Kentucky Department for Medicaid Services

Pharmacy and Therapeutics Advisory Committee Recommendations

March 17, 2011 Meeting

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics Advisory Committee at the March 17, 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	**Branded Products with Generic Components** Require prior authorization for the following products: • Nexiclon® XR • Millipred®	**Passed** 11 For 0 Against
2	**New Products to Market: Pradaxa®** Dabigatran will be approved for a diagnosis of non valvular atrial fibrillation via an ICD-9 Override.	**Passed** 10 For 1 Against
3	**New Products to Market: XGeva™** Denosumab (XGeva™) will be approved for a diagnosis of bone metastases resulting from solid tumors only.	**Passed** 10 For 0 Against
4	**New Products to Market: Kombiglyze™ XR** Place this product preferred with similar approval criteria and quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.	**Passed** 6 For 5 Against
5	**New Products to Market: Silenor®** Place this product non preferred with similar quantity limits in the PDL class titled Sedative Hypnotic Agents.	**Passed** 11 For 0 Against
6	**New Products to Market: Latuda®** Place this product non preferred with similar approval criteria and quantity limits in the PDL class titled Antipsychotic: Atypical.	**Passed** 11 For 0 Against
7	**New Products to Market: Kapvay™** Place this product non preferred with similar approval criteria and quantity limits in the PDL class titled Antihyperkinesis Agents.	**Passed** 11 For 0 Against
8	**New Products to Market: Butrans™** Place this product non preferred in the PDL class titled Narcotics: Long Acting.	**Passed** 11 For 0 Against
9	**New Products to Market: Lastacaft®** Place this product non preferred in the PDL class titled Ophthalmic Antihistamines.	**Passed** 11 For 0 Against
10	**New Products to Market: Amturnide™** Place this product preferred with similar approval criteria in the PDL class titled Direct Renin Inhibitors.	**Passed** 11 For 0 Against

	Description of Recommendation	P & T Vote
11	**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.	**Passed** 11 For 0 Against
12	**Banzel® Clinical Criteria** Banzel® will be approved if: • Diagnosis of Lennox-Gastaut syndrome; OR • Trial and failure of one other anticonvulsant.	**Passed** 10 For 0 Against
13	**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.	**Passed** 10 For 0 Against
14	**Sabril™ Clinical Criteria** Sabril™ will be approved if: • Diagnosis of infantile spasms; OR • Trial and failure of one other anticonvulsant.	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
15	**<u>Anticonvulsants, Carbamazepine Derivatives</u>** 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.	**Passed** 11 For 0 Against
16	**<u>Oral Oncology Agents</u>** 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.	**Passed** 10 For 0 Against
17	**<u>Anticoagulants</u>** 1. Rename this class Anticoagulants. 2. DMS to select preferred agent (s) based on economic evaluation; however, at least one low molecular weight heparin, one factor Xa inhibitor and warfarin should be preferred. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Anticoagulants class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
18	**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.	**Passed** 9 For 1 Against
19	**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.	**Passed** 10 For 0 Against
20	**Colcrys™ Clinical Criteria** Colcrys™ will be approved if any one of the following is true: • Diagnosis of Familial Mediterranean Fever; OR • Trial and failure, via an electronic step edit, of one of the following: o NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen) or o Corticosteroid.	**Passed** 10 For 0 Against
21	**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.	**Passed** 10 For 0 Against
22	**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 one NSAID.	**Passed** 10 For 0 Against