV specialist.

Note: All other criteria continue to apply.

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.

- Absorbable Sulfonamides
- Antibiotics, GI
- Antibiotics, Vaginal
- Antifungals, Oral
- Antihistamines, Minimally Sedating
- Bronchodilators, Beta Agonist
- Epinephrine, Self-Injected
- Fluoroquinolones, Oral
- Glucocorticoids, Inhaled
- Hepatitis C Agents
- Hypoglycemics, Alpha-Glucosidase Inhibitors
- Hypoglycemics, Incretin Mimetics/Enhancers
- Hypoglycemics, Insulin and Related Agents
- Hypoglycemics, Meglitinides
- Hypoglycemics, Metformins
- Hypoglycemics, SGLT2
- Hypoglycemics, Sulfonylureas
- Hypoglycemics, Thiazolidinediones (TZD)
- Intranasal Rhinitis Agents
- Leukotriene Modifiers
- Macrolides
- Oxazolidenediones
- Penicillins
- Tetracyclines

New Products to Market

Drugs Requiring PA	Criteria
Epidiolex™	Non-prefer in the PDL class: *Anticonvulsants: Second Generation (Anticonvulsants)* **Length of Authorization:** 1 year • Epidiolex™ (cannabidiol), a non-psychoactive cannabinoid receptor antagonist, is approved for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients ≥ 2 years of age. The mechanism by which cannabidiol exerts its anticonvulsant effects is unknown. • Cannabidiol (Epidiolex) is a Schedule V controlled substance. **Criteria for Approval**: • Diagnosis of Lennox-Gastaut syndrome (LGS) OR Dravet syndrome (DS); AND • Prescriber is, or has a consultative relationship with, a neurology/epilepsy specialist; AND • Trial and failure (e.g., incomplete seizure control) of at least 2 antiepileptic drugs; AND • Must be used in adjunct with ≥ 1 antiepileptic drug. **Age Limit**: ≥ 2 years
Ajovy™	Non-prefer in the PDL class: *Antimigraine: CGRP Inhibitors (Antimigraine, Other)* **Length of Authorization:** 3 months initial; 1 year renewal • Ajovy™ (fremanezumab-vfrm) is a calcitonin gene-related peptide (CGRP) antagonist indicated for the preventive treatment of migraine in adults. **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 (3 months), intolerance, or contraindication to at least 1 preferred CGRP inhibitor. **Renewal Criteria** • Patient has an overall improvement in function with therapy (e.g., fewer and/or less severe migraine days per month); AND • If female of child-bearing age, continued monitoring for pregnancy. **Age Limit**: ≥ 18 years **Quantity Limit**: 1 syringe (225 mg) per 30 days

<table>
<tr><th>Drugs Requiring PA</th><th>Criteria</th></tr>
<tr><td>Emgality™</td><td>Prefer with clinical criteria in the PDL class: Antimigraine: CGRP Inhibitors (Antimigraine, Other)
Length of Authorization: 3 months initial; 1 year renewal
• Emgality™ (galcanezumab-gnlm) is a calcitonin gene-related peptide (CGRP) antagonist indicated for the preventive treatment of migraine in adults indicated for the preventative treatment of migraine in adults.
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 listed below from the 2012 American Academy of Neurology/American Headache Society guidelines – <u>at least 1 must be level A or B recommendation</u>:
<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 (e.g., fewer and/or less severe migraine days per month); AND
• If female of child-bearing age, continued monitoring for pregnancy.
Age Limit: <u>≥</u> 18 years
Quantity Limit: 240 mg (2 prefilled pens or syringes) once, then 120 mg (1 prefilled pen or syringe) per 30 days</td></tr>
</table>

Drugs Requiring PA	Criteria
Talzenna™	Prefer with clinical criteria in the PDL class: *Oral Oncology, Breast Cancer (Oncology, Oral – Breast)* **Length of Authorization:** 1 year • Talzenna™ (talazoparib) is a poly ADP-ribose polymerase (PARP) inhibitor indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer. Patient selection is based on confirmation of germline BRCA-mutated status via an FDA-approved companion diagnostic. **Criteria for Approval:** • Diagnosis of deleterious or suspected-deleterious germline BRCA-mutated locally advanced or metastatic breast cancer as detected by an FDA-approved test; AND • Member has NOT received prior therapy with a PARP inhibitor; AND • Medication will not be used in combination with another PARP inhibitor; AND • Medication is used as subsequent treatment to prior chemotherapy in the neoadjuvant, adjuvant, locally advanced or metastatic treatment setting, which included a taxane and/or an anthracycline. **Renewal Criteria:** • Continue to meet initial approval criteria; AND • Evidence of tumor response or lack of disease progression. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 mg: 1 per day; 0.25 mg: 3 per day

Copiktra™	Non-prefer in the PDL class: *Oral Oncology, Hematologic Cancer (Oncology, Oral – Hematologic)*
	Length of Authorization: 12 months
	• Copiktra™ (duvelisib) is a phosphtidylinositol-3 kinase (PI3K) inhibitor indicated for the treatment of adult patients with:
	  ○ Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies.
	  ○ Relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies.
	Criteria for Approval:
	• Diagnosis of chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/SLL) that has relapsed or is refractory after ≥ 2 prior therapies, which include treatment with ofatumumab; OR
	• Diagnosis of low-grade follicular lymphoma that has relapsed or is refractory, after ≥ 2 prior therapies including both rituximab AND chemotherapy OR radioimmunotherapy; AND
	• Medication will be used as a single agent; AND
	• Patient has not received previous therapy with a small-molecule inhibitor (phosphtidylinositol-3 kinase inhibitor [PI3-K]) therapy (e.g., idelalisib, copanlisib); AND
	• Patient has not received previous therapy with a Bruton's tyrosine kinase (BTK) inhibitor (e.g., ibrutinib, acalabrutinib).
	Renewal Criteria:
	• Continue to meet initial approval criteria; AND
	• Evidence of tumor response or lack of disease progression.
	Age Limit: ≥18 years
	Quantity Limit: 2 per day

Drugs Requiring PA	Criteria
Daurismo™	Prefer with clinical criteria in the PDL class: *Oral Oncology, Hematologic Cancer (Oncology, Oral – Hematologic)* **Length of Authorization:** 12 months • Daurismo™ (glasdegib) is an inhibitor of the hedgehog (Hh) signaling pathway and is indicated, in combination with low-dose cytarabine, for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adult patients who are ≥ 75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy. **Criteria for Approval**: • Diagnosis of acute myeloid leukemia (AML) that is newly diagnosed; AND • Member is ≥75 years old OR not a candidate for intensive induction chemotherapy; AND • Medication will be used with low-dose cytarabine. **Renewal Criteria:** • Evidence of disease response or stabilization. **Age Limit**: ≥18 years **Quantity Limit**: 100 mg: 1 per day; 25 mg: 3 per day
Xospata®	Non-prefer in the PDL class: *Oral Oncology, Hematologic Cancer (Oncology, Oral – Hematologic)* **Length of Authorization:** 12 months • Xospata® (gilteritinib) is an FMS-like tyrosine kinase 3 (FLT3) inhibitor indicated for the treatment of adults with relapsed or refractory acute myeloid leukemia (R/R AML) with a FLT3 mutation as detected by an FDA-approved test. **Criteria for Approval:** • Diagnosis of acute myeloid leukemia (AML) that is refractory to or relapsed after first-line AML therapy; AND • AML is positive for FLT3 mutation as detected by an FDA-approved test (e.g., Leukostrat CDx FLT3 Mutation Assay). **Renewal Criteria:** • Evidence of disease response or stabilization. **Age Limit**: ≥18 years **Quantity Limit**: 3 per day
Lorbrena®	Non-prefer in the PDL class: *Oral Oncology, Lung Cancer (Oncology, Oral – Lung)* **Length of Authorization:** 1 year • Lorbrena® (lorlatinib) is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease, or alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease. **Criteria for Approval**: • Patient has metastatic non-small cell lung cancer (NSCLC); AND • Confirmation of anaplastic lymphoma kinase (ALK)-positive as detected by FDA approved test; AND • Patient has tried and failed crizotinib and at least 1 other ALK inhibitor (e.g., alectinib or ceritinib); OR • Patient has tried and failed alectinib or ceritinib. **Renewal Criteria:** • Patient continues to meet the above criteria; AND • Evidence of response with stabilization of disease or decrease in size of tumor or tumor spread. **Age Limit**: ≥18 years **Quantity Limit**: 100 mg: 1 per day; 25 mg: 3 per day

Drugs Requiring PA	Criteria
Vizimpro®	Prefer with clinical criteria in the PDL class: *Oral Oncology, Lung Cancer (Oncology, Oral – Lung)* **Length of Authorization:** 1 year • Vizimpro® (dacomitinib) is a kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test. **Criteria for Approval**: • Patient has metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test. **Renewal Criteria:** • Patient continues to meet the above criteria; AND • Demonstrated tumor response with stabilization of disease or decrease in size of tumor or tumor spread. **Age Limit**: ≥18 years **Quantity Limit**: 1 per day
Arikayce®	Non-prefer in the PDL class: *Antibiotics, Inhaled* **Length of Authorization:** 3 months initial; 1 year renewal • Arikayce® (amikacin liposomal inhalation) is an aminoglycoside antibiotic indicated in adults who have limited or no alternative treatment options, for the treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. **Criteria for Approval**: • Diagnosis of Mycobacterium avium complex (MAC) lung disease as determined by the following: ○ chest radiography or high-resolution computed tomography (HRCT) scan; AND ○ at least 2 positive sputum cultures; AND ○ other conditions such as tuberculosis and lung malignancy have been ruled out; AND • Patient has failed a multi-drug regimen with a macrolide (clarithromycin or azithromycin), rifampin, and ethambutol. (Failure is defined as continual positive sputum cultures for MAC while adhering to a multi-drug treatment regimen for a minimum duration of 6 months); AND • Patient has documented failure or intolerance to aerosolized administration of amikacin solution for injection, including pretreatment with a bronchodilator; AND • Arikayce will be prescribed in conjunction with a multi-drug antimycobacterial regimen. **Age Limit**: ≥ 18 years **Quantity Limit**: 1 kit per 28 days (1 vial per day)

Drugs Requiring PA	Criteria
Xofluza™	Non-prefer in the PDL class: *Antivirals: Flu* (*Antivirals, Oral)* **Length of Authorization:** Date of service • Xofluza™ (baloxavir marboxil), a polymerase acidic (PA) endonuclease inhibitor, is indicated for the treatment of acute uncomplicated influenza in patients ≥ 12 years of age who have been symptomatic for ≤ 48 hours. **Criteria for Approval**: • Weight ≥ 40 kg; AND • Allergy, contraindication, intolerance or other reason a preferred influenza antiviral cannot be used; AND • Confirmed or suspected diagnosis of acute, uncomplicated, outpatient influenza; AND • Patient symptomatic for ≤ 48 hours; AND • Patient is NOT: ○ Taking concurrent neuraminidase inhibitors (e.g., Tamiflu, Relenza); OR ○ Taking polyvalent cation-containing laxatives, antacids, or oral supplements (e.g., calcium, iron, magnesium, selenium, or zinc); OR ○ Pregnant; OR ○ Hospitalized; AND • Xofluza is not being used for prophylaxis. **Age Limit**: ≥ 12 years **Quantity Limit**: 2 tablets (1 dose) per fill
Yupelri™	Non-prefer in the PDL class: *COPD Agents* **Length of Authorization:** 1 year • Yupelri™ (revefenacin) is a long-acting muscarinic antagonist (LAMA) indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). **Criteria for Approval**: • Diagnosis of chronic obstructive pulmonary disease (COPD); AND • Treatment failure with at least 1 other long-acting muscarinic antagonist (LAMA) due to technique/delivery mechanism. **Age Limit**: ≥ 18 years **Quantity Limit**: 1 vial per day

Brand/Generic Switches

The following brand/generic switches will also be implemented on June 3, 2019:

Drug Class	The following generics will become *preferred* products:	The following brand products will become *non-preferred* and require prior authorization (PA):
Anticonvulsants: Carbamazepine Derivatives	carbamazepine ER tablets	*Tegretol® XR*
Antiretrovirals: HIV/AIDS	tenofovir disoproxil fumarate tablets QL	*Viread® tablets QL*
Antivirals: Flu	oseltamivir QL	*Tamiflu® QL*
Immunosuppressants	mycophenolic acid	*Myfortic®*
Lipotropics: Omega-3 Fatty Acids	omega-3 acid ethyl esters ST	*Lovaza®*
Ophthalmic Antihistamines	olopatadine 0.2%	*Pataday™*
Oral Psoriasis Agents	acitretin	*Soriatane®*
Stimulants and Related Agents	mixed amphetamine salts ER CC, QL	*Adderall XR® QL*

To review the complete summary of the final PDL selections and new products to market updates and changes, please refer to the "Commissioner's Final Decisions" from March 21, 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,

Noah L Greenberg

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Pharmacist Account Manager
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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.