

Kentucky Department for Medicaid Services

Pharmacy and Therapeutics Advisory Committee Recommendations

May 19, 2011 Meeting

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics Advisory Committee at the May 19, 2011 meeting. Review of the recommendations by the Secretary of the Cabinet for Health and Family Services and final decisions are pending.

	Description of Recommendation	P & T Vote
1	<u>New Products to Market: Edarbi™</u> Place this product non preferred with similar approval criteria in the PDL class titled Angiotensin Receptor Blockers.	Passed 11 For 0 Against
2	<u>Pancreatic Enzymes</u> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one pancreatic enzyme product should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Pancreatic Enzyme class, require a PA until reviewed by the P&T Advisory Committee.	Passed 11 For 0 Against
3	<u>Antiparasitics, Topical</u> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least permethrin 5% cream and malathion should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Topical Antiparasitics class, require a PA until reviewed by the P&T Advisory Committee.	Passed 11 For 0 Against
4	<u>Androgenic Agents</u> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one gel formulation should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Androgenic Agents class, require a PA until reviewed by the P&T Advisory Committee.	Passed 11 For 0 Against

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5	<p><u>Oral Steroids</u></p> <ol style="list-style-type: none"> DMS to select preferred agent (s) based on economic evaluation; however at least budesonide and generic formulations of dexamethasone, methylprednisolone, prednisolone and prednisone should be preferred. The orally disintegrating formulation of prednisolone should be available for children < 12 years of age, and branded Orapred[®] liquid should be available for children < 6 years of age as a step edit. Agents not selected as preferred will be considered non preferred and require PA. For any new chemical entity in the Oral Steroids class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 10 For 1 Against</p>
6	<p><u>Makena[®] Clinical Criteria</u></p> <p>Makena[®] will be approved for members with a singleton pregnancy who have a history of singleton spontaneous preterm birth if:</p> <ul style="list-style-type: none"> Patient has experienced an adverse reaction to the compounded formulation of 17P hydroxyprogesterone caproate; OR Trial and failure (through previous miscarriage or pre-term birth) of the compounded formulation of 17P hydroxyprogesterone caproate; OR No access to a pharmacy which can compound 17P hydroxyprogesterone caproate. 	<p>Passed 11 For 0 Against</p>
7	<p><u>Vivitrol[®] Clinical Criteria</u></p> <p>Vivitrol[®] will be approved if both of the following are true:</p> <ul style="list-style-type: none"> Diagnosis of: <ul style="list-style-type: none"> Alcohol dependence; or Opioid dependence; AND Patient has had a lead in dose of oral naltrexone. 	<p>Passed 11 For 0 Against</p>
8	<p><u>Leukotriene Receptor Antagonists Clinical Criteria</u></p> <p>Leukotriene Receptor Antagonists will be approved if ONE of the following are true:</p> <ul style="list-style-type: none"> Diagnosis of Asthma; OR Diagnosis of Allergic Rhinitis <ul style="list-style-type: none"> After trial and failure of a nasal steroid + an oral antihistamine; or Patient is < 2 years of age. <p>**Additionally a quantity limit of 1 per day will be applied to Singulair[®], and a 2 per day quantity limit will be applied to Accolate[®] and zafirlukast. **</p>	<p>Passed 11 For 0 Against</p>
9	<p><u>Clonidine Patches Clinical Criteria</u></p> <p>Clonidine patches will be approved if any one of the following is true:</p> <ul style="list-style-type: none"> Patient is <15 years old; OR Patient cannot tolerate/absorb PO. 	<p>Passed 11 For 0 Against</p>

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10	<u>Regranex[®] Clinical Criteria</u> Regranex [®] will be approved for a diagnosis of lower extremity diabetic ulcers.	Passed 11 For 0 Against
11	<u>Granulocyte Colony Stimulating Factors Clinical Criteria</u> Granulocyte Colony Stimulating Factors (Leukine [®] [sargramostim], Neulasta [®] [pegfilgrastim], or Neupogen [®] [filgrastim]), will be approved for a diagnosis of: <ul style="list-style-type: none"> • Myelosuppressive chemotherapy; OR • Induction or consolidation chemotherapy in acute myeloid/myelogenous leukemia; OR • Bone marrow transplantation; OR • Bone marrow transplant failure or engraftment delay; OR • Peripheral blood progenitor cell collection and therapy; OR • Severe chronic neutropenia. 	Passed 11 For 0 Against
12	<u>Urinary Tract Antispasmodics</u> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. One should be liquid oxybutynin IR and the other should be fesoterodine ER. 2. Only patients who are unable to swallow or tolerate oral medications should be approved for non-oral formulations of agents in this class. 3. Continue current quantity limits on all agents in this class. 4. Agents not selected as preferred will be considered non preferred and require PA. 5. For any new chemical entity in the Urinary Tract Antispasmodic Class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 11 For 0 Against
13	<u>Progestins for Cachexia</u> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one unique chemical entity must be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Progestins for Cachexia class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 11 For 0 Against
14	<u>Angiotensin Receptor Blockers</u> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Angiotensin Receptor Blocker class, require a PA until reviewed by the P&T Advisory Committee. 	Passed 11 For 0 Against

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15	<p><u>Angiotensin Receptor Blockers + Diuretics</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Angiotensin Receptor Blocker + Diuretic class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>11 For 0 Against</p>
16	<p><u>Angiotensin Receptor Blockers + CCB (DHP)</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Angiotensin Receptor Blocker + CCB (DHP) class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>11 For 0 Against</p>
17	<p><u>Angiotensin Modulators + CCB Combinations</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non preferred and require PA. 1. For any new chemical entity in the Angiotensin Modulators + CCB Combinations class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>11 For 0 Against</p>
18	<p><u>Direct Renin Inhibitors</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation. 2. Agents not selected as preferred will be considered non-preferred and require prior authorization. 3. For any new chemical entity in the Direct Renin Inhibitor Class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>11 For 0 Against</p>
19	<p><u>Direct Renin Inhibitor Clinical Criteria</u></p> <p>Direct Renin Inhibitors will be approved after trial and failure of an ACE Inhibitor or an ARB.</p>	<p>Passed</p> <p>11 For 0 Against</p>
20	<p><u>Alpha/Beta Blockers</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least carvedilol should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Alpha/Beta Blockers class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>11 For 0 Against</p>

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21	<p><u>Beta Blockers</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation. At least two non-selective beta blockers, at least one of which should have ISA, should be preferred on the PDL. At least two cardioselective beta blockers, one of which should be metoprolol succinate, should be preferred on the PDL. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Beta Blockers class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>10 For 0 Against</p>
22	<p><u>Beta Blocker + Diuretics</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least three combination products, one of which should contain metoprolol, should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Beta Blocker + Diuretic class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>10 For 0 Against</p>
23	<p><u>Calcium Channel Blockers (non-DHP)</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Calcium Channel Blockers (Non-DHP) class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>10 For 0 Against</p>
24	<p><u>Vasodilator + Nitrate Combinations</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Vasodilator and Nitrate Combinations class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>10 For 0 Against</p>

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25	<p><u>Agents for Pulmonary Hypertension</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent representing each of the three mechanisms of action (prostacyclin and prostacyclin analogs, oral endothelin receptor antagonists and phosphodiesterase 5 inhibitors) should be preferred. 2. Sildenafil and tadalafil should be subject to prior authorization criteria to ensure they are being used for PAH. 3. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 4. Allow continuation of therapy for non preferred single source branded products via a 90 day look back. 5. For any new chemical entity in the Agents for Pulmonary Hypertension class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 10 For 0 Against</p>
26	<p><u>Flolan[®] Clinical Criteria</u></p> <p>Flolan[®] (IV epoprostenol) will be approved for a diagnosis of World Health Organization (WHO) functional class (FC) III or IV Pulmonary Arterial Hypertension (PAH).</p>	<p>Passed 10 For 0 Against</p>
27	<p><u>Sildenafil and Tadalafil Clinical Criteria</u></p> <p>Sildenafil and tadalafil will be approved for a diagnosis of Pulmonary Arterial Hypertension only. Non oral dosage forms will only be approved for patients who cannot tolerate/absorb medications by mouth.</p>	<p>Passed 10 For 0 Against</p>
28	<p><u>Platelet Inhibitors</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. Based on the clinical merits, place in therapy and utilization of clopidogrel, it must be a preferred agent. Prasugrel should also be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Platelet Inhibitors class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 10 For 0 Against</p>
29	<p><u>Bile Acid Sequestrants</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Bile Acid Sequestrants class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 10 For 0 Against</p>

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30	<p><u>Cholesterol Absorption Inhibitors</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Cholesterol Absorption Inhibitor class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>9 For 1 Against</p>
31	<p><u>Fibric Acid Derivatives</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one fenofibrate product should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Fibric Acid Derivatives class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>9 For 0 Against</p>
32	<p><u>Omega-3 Fatty Acids</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Omega-3 Fatty Acids class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>6 For 3 Against</p>
33	<p><u>Lovaza[®] Clinical Criteria</u></p> <p>Lovaza[®] will be approved after trial and failure of either of the following:</p> <ul style="list-style-type: none"> • fibric acid derivative; OR • statin 	<p>Passed</p> <p>9 For 0 Against</p>
34	<p><u>Statins</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Continue current quantity limits on agents in the class. 4. For any new chemical entity in the Low Potency Statins class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>9 For 0 Against</p>
35	<p><u>Statin + CCB Combination</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Statins + CCB Combinations class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>8 For 0 Against 1 Abstention</p>

	Description of Recommendation	P & T Vote
36	<p><u>Caduet[®] Clinical Criteria</u> Caduet[®] will be approved for patients currently taking amlodipine who have had a trial and failure of ALL of the following:</p> <ul style="list-style-type: none"> • simvastatin; AND • simvastatin / ezetimibe OR rosuvastatin. <p>**Additionally a quantity limit of 1 per day will be applied. **</p>	<p>Passed 9 For 0 Against</p>