

**Kentucky Department for Medicaid Services**

**Drug Review Options**

The following chart lists the agenda items scheduled and the options submitted for review at the May 20, 2004, meeting of the Pharmacy and Therapeutics Advisory Committee.

<b>Item</b>	<b>Options for Consideration</b>
<p align="center"><b>Oral Narcotic Analgesic Products Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All dosages and forms of codeine, oxycodone, and hydrocodone in combination with a non-narcotic analgesic are clinically equivalent in efficacy and safety.</li> <li>2. All dosages and forms of morphine, meperidine, hydromorphone, fentanyl, oxycodone, levorphanol, and methadone are clinically equivalent in efficacy and safety.</li> <li>3. The opiate analgesics all carry a significant abuse potential and therefore represent a safety issue that requires the Medicaid program to restrict access to this class of drugs.               <ol style="list-style-type: none"> <li>a. For the combination agents, continue the recommendations from January 2002 without change.</li> <li>b. For the single entity agents, continue to require prior authorization.</li> <li>c. For the single entity long acting oral agents (doses once or twice daily) select at least two products that will be preferred based on economic evaluation.</li> <li>d. All of the preferred products must be utilized before the non-preferred products unless there is a medical contradiction.</li> </ol> </li> <li>4. Place quantity limits, as follows:               <ol style="list-style-type: none"> <li>a. MS Contin, Oramorph, Kadian: #60/30 days (exception: MS Contin 60mg &amp; 200mg: #120/30 days)</li> <li>b. Avinza: #30/30 days</li> <li>c. Levorphanol: #240/30 days</li> <li>d. Oxycontin: #60/30 days</li> <li>e. Duragesic: #10/30 days</li> <li>f. Actiq: #12/30 days or #24/30 days</li> </ol> </li> <li>5. For any new chemical entity in the Opiate class require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p align="center"><b>COX-2 Inhibitor and NSAID Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. Continue previously approved recommendations from January 2003 as listed below:               <ol style="list-style-type: none"> <li>a. Require prior authorization for Celebrex, Vioxx, and Bextra for recipients less than 60 years of age with medical necessity approval based on the presence of one or more additional risk factors for gastrointestinal toxicity.</li> <li>b. Place an electronic age edit of 60 years on Celebrex, Vioxx and Bextra such that claims for members age 60 or greater will process without prior authorization. Patients over the age of 60 are recognized to be at increased risk for upper GI toxicity from NSAIDs.</li> </ol> </li> </ol>

	<p>c. Limit Vioxx 50mg to a 5 day supply per month (5 tablets) and limit Vioxx 12.5mg and 25mg to 30 tablets per month.</p> <ol style="list-style-type: none"> <li>2. All of the COX-2 inhibitors are considered equivalent in clinical efficacy.</li> <li>3. Select at least one COX-2 for the PDL based on economic evaluation.</li> <li>4. For any new chemical entity in the COX-2 class require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p><b>Angiotensin Converting Enzyme Inhibitor (ACEI) and Angiotensin II Receptor Blocker (ARB) Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All ACE Inhibitors are considered clinically equivalent in efficacy and safety.</li> <li>2. Consider preferring the lower cost generic ACEI with a PA requirement on the higher cost branded agents.</li> <li>3. All ARB's are considered clinically equivalent in efficacy and safety.</li> <li>4. Position all of the ARBs equally with respect to each other but prefer the ACEI as first-line prior to approval of an ARB. The ARBs will be reserved for intolerance of ACEI or for a diagnosis of CHF.</li> <li>5. Select at least two (2) branded ARB's to use as preferred products (after treatment failure with an ACEI or a diagnosis of CHF) based on economic evaluation, with all other ARB's as non-preferred products.</li> <li>6. For any new chemical entity in the ACEI or ARB class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p><b>Leukotriene Modifier Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All agents should be considered clinically equivalent in efficacy and safety.</li> <li>2. Select at least one (1) Leukotriene Modifier to use as preferred product(s) based on economic evaluation.</li> <li>3. Continue to provide Singulair and Accolate to recipients with a diagnosis of asthma. As a surrogate for the diagnosis, authorization can be granted at the point of sale by electronically checking claim history for use of a short-acting beta agonist, such as albuterol within the past 90 days.</li> <li>4. Require prior authorization for a diagnosis of allergic rhinitis for Singulair and Accolate. Authorization can be granted if the recipient has a concurrent diagnosis of asthma or continues to be symptomatic after an effective trial of an antihistamine <u>and</u> a nasal corticosteroid, or their use is otherwise not tolerated or medically contraindicated.</li> <li>5. Place a quantity limit of 60 tablets per 30 days on Accolate and 30 tablets per 30 days on Singulair due to flat pricing of the tablet strengths of these products.</li> <li>6. For any new chemical entity in the leukotriene inhibitor class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p><b>Serotonin (5-HT<sub>1</sub>) Receptor Agonist Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All triptans and all dosage forms are considered clinically equivalent in efficacy and safety.</li> <li>2. Select at least two (2) branded oral triptans to use as preferred agents based on economic evaluation.</li> <li>3. Implement a grandfather clause, which allows patients currently on medications not selected as first-line to continue to receive their medication.</li> <li>4. Require prior authorization for injectable and nasal spray forms after failure</li> </ol>

	<p>of oral agents.</p> <ol style="list-style-type: none"> <li>5. Limit the triptans to a quantity limit per month, with overrides requiring prior authorization for additional medication: <ol style="list-style-type: none"> <li>a. Amerge tab 1mg, 2.5mg; Frova tab 2.5mg; Imitrex tab 25mg, 50mg, 100mg – 9 tabs/30 days</li> <li>b. Axert tab 6.25mg, 12.5mg – 6 tabs/30 days</li> <li>c. Imitrex Nasal 5mg, 20mg; Zomig Nasal 5mg – 6 unit dose sprays/30 days</li> <li>d. Imitrex 6mg/0.5ml Injection – 4 injections/30 days</li> <li>e. Maxalt and Maxalt MLT tab 5mg, 10mg; Relpax 20mg, 40mg; Zomig and Zomig ZMT 2.5mg and 5mg tabs – 6 tabs/30 days</li> </ol> </li> <li>6. As part of the PA override criteria, require patients to be taking concurrent migraine prophylaxis medication (beta blocker, tricyclic antidepressant, calcium channel blocker, anticonvulsant, etc).</li> <li>7. For any new chemical entity in the triptan class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p><b>Antiemetic Agents to Treat Severe Nausea/Vomiting (5-HT<sub>3</sub>) Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All products in the 5-HT<sub>3</sub> class are considered clinically equivalent in efficacy and safety.</li> <li>2. Select at least two (2) products to use as preferred based on economic evaluation.</li> <li>3. Quantity limits (No PA) – Place quantity limits on the 5-HT<sub>3</sub> antagonists and on Emend with the quantity limits based on the average quantity per treatment session (and “X” number of sessions per month), and on available package size of each product. Requests for higher doses would require PA. The following are suggested quantity limits based on four cancer treatment cycles per month and adjusted for available package sizes. <ul style="list-style-type: none"> <li><u>Zofran</u> : 4mg and 8mg: 12 tablets per month  24mg: 4 tablets per month  Liquid: 60ml/month  Injection: 4 vials 20ml (40mg); and 8 vials 2ml (4mg)</li> <li><u>Kytril</u>: 1mg tablets: 8 tablets per month  Liquid: 80ml/month  Injection: 8 vials 1mg/1ml</li> <li><u>Anzemet</u>: 50mg and 100mg tablets: 5 tablets per month  Injection: 3 vials 100mg/5ml; and 8 ampules 12.5mg/0.625ml</li> <li><u>Emend</u>: 4 Tri-packs (9 tablets) per month</li> </ul> </li> <li>3. PA required. Approval based on stated chemo agent and/or type of radiation. Quantities restricted to those mentioned in guidelines above and number of requested cancer treatments per month. Non-oncology use will be approved on an individual basis based on prior use of first-line antiemetics.</li> <li>4. For any new chemical entity in the Antiemetic 5-HT<sub>3</sub> class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>

<p><b>Ophthalmic Antibiotic (Topical) Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All of the ophthalmic products within each class are considered clinically equivalent in efficacy and safety to the other products in that class, ie; <ol style="list-style-type: none"> <li>a. Combination Antibiotic Products,</li> <li>b. Miscellaneous Single Entity Antibiotic Products,</li> <li>c. Corticosteroid/Antibiotic Combination Products,</li> <li>d. Fluoroquinolones, 2<sup>nd</sup> and 3<sup>rd</sup> generation (Ofloxacin, Ciprofloxacin, Levofloxacin),</li> <li>e. Fluoroquinolones 4<sup>th</sup> generation (Gatifloxacin, Moxifloxacin) and</li> <li>f. Aminoglycosides</li> </ol> </li> <li>2. Select at least one (1) product from each class as preferred based on economic evaluation.</li> <li>3. Consider no more than 3 fills for any ophthalmic corticosteroid/antibiotic combination product during a six month period.</li> <li>4. For any new chemical entity in the Ophthalmic Antibiotic class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>
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The following terms will be utilized within the therapeutic monograph to classify medications during Drug Class Reviews. By using these terms, the reviewer will be able to easily identify any clinical differences between the medications within the class being reviewed.

Superior - Following evidence-based review, it is determined that the drug provides a therapeutic advantage, in terms of safety and/or efficacy, over other available products within the same treatment modality.

Novel - Following evidence-based review, the drug is therapeutically equivalent in both safety and efficacy, but represents a new therapeutic option, which expands the treatment modality.

Equivalent - Following evidence-based review, it is determined that the drug is therapeutically equivalent in both safety and efficacy to other available products within the same treatment modality.

Not Essential - Following evidence-based review, it is determined that the drug has no therapeutic advantage, due to either reduced safety or efficacy, over other available products within the same treatment modality.