Kentucky Department for Medicaid Services

Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the January 20, 2011 meeting of the Pharmacy and Therapeutics Advisory Committee

Item	Options for Consideration
New Products to Market: Pradaxa®	Dabigatran will be approved if all of the following are true: ▪ Diagnosis of non valvular atrial fibrillation; AND ▪ Patient has at least one risk factor for stroke: o History of stroke, TIA, or systemic embolism; or o Age ≥ 75 years; or o Diabetes mellitus; or o History of left ventricular dysfunction or heart failure; or o Age ≥65 years with the presence of one of the following: diabetes mellitus, coronary artery disease (CAD), or hypertension; AND ▪ Patient has taken warfarin for at least 6 months without INR (2 most recent INRs out of therapeutic range) and/or dose stabilization (dose changing at least monthly).
New Products to Market: XGeva™	Denosumab (XGeva™) will be approved for a diagnosis of bone metastases resulting from solid tumors only.
New Products to Market: Kombiglyze™ XR	Place this product non preferred with similar approval criteria and quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.
New Products to Market: Silenor®	Place this product non preferred with similar quantity limits in the PDL class titled Sedative Hypnotic Agents.
Second Generation Anticonvulsants	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 require prior authorization. 3. Require therapeutic failure of one preferred agent prior to approval of a non-preferred agent. 4. Non preferred products will continue to require a tier 1 co-payment for generics and a tier 2 co-payment for branded products. 5. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 6. For any new chemical entity in the Anticonvulsants: Second Generation class, require a PA until reviewed by the P&T Advisory Committee.
Banzel® Clinical Criteria	Banzel® will be approved if: • Diagnosis of Lennox-Gastaut syndrome; OR • Trial and failure of one other anticonvulsant.

Item	Options for Consideration
Lyrica® Clinical Criteria	Lyrica® will be approved if any ONE of the following are true: • Diabetic Peripheral Neuropathy (DPN); OR • Postherpetic Neuralgia (PHN) AFTER adequate trial and failure of OR intolerance OR contraindication to at least one of these first-line agents ▪ Tricyclic antidepressant (TCAs); or ▪ Anticonvulsant: gabapentin; or ▪ Topical: Lidocaine 5% patch. • Adjunct for partial onset seizure disorder; OR • Fibromyalgia.
Sabril™ Clinical Criteria	Sabril™ will be approved if: • Diagnosis of infantile spasms; OR • Trial and failure of one other anticonvulsant.
Anticonvulsants, Carbamazepine Derivatives	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 prior authorization. 3. Require therapeutic failure of one preferred agent prior to approval of a non-preferred agent. 4. Non preferred products will continue to require a tier 1 co-payment for generics and a tier 2 co-payment for branded products. 5. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 6. For any new chemical entity in the Anticonvulsants: Carbamazepine Derivatives class, require a PA until reviewed by the P&T Advisory Committee.
Oral Oncology Agents	1. Rename this class Oral Oncology Agents. 2. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a first-line recommendation by the NCCN for each cancer type should be preferred. Due to new data on the treatment of CML, both imatinib and EITHER dasatinib OR nilotinib should be preferred. 3. Continue quantity limits based on FDA-approved maximum dose. 4. Agents not selected as preferred will be considered non preferred and require PA. 5. All agents in the category will have no higher than a tier 2 copay regardless of PDL status. 6. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 7. For any new chemical entity in the Oral Oncology Agents class, require a PA until reviewed by the P&T Advisory Committee.
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.

Item	Options for Consideration
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.
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.
Oral Agents for Gout	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 Oral Agents for Gout class, require a PA until reviewed by the P&T Advisory Committee.
Uloric® Clinical Criteria	Uloric® will be approved after adequate trial (at least 3 months) of allopurinol without achievement of serum urate level below 6mg/dL **OR** intolerance **OR** contraindication to allopurinol.
Colcrys™ Clinical Criteria	Colcrys™ will be approved if any one of the following is true: • Diagnosis of Familial Mediterranean Fever; OR • Trial and failure of one of the following: o NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen) or o Corticosteroid.

Item	Options for Consideration
Prenatal Vitamins Clinical Criteria	Prenatal vitamins will be approved if one of the following is true: • Patient must be female and claim must be submitted with pregnancy indicator; OR • Patient is actively nursing; OR • Patient suffers from a chronic condition associated with wasting (i.e., HIV) or malabsorption.
Cymbalta® Clinical Criteria	Cymbalta® will be authorized for the following diagnoses: o Depression/Major Depressive Disorder/Generalized Anxiety Disorder/Social Anxiety Disorder/Panic Disorder: Approval after trial and failure or intolerance or contraindication to one preferred SNRI. o Diabetic peripheral neuropathic pain via an ICD-9 Override o Fibromyalgia via an ICD-9 Override o Chronic musculoskeletal pain: Approval after trial and failure of or intolerance or contraindication to all of the following: 1. Acetaminophen; AND 2. One NSAID; AND 3. Tramadol or preferred opiate analgesic.
Clonidine Patches Clinical Criteria	Clonidine patches will be approved if any one of the following is true: • Patient is <15 years old; OR • Trial and failure of oral clonidine; OR • Patient cannot tolerate/absorb PO.
Regranex® Clinical Criteria	Regranex® will be approved for a diagnosis of lower extremity diabetic ulcers.
Granulocyte Colony Stimulating Factors Clinical Criteria	Granulocyte Colony Stimulating Factors (Leukine® [sargramostim], Neulasta® [pegfilgrastim], or Neupogen® [filgrastim]), will be approved for a diagnosis of: • 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.