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 16, 2015 meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration
New Products to Market: Cresemba®	Place this product non preferred in the PDL class titled Oral Antifungals.
New Products to Market: Namzaric®	Place this product non preferred in the PDL class titled Alzheimer's Agents.
New Products to Market: Corlanor®	Ivabradine (Corlanor®) will be approved if ALL of the following criteria are met: • Diagnosis of chronic heart failure that is symptomatic; AND • Echocardiogram documentation of LVEF ≤ 35 percent; AND • Patient is in sinus rhythm; AND • Documentation of resting heart rate ≥ 70 bpm; AND • Patient is receiving maximally-tolerated doses of either bisoprolol, carvedilol, or metoprolol succinate extended release as verified by claims history. If no history of claims for a beta blocker, documentation of reason for contraindication to beta blocker therapy is required.
Short-Acting Beta$_2$ Adrenergic Agonists	1. DMS to select preferred agent (s) based on economic evaluation; however, at least a nebulized and metered dose inhaler formulation of albuterol must be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. For any new chemical entity in the Short-Acting Beta$_2$ Adrenergic Agonists class, require a PA until reviewed by the P&T Advisory Committee.
Long-Acting Beta$_2$ Adrenergic Agents	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity available in a metered dose inhaler should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. For any new chemical entity in the Long-Acting Beta$_2$ Adrenergic Agents class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Inhaled Corticosteroids	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 will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. Continue to allow budesonide respules without PA for patients less than 8 years of age. 5. For any new chemical entity in the Inhaled Corticosteroid class, require a PA until reviewed by the P&T Advisory Committee.
Beta Agonists: Combination Products	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity FDA-approved for asthma and COPD should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. For any new chemical entity in the Beta Agonists: Combination Products class, require a PA until reviewed by the P&T Advisory Committee.
COPD Agents	1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. At least one combination product and tiotropium should be among the preferred products. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. For any new chemical entity in the COPD Agents class, require a PA until reviewed by the P&T Advisory Committee.
Leukotriene Modifiers	1. DMS to select preferred agent (s) based on economic evaluation; however, at least montelukast should be preferred. 2. Continue to require Prior Authorization for all agents in this class. 3. Continue quantity limits on agents in this class based on maximum approved dose. 4. For any new chemical entity in the Leukotriene Modifiers class, require a PA until reviewed by the P&T Advisory Committee.
First-Generation Antipsychotics	1. DMS to select preferred agent(s) based on economic evaluation; however, at least four unique chemical entities, at least one representing an agent from each of the potency groups, should be preferred. 2. Agents not selected as preferred will be considered non preferred and require prior authorization 3. Allow continuation of therapy for non preferred single source branded products via a 90 day look back. 4. For any new chemical entity in the First-Generation Antipsychotics class, require a PA until reviewed by the P&T Advisory Committee.

<table>
<tr><th>Item</th><th>Options for Consideration</th></tr>
<tr><td><u>Second-Generation Antipsychotics</u></td><td>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 approval.
3. Continue quantity limits on agents in this class
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 Second-Generation Antipsychotics class, require a PA until reviewed by the P&T Advisory Committee.</td></tr>
<tr><td><u>Second-Generation Antipsychotics Clinical Criteria</u></td><td>Preferred Second-Generation Antipsychotics will be allowed for specific diagnoses only.
<table>
<tr><th>Approvable ICD-10 Block</th><th>Approvable ICD-10 Group</th><th>Approvable ICD-10</th><th>Approvable ICD-10 Description</th></tr>
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<tr><td></td><td>F20</td><td></td><td>Schizophrenia, schizotypal and delusional, and other non-mood psychotic disorders</td></tr>
<tr><td colspan="4">Episodic Mood Disorders</td></tr>
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<tr><td colspan="4">Dissociative, Conversion And Factitious Disorders</td></tr>
<tr><td></td><td>F44</td><td></td><td>Dissociative and conversion disorders</td></tr>
<tr><td colspan="4">Other</td></tr>
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		F06.2	Psychotic disorder with delusions due to known physiological condition
		F06.0	Psychotic disorder with hallucinations due to known physiological condition
	F95		Tic disorder
		F91.3	Oppositional defiant disorder
	G10		Huntington's disease

*Non preferred Second-Generation Antipsychotics will be approved after a 2-week trial of ONE preferred Second-Generation Antipsychotic at an appropriate dose.

** For a non-approvable diagnosis, a Second-Generation Antipsychotic may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.

Major Depressive Disorder (MDD) Criteria:

- Second-Generation Antipsychotics will be approved for MDD as adjunct therapy ONLY. Second-Generation Antipsychotics will be approved if any ONE of the following is true:
  - An adequate trial (4 weeks) of at least one agent in two of the following classes of antidepressants (unless contraindicated or intolerant to):
    - Selective Serotonins Reuptake Inhibitor (SSRIs)
    - Serotonin-Norepinephrine Reuptake Inhibitor (SNRIs)
    - Antidepressants, Other
    - Tricyclic antidepressants (TCAs); OR
  - A diagnosis of Major Depressive Disorder (MDD) with psychotic features.

Multiple Agents Criteria:

Patients who are on more than 2 Second-Generation Antipsychotic agents will require PA. Approval will be granted for the following reasons:

- A maximum of 2 months to allow patients to taper to dual therapy.
- Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose of each agent.

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<tr><td><u>Injectable Antipsychotics</u></td><td>1. DMS to select preferred agent(s) based on economic evaluation. Generic formulations of first generation injectable antipsychotics should be preferred. Additionally, two unique second generation injectable antipsychotics, one of which should have a duration of action of 2 weeks or longer, should be preferred.
2. Agents not selected as preferred will be considered non preferred and require prior approval.
3. Continue quantity limits on agents in this class.
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 Injectable Antipsychotics class, require a PA until reviewed by the P&T Advisory Committee.</td></tr>
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*Non preferred Injectable Antipsychotics will be approved after a 2-week trial of ONE preferred Antipsychotic (oral or parenteral) at an appropriate dose.

**For a non-approvable diagnosis, an injectable antipsychotic may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.

Multiple Therapy Criteria:
Patients who are on more than two Second-Generation Antipsychotic agents will require PA. Approval will be granted for the following reasons:

- A maximum of 2 months to allow patients to taper to dual therapy.
- Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose if each agent.

Second-Generation Antipsychotic and SSRI Combinaition

1. DMS to select preferred agent(s) based on economic evaluation.
2. Agents not selected as preferred will be considered non preferred and require prior approval.
3. Continue quantity limits on agents in this class.
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 Second-Generation Antipsychotic and SSRI Combination class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Second-Generation Antipsychotic and SSRI Combinaition Clinical Criteria	Olanzapine/fluoxetine will be approved if ONE of the following is true: • Diagnosis of depressive episodes associated with bipolar disorder after trial and failure of ONE of the following: o Lithium; OR o Lamotrigine; OR o Bupropion; OR o Paroxetine. • Diagnosis of treatment-resistant depression after trial and failure of one agent from THREE of the following classes of medications: o SSRI; o SNRI; o New Generation Antidepressant; o Tricyclic Antidepressant; o MAOI. ** For a non-approvable diagnosis, olanzapine/fluoxetine may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication. Multiple Therapy Criteria: • Patients who are on more than 2 Second-Generation Antipsychotic agents will require PA. Approval will be granted for the following reasons: o A maximum of 2 months to allow patients to taper to dual therapy. o Additional agents may be added to existing dual therapy after a 2-week trial at the maximum tolerated dose of each agent.
Stimulants and Related Agents	1. DMS to select preferred agent(s) based on economic evaluation; however, at least one sort-acting, one intermediate-acting and one long-acting formulation of methylphenidate and dextroamphetamine as well as atomoxetine should be preferred. 2. Agents not selected as preferred will be considered non preferred and require prior approval. 3. Continue current quantity limits. 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 Stimulants and Related Agents class, require a PA until reviewed by the P&T Advisory Committee.

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<tr><td><u>Stimulants and Related Agents Clinical Criteria</u></td><td>Stimulants and Related Agents will be approved for specific diagnoses only.

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<tr><th>Approvable ICD-10 Block</th><th>Approvable ICD-10 Group</th><th>Approvable ICD-10</th><th>Approvable ICD-10 Description</th></tr>
<tr><td></td><td>F90</td><td></td><td>Attention-deficit hyperactivity disorders</td></tr>
<tr><td></td><td></td><td>G47.419</td><td>Narcolepsy without cataplexy</td></tr>
<tr><td></td><td></td><td>G47.411</td><td>Narcolepsy with cataplexy</td></tr>
<tr><td></td><td></td><td>G47.421</td><td>Narcolepsy in conditions classified elsewhere with cataplexy</td></tr>
<tr><td></td><td></td><td>G47.429</td><td>Narcolepsy in conditions classified elsewhere without cataplexy</td></tr>
<tr><td></td><td></td><td>G47.30</td><td>Sleep apnea, unspecified</td></tr>
<tr><td></td><td></td><td>G47.20</td><td>Circadian rhythm sleep disorder, unspecified type</td></tr>
<tr><td></td><td></td><td>G47.21</td><td>Circadian rhythm sleep disorder, delayed sleep phase type</td></tr>
<tr><td></td><td></td><td>G47.22</td><td>Circadian rhythm sleep disorder, advanced sleep phase type</td></tr>
<tr><td></td><td></td><td>G47.23</td><td>Circadian rhythm sleep disorder, irregular sleep wake type</td></tr>
<tr><td></td><td></td><td>G47.24</td><td>Circadian rhythm sleep disorder, free running type</td></tr>
<tr><td></td><td></td><td>G47.25</td><td>Circadian rhythm sleep disorder, jet lag type</td></tr>
<tr><td></td><td></td><td>G47.26</td><td>Circadian rhythm sleep disorder, shift work type</td></tr>
<tr><td></td><td></td><td>G47.27</td><td>Circadian rhythm sleep disorder in conditions classified elsewhere</td></tr>
<tr><td></td><td></td><td>G47.29</td><td>Other circadian rhythm sleep disorder</td></tr>
</table>

**Agents may be approved for other diagnosis via the prior authorization process based on a review of the current literature by a clinical pharmacist.

Non preferred non-solid dosage forms will be approved if either of the following criteria is met:
• Trial and failure of two preferred products, one of which must be the same chemical as the requested medication; OR
• Inability to swallow/tolerate PO/whole tablets/capsules

Therapeutic Duplication
Prior authorization will be required for more than one long-acting or more than one short-acting stimulant at a time.</td></tr>
<tr><td><u>Narcolelpsy Agents</u></td><td>1. DMS to select preferred agent(s) based upon 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. Continue current quantity limits on agents in this class.
4. Any new chemical entity in the Narcolepsy Agents class should require a PA until reviewed by the P&T Advisory Committee.</td></tr>
<tr><td><u>Narcolelpsy Agents Clinical Criteria</u></td><td>Narcolepsy Agents will be approved based on their FDA-approved indications for the following diagnoses:
• Obstructive sleep apnea / hypopnea syndrome; OR
• Shift work sleep disorder; OR
• Narcolepsy; OR
• Cataplexy Associated with Narcolepsy.</td></tr>
</table>