Kentucky Department for Medicaid Services

Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the July 15, 2010 meeting of the Pharmacy and Therapeutics Advisory Committee

Item	Options for Consideration
Urinary Tract Antispasmodics	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 EITHER darifenacin OR 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.
Branded Products with Generic Components	Require prior authorization for the following products: • Saklera® Foam • Orbivan® • Cambia®
New Products to Market: Zirgan™	Place this product preferred in the PDL class titled Ophthalmic Antivirals.
New Products to Market: Qutenza®	Qutenza® will be approved for a diagnosis of postherpetic neuralgia after trial and failure of one of the following agents: • gabapentin; OR • tricyclic antidepressant; OR • SNRI; OR • pregabalin.
New Products to Market: Oravig™	Place this product non preferred in the PDL class titled Antifungals: Oral.
New Products to Market: Zortress®	Place this product non preferred in the PDL class titled Immunosuppressants.
New Products to Market: Vimavo™	Place this product non preferred with similar quantity limits in the PDL class titled Proton Pump Inhibitors.
New Products to Market: Livalo®	Place this product non preferred with similar quantity limits in the PDL class titled High Potency Statins.

Item	Options for Consideration
Suboxone®/Subutex® Clinical Criteria	All of the following must be met: 1. Diagnosis of opiate dependency. 2. Patient must be 16 years of age or older. 3. Prescriber must have UIN # (Drug Addiction Treatment Act waiver). 4. There must be evidence of active substance abuse counseling. 5. Prescriber must perform monthly KASPER report. 6. Request must come from prescriber. **Additionally any claim for Suboxone®/Subutex® will require prior approval if there is a claim for any opioid in the past 30 days of history.** Proposed Quantity Limits: • Subutex® o 2 mg: 3 tablets/day o 8 mg: 3 tablets/day • Suboxone® o 2 mg/0.5 mg: 3 tablets/day o 8 mg/2 mg: 3 tablets/day Quantity Limit Exception Criteria: Approval for quantities greater than 24 mg per day will be approved based on the following: 1. Member is being treated in initial induction phase; OR 2. Member is being treated for addiction with concomitant need for short term (30 days) pain management. **Dose greater than 32 mg will not be approved.
Prenatal Vitamins	1. DMS to select preferred agent (s) based on economic evaluation; however, at least multiple generic formulations should be preferred. 2. All agents in this class will be limited to female patients under the age of 40 years old. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Prenatal Vitamins class, require a PA until reviewed by the P&T Advisory Committee.
Prenatal Vitamins Clinical Criteria	Prenatal vitamins will be limited to female patients less than 40 years old unless one of the following is true: 1. Patient is 40 years of age or older and pregnant; OR 2. Patient suffers from a chronic condition associated with wasting (i.e., HIV).
Oral Steroids	1. 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. 2. The orally disintegrating formulation of prednisolone should be available for children < 12 years of age. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Oral Steroids class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Angiotensin Modulators + CCB Combinations	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 Modulators + CCB Combinations class, require a PA until reviewed by the P&T Advisory Committee.
Angiotensin Receptor Blockers + CCB (DHP)	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.
Direct Renin Inhibitors	1. DMS to select preferred agent (s) based upon economic evaluation. 2. Require a Step Therapy Edit for trial and failure of either an ACE or an ARB. 3. Agents not selected as preferred will be considered non-preferred. 4. For any new chemical entity in the Direct Renin Inhibitor Class, require a PA until reviewed by the P&T Advisory Committee.
Direct Renin Inhibitors Clinical Criteria	Direct Renin Inhibitors will be approved after trial and failure of an ACE Inhibitor **OR** an ARB.
Beta Blockers	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.
Beta Blockers + Diuretics	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.
Alpha/Beta Blockers	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.
Calcium Channel Blockers (Non-DHP)	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.
Vasodilator and Nitrate Combinations	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 Vasodilator and Nitrate Combinations class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Agents for Pulmonary Hypertension	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 antagonist 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. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 day. 5. For any new chemical entity in the Agents for Pulmonary Hypertension class, require a PA until reviewed by the P&T Advisory Committee.
Sildenafil and Tadalafil Clinical Criteria	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.
Flolan® Clinical Criteria	Flolan® (IV epoprostenol) will be approved for a diagnosis of World Health Organization (WHO) functional class (FC) III or IV Pulmonary Arterial Hypertension (PAH).
Lipotropics: Bile Acid Sequestrants	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.
Lipotropics: Cholesterol Absorption Inhibitors	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.
Lipotropics: Fibric Acid Derivatives	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one fibric acid 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.
Lovaza® Clinical Criteria	Lovaza® will be approved if: • trial and failure of a fibric acid derivative; OR • dual therapy with a fibric acid derivative; OR • dual therapy with a statin.
Lipotropics: Low Potency Statins	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.
Lipotropics: Statin + CCB Combination	1. DMS to select preferred agent (s) based on economic evaluation. 2. All agents in this category should require prior approval and quantity limits. 3. For any new chemical entity in the Statins + CCB Combinations class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Caduet® Clinical Criteria	Caduet® will be approved for patients currently taking amlodipine who have had a trial and failure of ALL of the following: • simvastatin; AND • simvastatin / ezetimibe OR rosuvastatin. **Additionally a quantity limit of 1 per day will be applied. **
Platelet Inhibitors	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. 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.
Low Molecular Weight Heparins	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one low molecular weight heparin and one factor Xa inhibitor 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 Low Molecular Weight Heparins class, require a PA until reviewed by the P&T Advisory Committee.