

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 21, 2009, meeting of the Pharmacy and Therapeutics Advisory Committee

| Item | Options for Consideration |
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| <u>New Drugs to Market:</u> <u>Sancuso®</u> | Place this product non preferred with appropriate quantity limits in the PDL category titled Anti-Emetics: 5-HT3 Antagonists. |
| <u>Antibiotics:</u> <u>Oxazolidinones</u> | <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 overutilization 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. |
| <u>Zyvox® Clinical Criteria</u> | <ul style="list-style-type: none"> • Diagnoses to approve: <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; AND • Request is NOT for more than a 28 day supply (Pass to RPh if days supply exceeds this) <p>Refer all other requests to a clinical pharmacist Clinical consideration: 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> |
| <u>New Drugs to Market:</u> <u>Aplenzin™</u> | Place this product non preferred in the PDL category titled Antidepressants: New Generation. |
| <u>New Drugs to Market:</u> <u>Acanya™</u> | Place this product non preferred in the PDL category titled Dermatologics: Antibiotic Agents for Acne. |
| <u>New Drugs to Market:</u> <u>Degarelix Acetate®</u> | Allow this product to pay unrestricted until the Gonadotropin Releasing Hormone Receptor Antagonists are reviewed for PDL placement. |
| <u>Penicillins</u> | <ol style="list-style-type: none"> 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. |

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| <u>Penicillin/Beta-Lactamase Inhibitor Combinations</u> | <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least amoxicillin/clavulanate should be preferred on the PDL. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Penicillin/Beta-Lactamase Inhibitor Combination class, require a PA until reviewed by the P&T Advisory Committee. |
| <u>First Generation Cephalosporins</u> | <ol style="list-style-type: none"> 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. |
| <u>Second Generation Cephalosporins</u> | <ol style="list-style-type: none"> 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. |
| <u>Third Generation Cephalosporins</u> | <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. |
| <u>Ketolides</u> | <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. |
| <u>Ketek® Clinical Criteria</u> | <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. Fluroquinolone (e.g., levofloxacin, gatifloxacin, moxifloxacin) e. Tetracycline (e.g., doxycycline) f. Trimethoprim/sulfamethaxole (e.g., Bactrim) AND 3. Request is not for more than a 10 day supply. <p><u>Clinical Consideration</u> If Ketek™ was initiated in the hospital; approve to complete the course of antibiotic therapy.</p> |

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| <u>Tetracyclines</u> | <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. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Tetracycline class, require a PA until reviewed by the P&T Advisory Committee. |
| <u>Sulfonamides, Folate Antagonist</u> | <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. |
| <u>Oral Antifungals</u> | <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. |

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| <p><u>Terbinafine/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 <u>Tinea Capitis</u> 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 <u>initial treatment</u> of a fingernail or toenail infection (rather than continuation of therapy or retreatment) AND ALSO • For <u>retreatment</u> 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. • 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><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 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. |

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| <u>Antivirals: Influenza</u> | <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. |
| <u>Hepatitis C: Pegylated Interferons</u> | <ol style="list-style-type: none"> 1. Rename the category Hepatitis C: Interferons. 2. DMS to select preferred agent (s) based on economic evaluation; however, at least peginterferon alfa-2a and peginterferon alfa-2b should be preferred. 3. Agents not selected as preferred will be considered non preferred. 4. PDL selected agents will apply for any new courses of therapy only. 5. Place clinical prior authorization around the entire class to ensure appropriate utilization. 6. For any new chemical entity in the Hepatitis C: Interferons class, require a PA until reviewed by the P&T Advisory Committee. |
| <u>Hepatitis C: Pegylated Interferons Clinical Criteria</u> | <p>All preferred and non-preferred pegylated interferons will require a prior authorization after the initial 16 weeks of therapy.</p> <p><u>After the initial 16 weeks of therapy pegylated interferons will be approved if:</u></p> <ol style="list-style-type: none"> 1. HCV RNA Assay results obtained prior to initiation of therapy AND 12 weeks after initiation of therapy must be provided. If the difference between the two assays is at least a 2 logarithmic unit decrease (example: from 2,000,000 IU to 20,000 IU), THEN approve for duration of therapy as defined below. 2. If the assays were done BUT the difference between the two assays WAS NOT at least a 2 logarithmic unit decrease (example: from 2,000,000 IU to 20,000 IU), THEN refer the request to a clinical pharmacist who will deny the request. 3. If there is any other valid medical reason why the patient should require this therapy, a clinical pharmacist may approve the request for the total length of therapy as listed below. <p><i>LIMITATION ON LENGTH OF THERAPY IS BASED ON PRODUCT</i></p> <ol style="list-style-type: none"> 1. Interferon alfacon-1 <ol style="list-style-type: none"> a. IFN naïve – 24 weeks total therapy b. INF relapse – 48 weeks total therapy 2. Peginterferon alfa-2a <ol style="list-style-type: none"> a. Genotype 1, 4 OR HIV positive – 48 weeks total therapy b. Genotype 2, 3 – 24 weeks total therapy 3. Peginterferon alfa-2b – 1 year total therapy |
| <u>Hepatitis C: Ribavirins</u> | <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least ribavirin should be preferred. 2. Agents not selected as preferred will be considered non preferred. 3. PDL selected agents will apply for any new courses of therapy only. 4. Place clinical prior authorization around the entire class of ribavirins to ensure appropriate utilization. 5. For any new chemical entity in the Hepatitis C: Ribavirins class, require a PA until reviewed by the P&T Advisory Committee. |

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| <u>Hepatitis C: Ribavirins Clinical Criteria</u> | Ribavirins will pay at point-of-sale if there is concurrent interferon therapy in history. |
| <u>Ranexa® Clinical Criteria</u> | <p>Ranexa® (ranolazine) will be approved if the patient has a history of one agent in any of the following drug classes within the past 90 days (unless ALL are contraindicated).</p> <ul style="list-style-type: none"> • Beta Blocker • Nitrate • Calcium Channel Blocker |
| <u>Lidoderm® Clinical Criteria</u> | <p>Lidoderm will be approved if any one of the following criteria are met:</p> <ul style="list-style-type: none"> • Diagnosis of Post Herpetic Neuralgia via an ICD-9 override; OR • History of one agent in any of the following medication classes in the past 90 days: <ul style="list-style-type: none"> • Tricyclic antidepressant • Anticonvulsant • SNRI |