Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations
March 21, 2013 Meeting

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics Advisory Committee at the March 21, 2013 meeting. Review of the recommendations by the Commissioner of the Cabinet for Health and Family Services and final decisions are pending.

	Description of Recommendation	P & T Vote
1	**New Products to Market: Stivarga®** Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Stivarga® for: • A diagnosis of metastatic colorectal cancer (mCRC) after trial and failure of all of the following: o Fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy; AND o An anti-VEGF therapy, AND o If KRAS wild type, an anti-EGFR therapy; OR • A diagnosis of gastrointestinal stromal tumors (GIST) after trial and failure of one preferred oral oncology agent that is FDA-approved for GIST.	**Passed** 8 For 0 Against
2	**New Products to Market: Vascepa®** Place this product non preferred with similar approval criteria in the PDL class titled Lipotropics: Omega-3 Fatty Acids.	**Passed** 8 For 0 Against
3	**New Products to Market: Prepopik™** Place this product non preferred in the PDL class titled Laxative and Cathartics.	**Passed** 8 For 0 Against
4	**New Products to Market: Linzess™** Place this product non preferred in the PDL class titled Laxatives and Cathartics.	**Passed** 8 For 0 Against
5	**New Products to Market: Ultresa™** Place this product non preferred in the PDL class titled Pancreatic Enzymes.	**Passed** 8 For 0 Against
6	**New Products to Market: Xeljanz™** Place this product preferred with appropriate quantity limits and similar approval criteria in the PDL class titled Immunomodulators.	**Passed** 5 For 3 Against
7	**New Products to Market: Eliquis®** Place this product non preferred in the PDL class titled Anticoagulants.	**Passed** 7 For 1 Against
8	**New Products to Market: Iclusig™** Place this product non preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.	**Passed** 8 For 0 Against
9	**New Products to Market: Aubagio®** Place this product non preferred with appropriate quantity limits in the PDL class titled Multiple Sclerosis Agents.	**Passed** 8 For 0 Against

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10	**<u>Multiple Sclerosis Agents</u>** 1. DMS to select preferred agent (s) based on economic evaluation; however, at least glatiramer, one interferon β-1b and one interferon β-1a product should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Place quantity limits on these products based on maximum recommended dose. 4. For any new chemical entity in the Multiple Sclerosis Agents class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
11	**<u>New Generation Antidepressants</u>** 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least bupropion and trazodone 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 New Generation Antidepressants class should require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
12	**<u>Tricyclic Antidepressants</u>** 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least four 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 Tricyclic Antidepressants class should require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
13	**<u>Antimigraine: 5-HT1 Receptor Agonists</u>** 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. At least one non-oral dosage form should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Agents in this class should have quantity limits based on the FDA-approved maximum dose and duration. 4. As part of quantity limit override criteria, patients should be on concurrent migraine prophylaxis therapy (beta blocker, tricyclic antidepressant, calcium channel blocker, etc.) at a therapeutic dose. 5. For any new chemical entity in the Anti-Migraine: 5-HT1 Receptor Agonists class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against

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14	**<u>Anxiolytics</u>** 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least five unique chemical entities, one of which is not a controlled substance, 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 Anxiolytics class should require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
15	**<u>Anxiolytics Duration Edit</u>** Benzodiazepines, with the exception of clonazepam, should be available without requiring a prior authorization for the initial 60 days per a 365 day period. For therapy beyond 60 days, prior authorization should be required and approved if requested by the prescriber as follows: • Approve for 6 months for the following diagnoses: o Anxiety o Anxiety disorder o Panic attacks/disorder o Agoraphobia o Social phobia o Depression o Chemotherapy-induced nausea & vomiting o Status epilepticus • Approve for 1 month for a diagnosis of acute alcohol withdrawal • Approve for 1 year for a diagnosis of seizures.	**Passed** 8 For 0 Against
16	**<u>Alzheimer's: Cholinesterase Inhibitors</u>** 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 will require Prior Authorization. 3. Allow continuation of therapy for non preferred single-source branded products. 4. For any new chemical entity in the Alzheimer's: Cholinesterase Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
17	**<u>Alzheimer's: NMDA Receptor Antagonists</u>** 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 will require Prior Authorization. 3. For any new chemical entity in the NMDA Receptor Antagonist class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against

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18	**<u>Antialcoholic Agents</u>** 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least two unique chemical entities, one of which should be intramuscular naltrexone, 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 Antialcoholic Agents class should require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
19	**<u>Narcolepsy Agents</u>** 1. Move modafinil and armodafinil products into this PDL class. 2. DMS to select preferred agent(s) based upon economic evaluation; however, at least one unique chemical entity should be preferred. 3. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 4. Continue current quantity limits on agents in this class. 5. Any new chemical entity in the Narcolepsy Agents class should require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
20	**<u>Skeletal Muscle Relaxants</u>** 1. DMS to select preferred agent (s) based on economic evaluation; however, at least four unique chemical entities, two typically used for spasticity and two typically used as an antispasmodic, should be preferred. Carisoprodol can be considered an inferior product in this category due to abuse potential; therefore, it should be non preferred and require PA. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Continue current quantity limits on agents in this category based on FDA maximum recommended dose and duration. 4. For any new chemical entity in the Skeletal Muscle Relaxants class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
21	**<u>Tobacco Cessation</u>** 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. Continue quantity limits on drugs in this class based on maximum FDA-approved dose. 4. For any new chemical entity in the Tobacco Cessation class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against

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22	**<u>Dopamine Receptor Agonists</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 will require Prior Authorization. 3. For any new chemical entity in the Dopamine Receptor Agonists class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
23	**<u>Anticholinergics, Parkinson's</u>** 1. DMS to select preferred agent (s) based on economic evaluation; however, at least benztropine 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 Anticholinergics, Parkinson's disease class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
24	**<u>Catechol-O-Methyltransferase (COMT) Inhibitors</u>** 1. DMS to select preferred agent (s) based on economic evaluation; however, at least entacapone should be preferred. Tolcapone can be considered an inferior product in this category due to potential liver toxicity; therefore, it should be non preferred and require PA. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Catechol-O-Methyltransferase (COMT) Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
25	**<u>Dopamine Precursor/Dopa Decarboxylase Inhibitors</u>** 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 will require Prior Authorization. 3. For any new chemical entity in the Dopamine Precursor/Dopa Decarboxylase Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
26	**<u>Dopamine Precursor/Dopa Decarboxylase Inhibitor/COMT Inhibitor</u>** 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Dopamine Precursor / Dopa Decarboxylase Inhibitor / COMT Inhibitor class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against

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27	**MAO-B 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 will require Prior Authorization. 3. For any new chemical entity in the Monoamine Oxidase (MAO)-B Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against
28	**MAOIs** 1. DMS to select preferred agent(s) based upon economic evaluation. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Any new chemical entity in the Monoamine Oxidase Inhibitors class should require a PA until reviewed by the P&T Advisory Committee.	**Passed** 8 For 0 Against