Kentucky Department for Medicaid Services
Drug Review and Options for Consideration

The following tables list the Agenda items as well as the Options for Consideration that are scheduled to be presented and reviewed at the **March 21, 2019** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
New Product to Market: **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) by a pediatric neurologist or pediatric epileptologist; 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; AND **Age Limit**: ≥ 2 years
New Product to Market: **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>Single Agent Reviews</th><th>Options for Consideration</th></tr>
<tr><td>New Product to Market:
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>
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Single Agent Reviews	Options for Consideration
New Product to Market: **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

New Product to Market: **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 capsules per day

Single Agent Reviews	Options for Consideration
New Product to Market: **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
New Product to Market: **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
New Product to Market: **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

Single Agent Reviews	Options for Consideration
New Product to Market: **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**: 100 mg: 1 per day; 25 mg: 3 per day

Criteria Review	Options for Consideration
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.

Full Class Reviews	Options for Consideration
Antibiotics, Inhaled	**Antibiotics, Inhaled** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Antibiotics, Inhaled* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class: 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: o chest radiography or high-resolution computed tomography (HRCT) scan; AND o at least 2 positive sputum cultures; AND o 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)
Antivirals, Oral **(Antivirals: Herpes, Antivirals: Influenza)**	**Antivirals: Herpes** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antivirals: Herpes* class, require PA until reviewed by the P&T Advisory Committee. **Antivirals: Influenza** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antivirals: Influenza* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class: Xofluza™** Non-prefer in the PDL class: *Antivirals: Flu* (*Antivirals, Oral)* **Length of Authorization:** Date of service

Full Class Reviews	Options for Consideration
	• 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: o Taking concurrent neuraminidase inhibitors (e.g., Tamiflu, Relenza); OR o Taking polyvalent cation-containing laxatives, antacids, or oral supplements (e.g., calcium, iron, magnesium, selenium, or zinc); OR o Pregnant; OR o Hospitalized; AND • Xofluza is not being used for prophylaxis. **Age Limit**: ≥ 12 years **Quantity Limit**: 2 tablets (1 dose) per fill
Cephalosporins and Related Antibiotics **(Antibiotics: Cephalosporins 1st Generation, Antibiotics: Cephalosporins 2nd Generation; Antibiotics: Cephalosporins 3rd Generation)**	**Antibiotics: Cephalosporins 1st Generation** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antibiotics: Cephalosporins 1st Generation* class, require PA until reviewed by the P&T Committee. **Antibiotics: Cephalosporins 2nd Generation** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antibiotics: Cephalosporins 2nd Generation* class, require PA until reviewed by the P&T Committee. **Antibiotics: Cephalosporins 3rd Generation** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antibiotics: Cephalosporins 3rd Generation* class, require PA until reviewed by the P&T Committee.
COPD Agents	**COPD Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 short-acting and 1 long-acting product should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *COPD Agents* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class: Yupelri™** Non-prefer in the PDL class: *COPD Agents* **Length of Authorization:** 1 year

Full Class Reviews	Options for Consideration
	• 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
Hepatitis B Agents **(Anti-Infectives: Hepatitis B)**	**Anti-Infectives: Hepatitis B** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Anti-Infectives: Hepatitis B* class, require PA until reviewed by the P&T Committee.
HIV/AIDS	**HIV/AIDS** • DMS to select preferred agent(s) based on economic evaluation; however, first-line treatment regimens should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *HIV/AIDS* class, require PA until reviewed by the P&T Advisory Committee.

Consent Agenda	Options for Consideration
For the following therapeutic classes, there are **no recommended changes to the currently posted Preferred Drug List (PDL) status**; these may be voted on as a group:	
Absorbable Sulfonamides	Hypoglycemics, Insulin and Related Agents
Antibiotics, GI	Hypoglycemics, Meglitinides
Antibiotics, Vaginal	Hypoglycemics, Metformins
Antifungals, Oral	Hypoglycemics, SGLT2
Antihistamines, Minimally Sedating	Hypoglycemics, Sulfonylureas
Bronchodilators, Beta Agonist	Hypoglycemics, Thiazolidinediones (TZD)
Epinephrine, Self-Injected	Intranasal Rhinitis Agents
Fluoroquinolones, Oral	Leukotriene Modifiers
Glucocorticoids, Inhaled	Macrolides
Hepatitis C Agents	Oxazolidenediones
Hypoglycemics, Alpha-Glucosidase Inhibitors	Penicillins
Hypoglycemics, Incretin Mimetics/Enhancers	Tetracyclines