

**Kentucky Department for Medicaid Services**

**Drug Review Options**

The following chart lists the agenda items scheduled and the options submitted for review at the August 5, 2004, meeting of the Pharmacy and Therapeutics Advisory Committee.

<b>Item</b>	<b>Options for Consideration</b>
<p align="center"><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 align="center"><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> </ol>

	<ol style="list-style-type: none"> <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>
<p><b>Selective Serotonin Reuptake Inhibitors Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All SSRIs and all dosage forms are clinically equivalent in both efficacy and safety.</li> <li>2. Quantity limits of 30 units/30 days</li> <li>3. Select at least two (2) branded SSRIs to use as preferred agents based on economic evaluation, in addition to generic fluoxetine and paroxetine.</li> <li>4. Implement a grandfather clause, which allows patients currently on medications not selected as first-line to continue to receive their medication.</li> <li>5. For any new chemical entity in the SSRI class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p><b>Osteoporosis Agents Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All products in each group are considered clinically equivalent in efficacy: <ul style="list-style-type: none"> <li>• Estrogen replacement</li> <li>• SERMs</li> <li>• Bisphosphonates</li> </ul> </li> <li>2. Select in each group: <ul style="list-style-type: none"> <li>• Estrogen replacement -- at least one (1) product to use as preferred based on economic evaluation.</li> <li>• SERMs - at least one (1) product to use as preferred based on economic evaluation.</li> <li>• Bisphosphonates -- at least one (1) product to use as preferred based on economic evaluation.</li> </ul> </li> <li>3. Quantity limits of 30 units/30 days for daily dosing regimens.</li> <li>4. For any new chemical entity in the Osteoporosis Agents class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p><b>Attention Deficit/Hyperactivity Disorder Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All dosages and forms of stimulants (long and short acting) are clinically equivalent in efficacy and safety.</li> <li>2. All immediate release generic products will be available with out prior authorization.</li> <li>3. Focalin is PA required (failure of IR generic stimulants first).</li> <li>4. All extended release stimulant agents are equivalent efficacy and safety.</li> <li>5. Select at least one methylphenidate extended release product (Ritalin LA, Concerta or Metadate CD) that will be preferred based on economic evaluation.</li> <li>6. All of the preferred products must be utilized before the non-preferred products unless there is a medical contraindication.</li> <li>7. Continue with quantity limits on Strattera.</li> <li>8. For all controlled stimulant agents, recommend continue Prior Authorization for any patient &gt; 18 years old.</li> </ol>

	<ol style="list-style-type: none"> <li>9. For all stimulant agents, allow only one prescription per month unless switching agents due to therapeutic failure.</li> <li>10. Grandfather any patient who in the past 3 months has been stabilized on any ADHD treatment protocol.</li> <li>11. For any new chemical entity in the Stimulant class require a PA and quantity limit until reviewed by the P&amp;T advisory Committee.</li> </ol>
<p><b>Cephalosporin Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All cephalosporins in each generation are equivalent in safety and efficacy.</li> <li>2. Select at least one (1) branded cephalosporin to use as preferred agents based on economic evaluation, in each generation.</li> <li>3. For any new chemical entity in the cephalosporin class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p><b>Macrolide/ Ketolide Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All macrolides are equivalent in safety and efficacy.</li> <li>2. Select at least one (1) branded macrolide to use as preferred agents based on economic evaluation, in addition to generic erythromycin.</li> <li>3. For all branded agents, recommend quantity limits. <ul style="list-style-type: none"> <li>- Zithromax 100mg/5ml suspension: 150ml per 30 days.</li> <li>- Zithromax 1gm packet: #4 per 30days.</li> <li>- Zithromax 200mg/5ml suspension: 75ml per 30days.</li> <li>- Zithromax 250mg tablets: #12 per 30 days.</li> <li>- Zithromax 600mg tablets: #10 per 30days.</li> <li>- Biaxin XL #28 per 30 days</li> <li>- Ketek #20 per 30 days</li> </ul> </li> <li>4. For any new chemical entity in the macrolide class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<p><b>Non-Antibiotic Ophthalmic Agents Therapeutic Class Review</b></p>	<ol style="list-style-type: none"> <li>1. All subgroups of drugs listed in each of the 4 main ophthalmic groups, Glaucoma, Allergic Conjunctivitis, Dry Eye Syndrome and Miscellaneous are equivalent in safety and efficacy.</li> <li>2. Select at least one (1) branded ophthalmic drug from each subgroup to use as preferred agents based on economic evaluation.</li> <li>3. For all branded ophthalmic antihistamine agents, recommend quantity limits. <ul style="list-style-type: none"> <li>- Optivar (azelastine): 6ml per 28 days.</li> <li>- Zaditor (ketotifen): 5ml per 23 days.</li> <li>- Livostin (levocabastine): 10ml per 23 days.</li> <li>- Patanol (olopatadine): 5ml per 23 days.</li> <li>- Elestat (epinastine): 5ml per 23 days.</li> <li>- Emadine (emedastine): 10ml (2 vials) per 23 days.</li> </ul> </li> <li>4. For any new chemical entity in the ophthalmic non-antibiotic class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>

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.