Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations

September 20, 2018

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **September 20, 2018** meeting.

Although the Committee met on September 20, 2018, the necessary quorum was not achieved; however, the expertise, vote and recommendations of the Committee members in attendance were captured and the Committee delivered the unofficial recommendations reflected below for review. Pending is the review by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services of these recommendations and final decisions.

<table>
<tr><th></th><th>Description of Recommendation</th><th>P & T Vote</th></tr>
<tr><td>1</td><td>
<u>New Product to Market:</u> Aimovig™
Non-prefer in the PDL class: 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.
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 – at least 1 must be level A or B recommendation – 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>
</td><td>Passed
5 For
0 Against</td></tr>
</table>

	Description of Recommendation	P & T Vote
	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:** ≥ 18 years **Quantity Limit:** 1 package (70 or 140 mg) per month	
2	**New Product to Market: 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®) **Renewal Criteria:** • 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. **Age Limit:** ≥18 years **Quantity Limit:** 1 tablet per day	**Passed** 5 For 0 Against
3	**New Products to Market: Rhopressa™** Non-prefer in the PDL class: *Ophthalmics, Glaucoma Agents* **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.	**Passed** 5 For 0 Against

	Description of Recommendation	P & T Vote
	Age Limit: ≥ 18 years **Quantity Limit**: 5 mL per 30 days	
4	**New Product to Market: Lucemyra™** The committee voted to table this topic for further discussion. Revised criteria will be presented at the November P&T Meeting.	**Passed** 6 For 0 Against
5	**New Product to Market: 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 109/L). **Age Limit**: ≥ 18 years **Quantity Limit**: 2 tablets per day	**Passed** 6 For 0 Against
6	**Compound Claims Criteria Review** **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. **Exception:** 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	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote

	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.
	Note: The committee accepted this recommendation with the condition that a 6-month data summary be presented at a future meeting.	

7	**Anticonvulsants: First Generation** • 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 *Anticonvulsants: First Generation* class, require PA until reviewed by the P&T Advisory Committee. **Anticonvulsants: Second Generation** • 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 *Anticonvulsants: Second Generation* class, require PA until reviewed by the P&T Advisory Committee. **Anticonvulsants: Carbamazepine Derivatives** • 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. • For any new chemical entity in the *Anticonvulsants: Carbamazepine Derivatives* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote
8	**Dopamine Receptor Agonists** • 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 *Dopamine Receptor Agonists* class, require PA until reviewed by the P&T Advisory Committee. **Parkinson's Disease** • 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 *Parkinson's Disease* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against
9	**Bladder Relaxants** • 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 *Bladder Relaxants* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against
10	**Movement Disorders** • 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 *Movement Disorders* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against
11	**Neuropathic Pain** • 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 *Neuropathic Pain* class, should require PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against
12	**Pulmonary Arterial Hypertension (PAH) Agents** • 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 *Pulmonary Arterial Hypertension (PAH)* Agents class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against

	Description of Recommendation	P & T Vote
13	**Platelet Aggregation Inhibitors** • 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 *Platelet Aggregation Inhibitors* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against
14	**Narcolepsy Agents** • 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 *Narcolepsy Agents* class, require PA until reviewed by the P&T Advisory Committee. **Stimulants and Related Agents** • 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 *Stimulants and Related Agents* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 0 Against

Consent Agenda

For the following therapeutic classes, the P&T Committee had no recommended changes to the currently posted Preferred Drug List (PDL) status.

	Therapeutic Classes	P & T Vote
17	• 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	**Passed** 6 For 0 Against