

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 **September 20, 2018** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration																
New Product to Market: Aimovig™	<p>Non-prefer in the PDL class: <i>Antimigraine, Other (Antimigraine: CGRP Inhibitors)</i></p> <p>Length of Authorization: 3 months initial; 1 year renewal</p> <ul style="list-style-type: none">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. <p>Criteria for Approval:</p> <ul style="list-style-type: none">Diagnosis of migraine with or without aura; ANDIf female of child-bearing age (18-45), negative pregnancy screening; ANDTrial 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><i>AEDs:</i> -divalproex sodium -sodium valproate -topiramate</td><td><i>Antidepressants:</i> -amitriptyline -venlafaxine</td><td><i>Alpha-agonists:</i> -clonidine -guanfacine</td><td><i>ACE/ARB:</i> -lisinopril -candesartan</td></tr><tr><td><i>Beta blockers:</i> -metoprolol -propranolol -timolol</td><td><i>Beta blockers:</i> -atenolol -nadolol</td><td><i>AEDs:</i> -carbamazepine</td><td><i>Beta blockers:</i> -nebivolol -pindolol</td></tr><tr><td></td><td><i>NSAIDs:</i> -fenoprofen -ibuprofen -ketoprofen -naproxen</td><td><i>Antihistamines:</i> -cyproheptadine</td><td><i>NSAIDs:</i> -flurbiprofen -mefenamic acid</td></tr></table> <p>AED = antiepileptic drug; ACE = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor blocker; NSAID = nonsteroidal anti-inflammatory drug</p> <p>Renewal Criteria</p> <ul style="list-style-type: none">Patient has an overall improvement in function with therapy; ANDIf female of child-bearing age, continued monitoring for pregnancy. <p>Age Limit: ≥ 18 years</p> <p>Quantity Limit: 1 package (70 or 140 mg) per month</p>	Level A	Level B	Level C		<i>AEDs:</i> -divalproex sodium -sodium valproate -topiramate	<i>Antidepressants:</i> -amitriptyline -venlafaxine	<i>Alpha-agonists:</i> -clonidine -guanfacine	<i>ACE/ARB:</i> -lisinopril -candesartan	<i>Beta blockers:</i> -metoprolol -propranolol -timolol	<i>Beta blockers:</i> -atenolol -nadolol	<i>AEDs:</i> -carbamazepine	<i>Beta blockers:</i> -nebivolol -pindolol		<i>NSAIDs:</i> -fenoprofen -ibuprofen -ketoprofen -naproxen	<i>Antihistamines:</i> -cyproheptadine	<i>NSAIDs:</i> -flurbiprofen -mefenamic acid
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Single Agent Reviews	Options for Consideration
<p>New Product to Market: Olumiant®</p>	<p>Non-prefer in the PDL class: <i>Cytokine and CAM Antagonists (Immunomodulators)</i></p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> • 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. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • 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®) <p>Renewal Criteria:</p> <ul style="list-style-type: none"> • Meet initial approval criteria; AND • Ongoing monitoring for TB; AND • Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts. <p>Age Limit: ≥ 18 years Quantity Limit: 1 tablet per day</p>
<p>New Product to Market: Rhopressa™</p>	<p>Non-prefer in the PDL class: <i>Ophthalmics, Glaucoma Agents</i></p> <p>Length of Authorization: 1 year</p> <ul style="list-style-type: none"> • 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. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • 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. <p>Age Limit: ≥ 18 years Quantity Limit: 5 mL per 30 days</p>

Single Agent Reviews	Options for Consideration
<p>New Product to Market: Lucemyra™</p>	<p>Non-prefer in the PDL class: <i>Opiate Dependence Treatments</i> Length of Authorization: 5 days</p> <ul style="list-style-type: none"> • Lucemyra™ (lofexidine) is a central alpha-2 adrenergic agonist indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • Medication is being used to mitigate opioid withdrawal symptoms and facilitate abrupt discontinuation of opioids; AND • Patient is NOT pregnant or breastfeeding; AND • Patient does NOT have a prolonged QT interval (> 450 msec for males, > 470 msec for females); AND • If patient is currently taking methadone, prescriber attestation that a baseline electrocardiogram (ECG) has been performed; AND • Patient has tried and failed, had a contraindication to, or experienced an adverse reaction/intolerance to clonidine; AND • Prescriber to provide verbal attestation of a comprehensive treatment plan between provider and patient; AND • Prescriber to provide verbal attestation that the patient is capable of and instructed how to self-monitor for hypotension, orthostasis, bradycardia, and associated symptoms; AND • Prescriber to provide verbal attestation that the patient has been provided with a tapering schedule and instructions on when to contact their healthcare provider for further guidance. <p>Age Limit: ≥ 18 years Quantity Limit: 48 tablets with 1 refill (96 tabs per treatment course)</p>
<p>New Product to Market: Tavalisse™</p>	<p>Non-prefer in the PDL class: <i>Thrombopoiesis Stimulating Agents</i> Length of Authorization: 3 months initial; 1 year renewal</p> <ul style="list-style-type: none"> • 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. <p>Criteria for Approval:</p> <ul style="list-style-type: none"> • Diagnosis of chronic immune thrombocytopenia (ITP); AND • Trial and failure (e.g., not achieved a platelet count ≥ 50 x 10⁹/L) of at least 1 other therapy for chronic ITP such as corticosteroids, IV immune globulin, RhO(D) immune globulin, thrombopoietin receptor antagonists, etc. <p>Criteria for Renewal:</p> <ul style="list-style-type: none"> • Laboratory values documenting platelet response to therapy (platelet count ≥ 50 x 10⁹/L). <p>Age Limit: ≥ 18 years Quantity Limit: 2 tablets per day</p>

Criteria Review	Options for Consideration
Compound Claims	<p>Proposal: 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.</p> <p>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.</p> <p>Length of Authorization: 1 year</p> <p>Criteria for Approval (ALL of the following conditions MUST be met):</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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.

Full Class Reviews	Options for Consideration
Anticonvulsants (Anticonvulsants: First Generation; Anticonvulsants: Second Generation; Anticonvulsants: Carbamazepine Derivatives)	<p>Anticonvulsants: First Generation</p> <ul style="list-style-type: none"> • DMS to select preferred agent(s) based on economic evaluation; however, at least 6 unique chemical entities, including generic forms of clonazepam, divalproex, ethosuxamide, phenobarbital, phenytoin, and valproate/valproic acid should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the <i>Anticonvulsants: First Generation</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Anticonvulsants: Second Generation</p> <ul style="list-style-type: none"> • DMS to select preferred agent(s) based on economic evaluation; however, at least 6 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the <i>Anticonvulsants: Second Generation</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Anticonvulsants: Carbamazepine Derivatives</p> <ul style="list-style-type: none"> • 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 require PA.

Full Class Reviews	Options for Consideration
<p>Antiparkinson's Agents</p> <p>(Dopamine Receptor Agonists; Parkinson's Disease)</p>	<ul style="list-style-type: none"> For any new chemical entity in the <i>Anticonvulsants: Carbamazepine Derivatives</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Dopamine Receptor Agonists</p> <ul style="list-style-type: none"> 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 <i>Dopamine Receptor Agonists</i> class, require PA until reviewed by the P&T Advisory Committee. <p>Parkinson's Disease</p> <ul style="list-style-type: none"> DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities, including levodopa/carbidopa should be preferred. Agents not selected as preferred will be considered non-preferred and will require PA. For any new chemical entity in the <i>Parkinson's Disease</i> class, require PA until reviewed by the P&T Advisory Committee.
<p>Bladder Relaxant Preparations</p> <p>(Bladder Relaxants)</p>	<p>Bladder Relaxants</p> <ul style="list-style-type: none"> DMS to select preferred agent(s) based on economic evaluation; however, at least 3 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 <i>Bladder Relaxants</i> class, require PA until reviewed by the P&T Advisory Committee.
<p>Movement Disorders</p>	<p>Movement Disorders</p> <ul style="list-style-type: none"> DMS to select preferred agent(s) based on economic evaluation. Agents not selected as preferred will be considered non-preferred and will require PA. For any new chemical entity in the <i>Movement Disorders</i> class, require PA until reviewed by the P&T Advisory Committee.
<p>Neuropathic Pain</p>	<p>Neuropathic Pain</p> <ul style="list-style-type: none"> DMS to select preferred agent(s) based upon 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 <i>Neuropathic Pain</i> class, should require PA until reviewed by the P&T Advisory Committee.
<p>PAH Agents, Oral and Inhaled</p> <p>(Pulmonary Arterial Hypertension (PAH) Agents)</p>	<p>Pulmonary Arterial Hypertension (PAH) Agents</p> <ul style="list-style-type: none"> DMS to select preferred agent(s) based on economic evaluation; however, at least 3 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 <i>Pulmonary Arterial Hypertension (PAH) Agents</i> class, require PA until reviewed by the P&T Advisory Committee.

Full Class Reviews	Options for Consideration
Platelet Aggregation Inhibitors	Platelet Aggregation Inhibitors <ul style="list-style-type: none"> DMS to select preferred agent(s) based on economic evaluation; however, at least 4 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 <i>Platelet Aggregation Inhibitors</i> class, require PA until reviewed by the P&T Advisory Committee.
Stimulants and Related Agents (Narcolepsy Agents; Stimulants and Related Agents)	Narcolepsy Agents <ul style="list-style-type: none"> 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 <i>Narcolepsy Agents</i> class, require PA until reviewed by the P&T Advisory Committee. Stimulants and Related Agents <ul style="list-style-type: none"> DMS to select preferred agent(s) based on economic evaluation; however, at least 5 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 <i>Stimulants and Related Agents</i> 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:	
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