

Kentucky Department for Medicaid Services

Pharmacy and Therapeutics Advisory Committee Recommendations

July 16, 2009 Meeting

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics Advisory Committee at the July 16, 2009 meeting. Review of the recommendations by the Secretary of the Cabinet for Health and Family Services and final decisions are pending.

	Description of Recommendation	P & T Vote
1	<p><u>High Potency Statins</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least simvastatin and EITHER Lipitor[®] or Crestor[®] should be preferred. 2. Continue quantity limits on agents in this class based on maximum recommended dose. 3. Agents not selected as preferred will be considered non preferred and require PA via an electronic step edit. 4. For any new chemical entity in the High Potency Statin class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 12 For 0 Against</p>
2	<p><u>New Drugs to Market: Sancuso[®]</u></p> <p>Place this product non preferred with appropriate quantity limits in the PDL category titled Anti-Emetics: 5-HT3 Antagonists; however allow for its use if the following criteria are met:</p> <p>Sancuso[®] will be approved if either of the following criteria are met:</p> <ul style="list-style-type: none"> • Current treatment with chemotherapy to avoid the need for IV antiemetics (both active and new chemotherapy patients); OR, • Trial and failure of ondansetron. 	<p>Passed 12 For 0 Against</p>
3	<p><u>Antibiotics: Oxazolidinones</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least linezolid should be preferred. 2. Place PA criteria around linezolid to prevent over utilization and preserve it as a last line drug. 3. Continue appropriate quantity limits. 4. For any new chemical entity in the Oxazolidinones class, require a PA and quantity limit until reviewed by the P&T Advisory Committee. 	<p>Passed 12 for 0 Against</p>

	Description of Recommendation	P & T Vote
4	<p>Zyvox[®] Clinical Criteria</p> <p>1. Diagnoses to approve:</p> <ul style="list-style-type: none"> • Vancomycin-Resistant Gram Positive Infections (VRE) via current culture and sensitivity testing <ul style="list-style-type: none"> ▪ Enterococcus faecium ▪ Enterococcus faecalis • Methicillin-Resistant Staph Aureus Infections (MRSA) via current culture and sensitivity testing • Empiric management of suspected MRSA infection without culture confirmation if any of the following are true: <ul style="list-style-type: none"> ▪ Previously documented MRSA infection, ▪ Previous cellulitis caused by documented MRSA, ▪ Skin and soft tissue infection with abscess, <ul style="list-style-type: none"> ▪ Patient meets BOTH of the following criteria: <ul style="list-style-type: none"> ▪ Has tried and failed within the past month any of the following antibiotics: <ul style="list-style-type: none"> • Tetracycline, or • Sulfamethasoxazole/trimethoprim, or • Clindamycin, or • Any fluoroquinolone AND ▪ Patient presents with any one of the following risk factors: <ul style="list-style-type: none"> • Health facility stay/visit (current or within the past month) • Surgery in the past month • Participation in team sports (current or past month) • Jail/Prison (current or in past month) • Military (current or in past month) • History of “spider bite” within the past month • Pediatrics enrolled in daycare or school (current or in past month) • Multiple areas of induration • HIV • Permanent indwelling catheters • Percutaneous implanted device • IV drug user • Previously colonized with multi-drug resistant pathogens including MRSA • Diabetic foot ulcer • End stage renal disease; AND <p>2. Request is NOT for more than a 28 day supply (Pass to RPh if days supply exceeds this)</p>	<p>Passed</p> <p>12 For</p> <p>0 Against</p>

	<p><u>Clinical consideration:</u> If Zyvox[®] was initiated in the hospital; approve to complete the course of antibiotic therapy. Number of days of hospital therapy is included in 28-day total therapy.</p>	
5	<p><u>Impact Analysis on Branded Products with Generic Components:</u> The following branded product with generic components should now require prior authorization: 1. Kenalog[®] Spray</p>	<p>Passed 11 For 1 Abstention 0 Against</p>
6	<p><u>New Drugs to Market: Degarelix Acetate[®]</u> Allow this product to pay unrestricted until the Gonadotropin Releasing Hormone Receptor Antagonists are reviewed for PDL placement.</p>	<p>Passed 11 For 0 Against</p>
7	<p><u>New Drugs to Market: Afinitor[™]</u> Allow this product to pay after the following clinical criteria are met: Afinitor[™] (everolimus) will be approved if the patient has a history of either of the following agents within the past 90 days (unless ALL are contraindicated). <ul style="list-style-type: none"> • sunitinib (Sutent[®]) • sorafenib (Nexavar[®]) </p>	<p>Passed 11 For 0 Against</p>
8	<p><u>New Drugs to Market: Lamictal ODT[®]</u> Based on the Committee's recommendation when this class was reviewed, place this product preferred in the PDL category titled: Anticonvulsants: Second Generation.</p>	<p>Passed 6 For 5 Against</p>
9	<p><u>New Drugs to Market: Acanya[™]</u> Place this product non preferred in the PDL category titled Dermatologics: Antibiotic Agents for Acne.</p>	<p>Passed 11 For 0 Against</p>
10	<p><u>New Drugs to Market: Aplenzin[™]</u> Place this product non preferred in the PDL category titled Antidepressants: New Generation.</p>	<p>Passed 11 For 0 Against</p>
11	<p><u>New Drugs to Market: Asacol HD[®]</u> Place this product non preferred in the PDL category titled 5-ASA Derivatives, Oral Preparations.</p>	<p>Passed 11 For 0 Against</p>
12	<p><u>New Drugs to Market: Besivance[™]</u> Place this product non preferred in the PDL category titled Ophthalmic Antibiotics, Quinolones.</p>	<p>Passed 11 For 0 Against</p>
13	<p><u>New Drugs to Market: Exforge HCT[®]</u> Place this product preferred in the PDL category titled Angiotensin Receptor Blockers + CCB (DHP) with the following clinical criteria. Exforge HCT[®] will be approved if the patient has a history of either of the following agents within the past 365 days: <ul style="list-style-type: none"> • ACE Inhibitor, OR • Exforge[®] </p>	<p>Passed 11 For 0 Against</p>

	Description of Recommendation	P & T Vote										
14	<p><u>New Drugs to Market: Gelnique™</u> Place this product non preferred in the PDL category titled Urinary Tract Antispasmodics; however, allow for its use in patients who cannot tolerate/swallow oral medications.</p>	<p>Passed 11 For 0 Against</p>										
15	<p><u>New Drugs to Market: Lovaza®</u> Place this product preferred in the PDL category titled Lipotropics: Fibric Acid Derivatives with the following clinical criteria.</p> <p>Lovaza® will be approved if the patient has a history of either of the following agents within the past 90 days:</p> <ul style="list-style-type: none"> Fibric Acid Derivative, OR Statin 	<p>Passed 12 For 0 Against</p>										
16	<p><u>New Drugs to Market: Nuvigil®</u> Place this product non preferred with appropriate quantity limits in the PDL category titled Antihyperkinesia Agents with the following criteria:</p> <p>Nuvigil® (armodafinil) will be approved if both of the following criteria are met:</p> <ul style="list-style-type: none"> One of the following approvable diagnosis (via ICD-9 override): <table border="1" data-bbox="251 1039 1242 1312"> <tbody> <tr> <td rowspan="3">Narcolepsy</td> <td>347.00</td> </tr> <tr> <td>347.01</td> </tr> <tr> <td>347.11</td> </tr> <tr> <td rowspan="3">Sleep apnea/hypoapnea syndrome</td> <td>780.57</td> </tr> <tr> <td>780.51</td> </tr> <tr> <td>780.53</td> </tr> <tr> <td>Shift work sleep disorder</td> <td>307.45</td> </tr> </tbody> </table> <ul style="list-style-type: none"> Trial and failure of Provigil® (modafinil) via a 90 day look back. 	Narcolepsy	347.00	347.01	347.11	Sleep apnea/hypoapnea syndrome	780.57	780.51	780.53	Shift work sleep disorder	307.45	<p>Passed 11 For 0 Against</p>
Narcolepsy	347.00											
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	347.11											
Sleep apnea/hypoapnea syndrome	780.57											
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Shift work sleep disorder	307.45											
17	<p><u>New Drugs to Market: Ryzolt™</u> Place this product non preferred in the PDL category titled Non-Narcotics.</p>	<p>Passed 11 For 0 Against</p>										
18	<p><u>New Drugs to Market: Savella™</u> Place this product preferred in the PDL category titled Antidepressants: SNRIs, and allow for its use in fibromyalgia only via an ICD-9 Override.</p>	<p>Passed 12 For 0 Against</p>										
19	<p><u>New Drugs to Market: Simponi®</u> Place this product non preferred in the PDL category titled Immunomodulators with quantity limits based on the FDA-approved maximum dose and clinical criteria similar to the other Immunomodulators.</p>	<p>Passed 11 For 0 Against</p>										

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20	<u>New Drugs to Market: Zinotic ES®</u> Place this product non preferred in the PDL category titled Otic: Miscellaneous.	Passed 11 For 0 Against
21	<u>Penicillins</u> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least amoxicillin, ampicillin, dicloxacillin and penicillin V should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Penicillin class, require a PA until reviewed by the P&T Advisory Committee.	Passed 11 For 0 Against
22	<u>Penicillin/Beta-Lactamase Inhibitor Combinations</u> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least amoxicillin/clavulanate should be preferred on the PDL. 2. If amoxicillin/clavulanate ES is selected as non preferred allow for its use in patients less than 12 years of age. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Penicillin/Beta-Lactamase Inhibitor Combination class, require a PA until reviewed by the P&T Advisory Committee.	Passed 11 For 0 Against
23	<u>First Generation Cephalosporins</u> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least cephalexin should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the First Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee.	Passed 11 For 0 Against
24	<u>Second Generation Cephalosporins</u> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least cefuroxime should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Second Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee.	Passed 11 For 0 Against

	Description of Recommendation	P & T Vote
25	<p><u>Third Generation Cephalosporins</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least cefixime and cefpodoxime should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Third Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 11 For 0 Against</p>
26	<p><u>Ketolides</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation. 2. Maintain prior authorization criteria for telithromycin to ensure this product is being used for multi-drug resistant infections only. 3. Continue current quantity limit (10 days supply per month). 4. For any new chemical entity in the Ketolide class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 11 For 0 Against</p>
27	<p><u>Ketek[®] Clinical Criteria</u></p> <ol style="list-style-type: none"> 1. Diagnosis of Community Acquired Pneumonia (CAP) OR Acute Exacerbation of Chronic Bronchitis AND 2. Must have previously used (within the past 28 days) ONE of the following: <ol style="list-style-type: none"> a. Penicillin (e.g., amoxicillin, amoxicillin-clavulanate, ampicillin-sulbactam, or piperacillin-tazobactam) b. 2nd or 3rd generation cephalosporins (e.g., cefuroxime, cefpodoxime, cefprozil, cefotaxime, ceftriaxone) c. Macrolide (e.g., azithromycin, clarithromycin, erythromycin) d. Fluoroquinolone (e.g., levofloxacin, gatifloxacin, moxifloxacin) e. Tetracycline (e.g., doxycycline) f. Trimethoprim/sulfamethoxazole (e.g., Bactrim) AND 3. Request is not for more than a 10 day supply. <p>Clinical Consideration If Ketek™ was initiated in the hospital; approve to complete the course of antibiotic therapy.</p>	<p>Passed 10 For 1 Abstention 0 Against</p>
28	<p><u>Tetracyclines</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least generic formulations of doxycycline, minocycline, and tetracycline should be preferred. 2. If demeclocycline is selected as non preferred, allow for its use in SIADH only via an ICD-9 override. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Tetracycline class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 10 For 1 Abstention 0 Against</p>

	Description of Recommendation	P & T Vote
29	<p><u>Sulfonamides, Folate Antagonist</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least trimethoprim/sulfamethoxazole should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Sulfonamides, Folate Antagonist class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>10 For 1 Abstention 0 Against</p>
30	<p><u>Oral Antifungals</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, all currently available unique chemical entities should be preferred on the PDL. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Remove prior authorization requirements from terbinafine; however, continue prior authorization requirements for itraconazole. 4. For any new chemical entity in the Oral Antifungal class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>11 For 0 Against</p>

	Description of Recommendation	P & T Vote
31	<p><u>Itraconazole Clinical Criteria</u></p> <p>Diagnoses to approve:</p> <ul style="list-style-type: none"> • Tinea corporis (body ringworm), Tinea cruris (jock itch), or Tinea pedis (athlete's foot): <ul style="list-style-type: none"> • If the patient has NOT had a therapeutic failure on at least one topical antifungal medication, refer the request to a clinical pharmacist. • If the patient has had a failure on at least one topical antifungal medication, approve: itraconazole capsules for once daily dosing for a 4-week continuous course of therapy. • Patient can receive itraconazole automatically if diagnosis is Tinea Capitis for up to 4 weeks • Onychomycosis (fungal infection of the fingernails or toenails): <ul style="list-style-type: none"> • Approval is based on initial vs. continuation or retreatment as follows: <ul style="list-style-type: none"> • For the initial treatment of a fingernail or toenail infection (rather than continuation of therapy or retreatment) AND ALSO • For retreatment if there has been an interval of 3 months between the initial treatment of fingernail infection and a second treatment or an interval of 6 months between the initial treatment of toenail infection and a second treatment: <ul style="list-style-type: none"> • Fingernail Infection: Approve: itraconazole capsules for twice daily dosing for an 8-week continuous course of therapy. • Toenail Infection: Approve: itraconazole capsules for once daily dosing for a 12-week continuous course of therapy. <p>For the treatment of a systemic or other serious fungal infection (e.g., esophageal candidiasis, blastomycosis, aspergillosis, cutaneous sporotrichosis), approve the requested quantity for 6 months.</p>	<p>Passed 11 For 0 Against</p>
32	<p><u>Antivirals: Herpes</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least acyclovir and either valacyclovir or famciclovir should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Antivirals, Herpes class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 11 For 0 Against</p>

	Description of Recommendation	P & T Vote
33	<p><u>Antivirals: Influenza</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least amantadine, oseltamivir, rimantadine and zanamivir should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. DMS to consider CDC recommendation updates regarding antiviral therapy for the treatment of influenza. The Medical Director, with Secretary approval, may make changes to the PDL listing based on the CDC recommendations until this class can be considered at the next scheduled review. 4. For any new chemical entity in the Antivirals, Influenza class, require a PA until reviewed by the P&T Advisory Committee, unless recommended to be preferred per #3 above. 	<p>Passed 11 For 0 Against</p>