Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations

January 25, 2016

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics Advisory Committee at the January 21, 2016 meeting.

*Note: a quorum was not achieved, however, the meeting was held with the members present and the below reflects their recommendations.

Review of the recommendations by the Commissioner of the Cabinet for Health and Family Services and final decisions are pending.

	Description of Recommendation	P & T Vote
1	**New Products to Market: Orkambi®** This drug is not on the PDL, the vote was on the clinical criteria. The Committee voted to approve criteria as: • Initially (6 months) if **ALL** of the following criteria are met: – Age ≥ 12 years; **AND** – Diagnosis of cystic fibrosis homozygous for the F508del mutation in the CFTR gene confirmed by an FDA-cleared CF mutation test; **AND** – Baseline ophthalmic examinations if patient is 12 to 18 years of age. • For continuation of therapy if ALL of the following criteria are met: – Stable or improved FEV_1; **AND** – Serum ALT or AST ≤5 x upper limit of normal (ULN), or ALT or AST ≤3 x ULN with bilirubin ≤2 x ULN.	**Passed** 7 For 0 Against
2	**New Products to Market: Durlaza ER®** Non-prefer in PDL class: *Platelet Aggregation Inhibitors* **Length of Authorization:** 1 year • Indicated to reduce the risk of death and myocardial infarction (MI) in patients with chronic coronary artery disease, such as patients with a history of MI or unstable angina pectoris or with chronic stable angina and to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack. • Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include: – Adverse reaction to preferred drugs – Allergy to preferred drugs – Contraindication to preferred drugs	**Passed** 7 For 0 Against

	Description of Recommendation	P & T Vote
	• Has the patient had a therapeutic trial and treatment failure with **ONE** preferred drug? Document the details. • Aspirin is covered without PA; clinical reason as to why aspirin cannot be used. • Quantity Limit = 1 tablet per day	
3	**New Products to Market: Odomzo®** Non-prefer in PDL class: *Oncology Agents, Oral* Approve Odomzo® if **ALL** of the following criteria are met: **Length of Authorization:** 1 year • Indicated for use in basal cell carcinoma (BCC) that has recurred after surgery or radiation therapy or in those with basal cell carcinoma who are not candidates for surgery or radiation therapy. • Verify patient is **NOT** pregnant. Use is contraindicated in pregnancy. • Obtain serum creatine kinase level and perform renal function tests prior to initiation of therapy for all patients. • Minimum age restriction of 18 years of age – Maximum Quantity Limit = 1 per day	**Passed** 7 For 0 Against
4	**New Products to Market: Lonsurf®** Non-prefer in PDL class: *Oncology Agents, Oral* Approve Lonsurf® if patient has metastatic colorectal cancer and has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and anti-VEGF biological therapy, and if RAS wild-type, then with an anti-EGFR therapy. Safety and efficacy of Lonsurf® have not been established in pediatric patients.	**Passed** 7 For 0 Against
5	**New Products to Market: Aristada ER™** Non-prefer in PDL class: *Antipsychotics* *Non preferred Injectable Antipsychotics will be approved after a 2-week trial of **ONE** preferred Antipsychotic (oral or parenteral) at an appropriate dose. **For a non-approvable diagnosis, an injectable antipsychotic may be approved if the prescriber can provide documented clinical evidence (peer reviewed literature or multiple case studies) supporting the use of the requested medication for the requested indication.	**Passed** 7 For 0 Against
6	**New Products to Market: Varubi™** Non-prefer in PDL class: *Anti-emetic & Antivertigo Agents* **Length of Authorization:** Length of chemotherapy regimen or a maximum of 6 months • Indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. • Varubi™ does **NOT** require treatment failure with preferred drugs when used for moderately or highly emetogenic chemotherapy. Approval may be granted if either of the bullet points below apply: – May be approved for use in patients receiving highly or moderately	**Passed** 7 For 0 Against

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	emetogenic chemotherapy in addition to dexamethasone and a 5-HT3 antagonist. – This includes patients on the following: AC combination (Doxorubicin or Epirubicin w/Cyclophosphamide), Aldesleukin, Amifostine, Arsenic trioxide, Azacitidine, Bendamustine, Busulfan, Carmustine, Carboplatin, Cisplatin, Clofarabine, Cyclophosphamide, Cytarabine, Dacarbazine, Dactinomycin, Daunorubicin, Doxorubicin, Epirubicin, Etoposide, Hexamethylmelamine, Idarubicin, Ifosfamide, Imatinib, Interferon alfa, Irinotecan, Mechlorethamine, Melphalan, Methotrexate, Oxaliplatin, Procarbazine, Streptozotocin, Temozolomide. – May be approved for other uses restricted to patients receiving other chemotherapy who have failed maximum doses of ondansetron combined with dexamethasone. Safety and efficacy of Varubi™ have not been established in pediatric patients.	
7	**New Products to Market: Prestalia®** Non-prefer in PDL class: *Angiotension Modulator Combinations* **Length of Authorization:** 1 year • Indicated for the treatment of hypertension to lower blood pressure: – In patients not adequately controlled with monotherapy. – As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. • Is there any reason that the patient cannot be switched to a preferred medication? Document the details and approve. Acceptable reasons include: – Adverse reaction to preferred drugs – Allergy to preferred drugs – Contraindication to preferred drugs • Has the patient had a therapeutic trial and treatment failure of single ingredient perindopril and amlodipine due to non-compliance within the last 12 months? Document the details and approve. • Do not administer Prestalia® to a pregnant female because it may cause fetal harm. – When pregnancy is detected, patient must discontinue Prestalia® as soon as possible. • The concomitant use of Prestalia® with aliskiren is contraindicated in patients with diabetes. • Safety and effectiveness of Prestalia® in pediatric patients have not been established. • Maximum Quantity Limit = 1 per day	**Passed** 7 For 0 Against

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8	**First Generation Cephalosporins:** • DMS to select preferred agent(s) based on economic evaluation; however, at least cephalexin should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the First Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against
9	**Second Generation Cephalosporins:** • DMS to select preferred agent(s) based on economic evaluation; however, at least cefuroxime should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Second Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against
10	**Third Generation Cephalosporins:** • DMS to select preferred agent(s) based on economic evaluation; however, at least cefixime and cefpodoxime should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Third Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against
11	**Antibiotics, GI:** • DMS to select preferred agent (s) based upon economic evaluation; however, at least metronidazole, oral vancomycin, paromomycin, and nitazoxanide should be preferred. • Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. • For any new chemical entity in the GI Antibiotic class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against
12	**Xifaxin® Clinical Criteria:** Approve Xifaxan® in the correct strength for the correct diagnosis for the correct quantity: • **200 mg Tablet Only –** Diagnosis of traveler's diarrhea caused by non-invasive strains of *E. coli* after a trial and failure of ciprofloxacin. (3-day course of therapy only) – QL = 9 tabs for 30 days • **550 mg Tablet Only –** Diagnosis of hepatic encephalopathy after a trial and failure of lactulose or neomycin. (Up to one year course of therapy). – QL = 2 tabs per day • **550 mg Tablet Only –** Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) in adults (dosed tid for 14 days). – QL = 42 tabs per 14 days (maximum = 3 treatment cycles)	**Passed** 7 For 0 Against

	Description of Recommendation	P & T Vote
13	**Ketolides:** • DMS to select preferred agent(s) based on economic evaluation. • Maintain prior authorization criteria for telithromycin to ensure this product is being used for multi-drug resistant infections only. • Continue current quantity limit (10 days supply per month). • For any new chemical entity in the Antibiotics: Ketolide class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against
14	**Ketek® Clinical Criteria:** • Diagnosis of community-acquired pneumonia (CAP); **AND** • Must have previous use (within the past 28 days) of **ONE** of the following: – Penicillin (e.g., amoxicillin, amoxicillin-clavulanate, ampicillin-sulbactam, or piperacillin-tazobactam); **OR** – Second or third generation cephalosporins (e.g., cefuroxime, cefpodoxime, cefprozil, cefotaxime, ceftriaxone); **OR** – Macrolides (e.g., azithromycin, clarithromycin, erythromycin); **OR** – Fluoroquinolone (e.g., levofloxacin, gatifloxacin, moxifloxacin); **OR** – Tetracyclines (e.g., doxycycline); **OR** – Trimethoprim/sulfamethoxazole (e.g., Bactrim); **AND** • Request is NOT for more than a 10-day supply If Ketek® was initiated in the hospital, can approve to complete the course of antibiotic therapy.	**Passed** 7 For 0 Against
15	**Macrolides:** • DMS to select preferred agent(s) based on economic evaluation; however, at least three unique chemical entities should be preferred. • Agents not selected as preferred will be considered non preferred and require PA. • For any new chemical entity in the Antibiotics: Macrolides class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against
16	**Oxazolidinones:** • DMS to select preferred agent(s) based on economic evaluation; however, at least linezolid should be preferred. • Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. • Continue appropriate quantity limits. • For any new chemical entity in the Oxazolidinones class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against

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17	**Oxazolidinones Clinical Criteria:** Linezolid (Zyvox) will be approved for 28 days maximum if the following criteria is met: • If Zyvox (*linezolid*) was initiated in the hospital, can approve to complete the course of antibiotic therapy. If the caller is from a hospital, we can waive the fax requirement for this medication and work the request over the phone. • Diagnosis of Vancomycin-Resistant Gram Positive Infections (VRE) via current culture and sensitivity testing for Enterococcus Faecium or Enterococcus Faecalis (must provide current culture/sensitivity testing dated within last 3-4 weeks); **OR** • Methicillin-Resistant Staph Aureus Infections (MRSA) via current culture and sensitivity testing (must provide current culture/sensitivity testing); **OR** • Empiric management of suspected MRSA infection without culture confirmation if any of the following are true: – Previously documented MRSA infection; **OR** – Previous cellulitis caused by documented MRSA; **OR** – Skin and soft tissue infection with abscess; **OR** – Patient meets **BOTH** of the following criteria: ▪ Has tried/failed within the past month any of the following antibiotics: ◆ Tetracycline; **OR** ◆ Sulfamethoxazole/trimethoprim; **OR** ◆ Any Fluoroquinolone; **OR** ◆ Clindamycin; **AND** ◆ Patient presents with any one of the following risk factors: ○ Health facility stay/visit (current or within past 30 days) ○ Surgery in the past 30 days ○ Participation in team sports (current or within past 30 days) ○ Jail/Prison in past 30 days (currently incarcerated patients are not eligible for coverage) ○ Military (current or within past 30 days) ○ History of "spider bite" within the past 30 days ○ Pediatric patients enrolled in daycare or school (current or within past 30 days) ○ Multiple areas of induration ○ HIV + ○ Permanent indwelling catheters ○ Percutaneous implanted device ○ Previously colonized with multi-drug resistant pathogens including MRSA ○ Diabetic foot ulcerEnd stage renal disease	**Passed** 7 For 0 Against

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18	**Penicillins:** • DMS to select preferred agent(s) based on economic evaluation; however, at least amoxicillin, ampicillin, dicloxacillin, and penicillin V should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Penicillin class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against
19	**Flouroquinolones:** • DMS to select preferred agent (s) based on economic evaluation; however, at least two agents, including either levofloxacin or ciprofloxacin, should be preferred. • Agents not selected as preferred will be considered non preferred and require PA. • For any new chemical entity in the Antibiotics: Quinolones class, require a PA until reviewed by the P&T Advisory Committee	**Passed** 7 For 0 Against
20	**Tetracyclines:** • DMS to select preferred agent(s) based on economic evaluation; however, at least generic formulations of doxycycline, minocycline, and tetracycline should be preferred. • If demeclocycline is selected as non-preferred, allow for its use in SIADH only. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Tetracycline class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against
21	**Antibiotics, Vaginal:** • DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Vaginal Antibiotics class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against
22	**Antifungals, Oral:** • DMS to select preferred agent(s) based on economic evaluation; however, at least fluconazole, griseofulvin, nystatin, and terbinafine should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Oral Antifungal class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against

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23	**Itraconazole Clinical Criteria:** Approve oral itraconazole for 6 months if: **Tinea capitis:** • Approve for up to 4 weeks **Tinea corporis (body ringworm), Tinea cruris (jock itch), or Tinea pedis (athlete's foot):** • Approve once daily dosing for a 4-week continuous course of therapy if the patient has tried and failed at least one topical antifungal agent. If the patient has not failed one topical antifungal, please escalate to a pharmacist. **Onychomycosis of the fingernails:** • **Initial therapy:** Approve itraconazole for twice daily dosing for an 8-week continuous course of therapy. • **Retreatment:** Approve itraconazole for twice daily dosing for an 8-week continuous course of therapy if there has been an interval of 3 months or longer from the initial treatment. **Onychomycosis of the toenails:** • **Initial therapy:** Approve itraconazole for once daily dosing for a 12-week continuous course of therapy • **Retreatment:** Approve itraconazole for once daily dosing for a 12-week continuous course of therapy if there has been an interval of 6 months or longer from the initial treatment. • Treatment of a systemic or other serious fungal infection (e.g., esophageal candidiasis, blastomycosis, aspergillosis, cutaneous sporotrichosis): • Approve the requested quantity for 6 months. • In addition to the clinical criteria noted above, the patient must have tried and failed the generic itraconazole before a non-preferred agent can be approved.	**Passed** 7 For 0 Against
24	**Sulfonamides, Folate Antagonists:** • DMS to select preferred agent(s) based on economic evaluation; however, at least trimethoprim/sulfamethoxazole should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Sulfonamides, Folate Antagonist class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 7 For 0 Against