



## Kentucky Department for Medicaid Services Drug Review and Options for Consideration

The following table lists the Agenda items scheduled, as well as the Options for Consideration, to be presented and reviewed at the **May 18, 2017** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
New Products to Market:	Eucrisa™ to be covered in the Immunomodulators, Atopic Dermatitis review.

Full Class Reviews	Options for Consideration
	Agents in the following Therapeutic Classes are subject to status changes from what is on the current Preferred Drug List (PDL).
<b>Acne Agents, Topical (Topical Acne Agents)</b>	<ul style="list-style-type: none"> <li>DMS to select preferred agent(s) based on economic evaluation; however, multiple generic formulations of benzoyl peroxide, 1 topical antibiotic agent for acne, and tretinoin should be preferred.</li> <li>Agents not selected as preferred will be considered non-preferred and require PA.</li> <li>For any new chemical entity in the <i>Topical Acne Agents</i> class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ul> <p><b><u>Criteria for Review:</u></b></p> <p><i>Topical Antibiotic Agents for Acne:</i>  <b>Length of Authorization:</b> 1 year  <b>Current Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>Trial and failure of a 1-month trial of at least 2 preferred agents in the same class, within the last 90 days</li> </ul> <p><i>Topical Retinoids for Acne:</i>  <b>Length of Authorization:</b> 1 year  <b>Current Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>Therapeutic failure of at least a 1-week trial of at least 2 preferred agents within the last 90 days</li> </ul> <p><b><u>Recommended Criteria Changes:</u></b>  <i>Topical Antibiotic Agents for Acne &amp; Topical Retinoids for Acne:</i></p>

Full Class Reviews	Options for Consideration
	<p><b>Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>• Must have a trial and failure of all preferred products.</li> </ul>
<p><b>Analgesics Narcotics: Long-Acting</b></p>	<ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 long-acting form of morphine and transdermal fentanyl should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and require PA.</li> <li>• For any new chemical entity in the <i>Analgesics Narcotics: Long-Acting</i> class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ul>
<p><b>Analgesics Narcotics: Short-Acting</b></p>	<ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least generic formulations of hydrocodone, hydromorphone, morphine, and oxycodone should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and require PA.</li> <li>• For any new chemical entity in the <i>Analgesics Narcotics: Short-Acting</i> class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ul> <p><b>Criteria for Review (no recommended change):</b> <i>Narcotic Analgesics: Short Acting Single Entity and Combination Products</i> <b>Length of Authorization:</b> 6 months</p> <p><b>Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>• Therapeutic failure to no less than a 1-week trial of at least 2 different preferred agents</li> </ul>
<p><b>Analgesics Narcotics: Fentanyl Buccal Products</b></p>	<ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation.</li> <li>• Require prior approval for all of these agents to ensure utilization based on FDA-approved indication.</li> <li>• For any new chemical entity in the <i>Fentanyl Buccal Products</i> class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ul>
<p><b>Legislative mandate applied to ALL Analgesic Narcotic classes (Informational Only)</b></p>	<p>House Bill 333 (17 RS HB 333/EN) places restrictions upon prescriptions for Schedule II controlled substances if written greater than a 3 days' supply. In order to comply with the requirements of HB 333, the following criteria changes are necessary.</p> <p><b>Length of Authorization:</b> Up to 6 months</p> <p><b>Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>➤ Exceptions to the 3 days' supply limit: <ul style="list-style-type: none"> <li>○ Lack of treatment options for the acute condition; OR</li> <li>○ Chronic pain diagnosis; OR</li> <li>○ Cancer diagnosis; OR</li> <li>○ Patient is receiving hospice or end-of-life treatment; OR</li> <li>○ Patient is in a narcotic treatment program licensed by the Cabinet for Health and Family Services; OR</li> </ul> </li> </ul>

Full Class Reviews	Options for Consideration
	<ul style="list-style-type: none"> <li>○ Treatment is necessary for pain following major surgery or significant trauma.</li> <li>➤ Short-acting Schedule II medications may be approved for up to 30 days given that one of the exceptions above are met.</li> <li>➤ Long-acting Schedule II medications may be approved for up to 6 months given that one of the exceptions above are met.</li> </ul>
<b>Antidepressants: Tricyclics</b>	<ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based upon economic evaluation; however, at least 4 unique chemical entities should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Antidepressants: Tricyclics</i> class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ul>
<b>Anxiolytics (Antianxiety Agents)</b>	<ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based upon economic evaluation; however, at least 5 unique chemical entities, 1 of which is not a controlled substance, should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• Any new chemical entity in the <i>Antianxiety Agents</i> class should require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ul>
<b>Glucocorticoids, Inhaled (Beta-Agonists: Combination Products &amp; Inhaled Corticosteroids)</b>	<p><b>Beta-Agonists: Combination Products:</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity FDA-approved for asthma and COPD should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• Continue quantity limits on agents in this class.</li> <li>• For any new chemical entity in the <i>Beta Agonists: Combination Products</i> class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ul> <p><b>Inhaled Corticosteroids:</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 3 unique chemical entities should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• Continue quantity limits on agents in this class.</li> <li>• Continue to allow budesonide respules without PA for patients less than 8 years of age.</li> <li>• For any new chemical entity in the <i>Inhaled Corticosteroids</i> class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ul>
<b>Glucocorticoids, Oral (Oral Steroids)</b>	<ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least generic formulations of budesonide, dexamethasone, methylprednisolone, prednisolone, and prednisone should be preferred.</li> </ul>

Full Class Reviews	Options for Consideration
	<ul style="list-style-type: none"> <li>The orally-disintegrating formulation of prednisolone should be available for children &lt; 12 years of age.</li> <li>Agents not selected as preferred will be considered non-preferred and require PA.</li> <li>For any new chemical entity in the <i>Oral Steroids</i> class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ul>
<b>Histamine II Receptor Blockers</b> <b>(H2 Receptor Antagonists)</b>	<ul style="list-style-type: none"> <li>DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.</li> <li>Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>For any new chemical entity in the <i>H2 Receptor Antagonists</i> class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ul>
<b>Immunomodulators, Atopic Dermatitis</b> <b>(Topical Immunomodulators)</b>	<ul style="list-style-type: none"> <li>DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.</li> <li>Agents not selected as preferred will be considered non-preferred and require PA.</li> <li>For any new chemical entity in the <i>Topical Immunomodulators</i> class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ul> <p><b>New addition to the class: Eucrisa™</b>  Non-prefer in this class  <b>Length of Authorization:</b> 6 months or length of prescription</p> <ul style="list-style-type: none"> <li>Eucrisa™ (crisaborole) ointment 2% for topical use is a phosphodiesterase-4 (PDE4) inhibitor indicated for the treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.</li> </ul> <p><b>Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>Must have a trial and failure of both Elidel and one topical steroid.</li> </ul>
<b>NSAIDs</b> <b>(Non-Steroidal Anti-Inflammatory Drugs)</b>	<ul style="list-style-type: none"> <li>DMS to select preferred agent(s) based upon economic evaluation; however, at least 6 unique chemical entities should be preferred.</li> <li>Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>For any new chemical entity in the <i>Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)</i> class, should require PA until reviewed by the P&amp;T Advisory Committee.</li> </ul>
<b>Sedative Hypnotic Agents</b>	<ul style="list-style-type: none"> <li>DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities should be preferred. One non-benzodiazepine sedative hypnotic should be among the preferred products.</li> <li>Place quantity limits on agents in the category according to the FDA-recommended maximum dose.</li> <li>Agents not selected as preferred will be considered non-preferred and require PA.</li> </ul>

Full Class Reviews	Options for Consideration
	<ul style="list-style-type: none"> <li>For any new chemical entity in the <i>Sedative Hypnotic Agents</i> class, require PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ul>
<b>Steroids Topical (Topical Steroids)</b>	<ul style="list-style-type: none"> <li>DMS to select preferred agent (s) based on economic evaluation; however, at least 1 agent in each of the potency categories (low, medium, high, and very high) should be preferred.</li> <li>Agents not selected as preferred will be considered non-preferred and require PA.</li> <li>For any new chemical entity in the <i>Topical Steroids</i> class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ul>

Consent Agenda	Options for Consideration	
	For the following therapeutic classes, there are <b>no recommended changes to the currently posted Preferred Drug List (PDL) status.</b>	
	<ul style="list-style-type: none"> <li>Acne Agents, Oral</li> <li>Anti-Alcoholic Preparations</li> <li>Anticholinergics/Antispasmodics</li> <li>Antidiarrheals</li> <li>Anti-Ulcer Protectants</li> <li>Bone Resorption Suppression &amp; Related</li> <li>Growth Hormone</li> <li>Immunosuppressives, Oral</li> <li>Multiple Sclerosis Agents</li> </ul>	<ul style="list-style-type: none"> <li>Oncology Oral – Breast Cancer</li> <li>Oncology Oral – Lung Cancer</li> <li>Oncology Oral – Prostate Cancer</li> <li>Oncology Oral – Renal Cell Carcinoma</li> <li>Oncology Oral – Skin Cancer</li> <li>Pancreatic Enzymes</li> <li>Progestins for Cachexia</li> <li>Skeletal Muscle Relaxants</li> <li>Tobacco Cessation Products</li> </ul>
	For the following therapeutic classes, there are <b>no recommended changes other than a brand/generic switch.</b>	
	<ul style="list-style-type: none"> <li>Antivirals, Oral</li> <li>Epinephrine, Self-Injectable</li> </ul>	<ul style="list-style-type: none"> <li>Hepatitis B Agents</li> <li>Intranasal Rhinitis Agents</li> </ul>
	For the following therapeutic classes, there are <b>no recommended changes other than specific formulation movement.</b>	
	<ul style="list-style-type: none"> <li>Antimigraine Agents - Triptans</li> </ul>	<ul style="list-style-type: none"> <li>Antiparkinson’s Agents</li> </ul>