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 19, 2012 meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration
New Products to Market: Jentadueto™	Place this product preferred with similar approval criteria and quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.
New Products to Market: Janumet® XR	Place this product preferred with similar approval criteria and quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.
New Products to Market: Kalydeco™	Kalydeco™ should have a quantity limit of 2 per day and only be approved if BOTH of the following are true: • Presence of specific *G551D* mutation in the CFTR gene; AND • Absence of homozygous *F508del* mutation in the CFTR gene.
New Products to Market: Inlyta®	Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Inlyta® after confirmation of a diagnosis of renal cell carcinoma (RCC) and trial/failure of at least one systemic therapy (e.g. bevacizumab plus interferon alpha, temsirolimus, or cytokines).

New Products to Market: Erivedge™	Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Erivedge™ for one of the following diagnoses:
	• Metastatic basal cell carcinoma; OR
	• Locally advanced basal cell carcinoma if:
	  ○ There is recurrence following surgery; OR
	  ○ Patient is not a candidate for surgery; OR
	  ○ Patient is not a candidate for radiation therapy.

New Products to Market: Bydureon®	Place this product non preferred in the PDL class titled Diabetes: Incretin Mimetics.
New Products to Market: Zioptan®	Place this product non preferred with similar quantity limits in the PDL class titled Ophthalmic Prostaglandin Agonists.
New Products to Market: Omontys®	Place this product non preferred in the PDL class titled Hematopoietic Agents; however, only approve Omontys® for a diagnosis of Chronic Kidney Disease (CKD) in patients on dialysis.
New Products to Market: Qnasl™	Place this product non preferred with appropriate quantity limits in the PDL class titled Corticosteroids, Intranasal.
New Products to Market: Potiga™	Place this product non preferred in the PDL class titled Anticonvulsants: Second Generation.

Item	Options for Consideration
Xolair® (omalizumab) Clinical Criteria	Xolair® (omalizumab) should be approved for a diagnosis of moderate to severe asthma (step 5 or higher) if ALL of the following are true: • Positive skin test or in vitro reactivity (RAST test) to a perennial aeroallergen; AND • FEV_1 of <80% while on asthma controller medication; AND • Has had failure of or contraindication to inhaled corticosteroid in combination with a second controller agent (such as a long-acting inhaled $beta_2$-agonist, ipratropium, leukotriene modifier, or theophylline) for a 60-day trial. Xolair® (omalizumab) should be approved for continuation of therapy for a diagnosis of moderate to severe asthma (step 5 or higher) if one of the following is true: • During previous treatment with Xolair®, the patient experienced a reduction in asthma exacerbations (e.g., hospitalizations, urgent or emergent care visits, use of rescue medications, etc.) from their pre-Xolair® baseline, OR • The patient was receiving maintenance therapy with an oral corticosteroid prior to initiation of Xolair® and the patient has been able to reduce their oral corticosteroid dose to less than their pre-Xolair® baseline or to ≤ 5 mg daily, OR • The patient was receiving maintenance therapy with an inhaled corticosteroid prior to initiation of Xolair® and the patient has been able to reduce their inhaled corticosteroid dose to less than their pre-Xolair® baseline.
Lipotropics: High Potency Statins	1. DMS to select preferred agent(s) based on economic evaluation; however, at least simvastatin and EITHER atorvastatin or rosuvastatin should be preferred. 2. Continue quantity limits on agents in this class based on maximum recommended dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the High Potency Statin class, require a PA until reviewed by the P&T Advisory Committee.
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 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.

Item	Options for Consideration
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.
Proton Pump Inhibitors	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. 2. Continue current quantity limits on all agents in this class. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Proton Pump Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.
Sedative Hypnotic Agents	1. DMS to select preferred agent(s) based on economic evaluation; however, at least four unique chemical entities should be preferred. One non-benzodiazepine sedative hypnotic should be among the preferred products. 2. Place quantity limits on agents in the category according to the FDA recommended maximum dose. 3. If ramelteon is not selected as preferred, it should be approved for patients with history of drug/alcohol dependence. 4. Agents not selected as preferred should be considered non preferred and require PA. 5. For any new chemical entity in the Sedative Hypnotic class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.
Antibiotics: Quinolones	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two agents, including either levofloxacin, gemifloxacin or moxifloxacin and either ciprofloxacin or ofloxacin, 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 Antibiotics: Quinolones class, require a PA until reviewed by the P&T Advisory Committee.
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	1. DMS to select preferred agent(s) based upon economic evaluation; however, at least six unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Any new chemical entity in the NSAIDs class should require a PA until reviewed by the P&T Advisory Committee.
Topical Diclofenac Clinical Criteria	Topical diclofenac products will be approved if ONE of the following is true: • Patient is unable to tolerate, swallow, or absorb oral NSAIDs; OR • Patient as a contraindication to an oral NSAID (e.g., GI bleed)
Narcotics: Short-Acting	1. DMS to select preferred agent (s) based on economic evaluation; however, at least generic formulations of hydrocodone, meperidine and oxycodone 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 Narcotics: Short Acting class, require PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Narcotics: Long-Acting	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one long acting form of morphine 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 Long-Acting Narcotics class, require PA until reviewed by the P&T Advisory Committee.
Fentanyl Transdermal Clinical Criteria	Fentanyl transdermal will be approved for a diagnosis of chronic pain after trial and failure of extended/controlled release morphine.
Butrans™ (buprenorphine) Clinical Criteria	Butrans™ will be approved if all of the following are true: • Diagnosis of chronic pain; AND • Trial and failure of extended/controlled release morphine (Of note: failure does not necessarily mean lack of efficacy. It could mean intolerance due to allergy or side effects.); AND • Patient does not have a history of opioid addiction.
Topical Immunomodulators	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 Topical Immunomodulators, require a PA until reviewed by the P&T Advisory Committee.
Dermatologics: Antibiotic Agents	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which should be mupirocin ointment, 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 Dermatologics Antibiotics class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Antihistamines	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 Ophthalmic Antihistamines class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Mast Cell Stabilizers	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 Ophthalmic Mast Cell Stabilizers class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Sympathomimetics	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 Ophthalmic Sympathomimetics class, require a PA until reviewed by the P&T Advisory Committee.

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Ophthalmic Prostaglandin Agonists	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. Continue current quantity limits on agents in this class 4. For any new chemical entity in the Ophthalmic Prostaglandin Agonists class, require a PA until reviewed by the P&T Advisory Committee.
Alpha Blockers for BPH	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two agents, one of which should be highly selective for the alpha receptors in the genitourinary tract, 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 Blockers for BPH class, require a PA until reviewed by the P&T Advisory Committee.
Otic Anti-Infective & Anesthetic	1. DMS to select preferred agent (s) based on economic evaluation; however, at least three 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 Otic Anti-Infective & Anesthetic class, require a PA until reviewed by the P&T Advisory Committee.
GI Antibiotics	1. DMS to select preferred agent (s) based upon economic evaluation; however, at least metronidazole, oral vancomycin and nitazoxanide should 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 GI Antibiotic class, require a PA until reviewed by the P&T Advisory Committee.
Xifaxan® Clinical Criteria	Xifaxan® will be approved if ONE of the following is true: • Diagnosis of travelers diarrhea caused by non-invasive strains of *E. coli* after trial and failure of ciprofloxacin (three day course of therapy only); OR • Diagnosis of hepatic encephalopathy after trial and failure of lactulose OR neomycin.
Oral Anti-Arrhythmics	1. DMS to select preferred agent (s) based on economic evaluation; however, at least five unique chemical entities should 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 Oral Antiarrhythmics class, require a PA until reviewed by the P&T Advisory Committee.