Kentucky Department for Medicaid Services

Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the September 19, 2013 meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration
New Products to Market: Kynamro™	Place this product preferred in the PDL class titled Familial Hypercholesterolemia Agents. Approval of mipomersen sodium will be granted as described below. • For initial treatment, approve for 6 months if ALL of the following are true: o Diagnoses of HoFH must be confirmed by the presence of at least one of the following: ▪ Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality; **OR** ▪ Skin fibroblast LDL receptor activity <20% normal; **OR** ▪ Untreated total cholesterol (TC) >500 mg/dL and triglycerides(TG) <300 mg/dL and both parents with documented untreated TC >250 mg/dL; **AND** o Must be used as an adjunct to a low-fat diet supplying < 20% of energy from fat; **AND** o Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; **AND** o Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment and required for renewal; **AND** o Patient tried and failed at least a 3 month trial of the maximally tolerated dose with two (2) of the following statins: simvastatin 40mg (Zocor), atorvastatin 80mg (Lipitor) OR rosuvastatin 40mg (Crestor), unless contraindicated; **AND** o Patient tried and failed at least a 3 month trial combination with both ezetimibe 10mg (Zetia) AND atorvastatin 80mg (Lipitor) OR simvastatin 40mg (Zocor), unless contraindicated; **AND** o Despite the pharmacological treatment with statins and ezetimibe, patient's LDL cholesterol ≥ 300 mg/dL (or non-HDL cholesterol ≥ 330 mg/dL). • For continuation of treatment, approve for one year if ALL of the following are true: o Documented reduction of low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) from baseline; **AND** o Documentation of dosage adjustment if ALT or AST is ≥ 3 times the upper limit of normal (ULN); **AND** o Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: elevations in transaminases (ALT, AST), hepatic steatosis, serious injection site reactions, and flu-like symptoms.

Item	Options for Consideration
New Products to Market: Juxtapid™	Place this product non preferred with similar approval criteria in the PDL class titled Familial Hypercholesterolemia Agents.
New Products to Market: Liptruzet™	Place this product as non preferred with appropriate quantity limits in the PDL class titled High Potency Statins.
New Products to Market: Tafinlar®	Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Tafinlar® for a diagnosis of unresectable or metastatic melanoma after confirmation that the BRAF (BRAF) V600E mutation has been detected by an FDA-approved test.
New Products to Market: Mekinist™	Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Mekinist™ for a diagnosis of unresectable or metastatic melanoma after confirmation that the BRAF (BRAF) V600E or V600K mutation has been detected by an FDA-approved test.
New Products to Market: Cometriq™	Place this product non preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.
New Products to Market: Rescula®	Place this product non preferred with appropriate quantity limits in the PDL class titled Prostaglandin Agonists.
New Products to Market: Simbrinza™	Place this product preferred in the PDL class titled Ophthalmic Carbonic Anhydrase Inhibitors.
New Products to Market: Fulyzaq™	Place this product non preferred with appropriate quantity limits in the PDL class titled Antidiarrheals. Approval of crofelemer will be granted as described below. • For initial treatment, approve for 6 months if ALL of the following are true: o Patient has been diagnosed with human immunodeficiency virus; **AND** o Patient is experiencing diarrhea; **AND** o Plasma CD4 cell count indicates measure response to HAART; **AND** o Active infection has been ruled out via fecal collection and microbiologic culture; **AND** o Other secondary causes of diarrhea (eg, irritable bowel syndrome, gluten and lactose intolerance, traveler's diarrhea, functional diarrhea, and HAART associated diarrhea) have been ruled out by complete and appropriate physical and historical examination; **AND** o Patient has tried and failed the preferred antidiarrheals: loperamide, atropine-diphenoxylate • For continuation of treatment, approve for one year if ALL of the following are true: o Documented reduction in the frequency and quantity of liquid stool volume for the previous 6 months; **AND** o Documented measured response to continued HAART; **AND** o Documented follow-up with patient that includes re-culture for microbiologic agents if breakthrough diarrhea occurs while on crofelemer therapy.
New Products to Market: Suclear™ Bowel Prep Kit	Place this product as non- preferred in the PDL class titled Laxative and Cathartics.
New Products to Market: Diclegis™	Place this product non preferred in the PDL class titled Oral Anti-emetics, Anticholinergics.

Item	Options for Consideration
New Products to Market: Osphena™	Osphena™ (ospemifene) should only be approved for patients meeting ALL of the following criteria: • Diagnosis of severe dyspareunia, due to vulvar and vaginal atrophy, in a post-menopausal woman; AND • Trial and failure of an over-the-counter vaginal lubricant; AND • Trial and failure of a prescription topical estrogen product, unless contraindicated.
New Products to Market: Tecfidera™	Place this product non preferred with appropriate quantity limits in the PDL class titled Multiple Sclerosis Agents.
New Products to Market: Breo Ellipta™	Place this product non preferred with appropriate quantity limits in the PDL class titled Beta Agonists: Combination Products.
New Products to Market: Invokana™	Invokana™ (canagliflozin) should only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.
New Products to Market: Nesina®	Place this product non preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.
New Products to Market: Kazano®	Place this product non preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.
New Products to Market: Oseni®	Place this product non preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.
DPP-4 Inhibitors	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity 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 DPP4-Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.
DPP-4 Inhibitors Clinical Criteria	DPP-4 Inhibitors will be approved for one of the following reasons: • Metformin, insulin, a sulfonylurea or a TZD is seen in history within the past 90 days; OR • Diagnosis of Chronic Renal Insufficiency/Failure.
Thiazolidinediones	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Continue quantity limits based on maximum recommended dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Diabetes: Thiazolidinediones class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Oral Steroids	1. DMS to select preferred agent (s) based on economic evaluation; however at least generic formulations of budesonide, dexamethasone, methylprednisolone, prednisolone and prednisone should be preferred. 2. The orally disintegrating formulation of prednisolone should be available for children < 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 Oral Steroids class, require a PA until reviewed by the P&T Advisory Committee.
Intranasal Steroids	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Continue to maintain quantity limits based on maximum daily dose. 4. For any new chemical entity in the Corticosteroids, Intranasal class, require a PA until reviewed by the P&T Advisory Committee.
Intranasal Antihistamines	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity 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 Intranasal Antihistamines class, require a PA until reviewed by the P&T Advisory Committee.
Topical Steroids	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent in each of the potency categories (low, medium, high and very high) 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 Topical Steroids class, require a PA until reviewed by the P&T Advisory Committee.
Topical Acne Agents	1. DMS to select preferred agent (s) based on economic evaluation; however, at least multiple generic formulations of benzoyl peroxide, one topical antibiotic agent for acne and tretinoin 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 Topical Acne Agents class, require a PA until reviewed by the P&T Advisory Committee.
Growth Hormone	1. DMS to select preferred agents based upon economic evaluation; however, one preferred agent should be supplied in a pediatric convenient dosing form. 2. Continue to require clinical PA for all agents, preferred or non-preferred. 3. For any new chemical entity in the Growth Hormone class, require a PA until reviewed by the P & T Advisory Committee.

Item	Options for Consideration
Growth Hormone Clinical Criteria	Growth Hormones will be approved for one of the following diagnoses: • Growth Hormone Deficiency or Pituitary dwarfism • Pituitary disease from known causes such as pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, or trauma such as Panhypopituitarism, Iatrogenic pituitary disorders. Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin. Other disorders of the pituitary gland and craniopharyngeal duct • Turner's Syndrome • Chronic renal insufficiency & end-stage renal disease (pre transplant) • Prader-Willi Syndrome • Idiopathic Short Stature (meaning of unknown origin). Also called non-growth hormone deficient short stature • Small for gestational age • Short Stature Homeobox Gene • Noonan Syndrome • HIV wasting or cachexia • Short bowel syndrome Non-preferred growth hormones require trial and failure of two preferred agents.
Narcotic Agonists/Antagonists	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities 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 Narcotic Agonist / Antagonists class, require PA until reviewed by the P&T Advisory Committee.
Fentanyl Buccal Products	1. DMS to select preferred agent (s) based on economic evaluation. 2. Require prior approval for all of these agents to ensure utilization based on FDA-approved indication. 3. For any new chemical entity in the Narcotics: Fentanyl Buccal Products class, require PA until reviewed by the P&T Advisory Committee.
Fentanyl Buccal Products Clinical Criteria	Fentanyl Buccal products will be approved if ALL of the following are true: • Diagnosis of cancer pain; AND • Receiving and tolerant to opioid therapy, as evident by trial of opioid doses equal to, or greater than, morphine 60 mg daily or fentanyl patches 50 mcg/hr for at least one week without adequate pain control; AND • Unresponsive to therapy with three other immediate-released unique chemical entities utilized for breakthrough pain.
GI Antibiotics	1. DMS to select preferred agent (s) based upon economic evaluation; however, at least metronidazole, oral vancomycin, paromomycin and nitazoxanide should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the GI Antibiotic class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
1st Generation Cephalosporins	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.
2nd Generation Cephalosporins	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.
3rd Generation Cephalosporins	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.
Penicillins	1. DMS to select preferred agent(s) based on economic evaluation; however, at least amoxicillin, amoxicillin/clavulanate, 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.
Tetracyclines	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. 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.
Ketolides	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 Antibiotics: Ketolide class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Ketek® Clinical Criteria	Telithromycin (Ketek®) should be approved for a diagnosis of community-acquired pneumonia (CAP) IF: • There has been previous use (within the past 28 days) of ONE of the following: o Penicillin (e.g., amoxicillin, amoxicillin-clavulanate, ampicillin-sulbactam, or piperacillin-tazobactam); OR o 2nd or 3rd generation cephalosporins (e.g., cefuroxime, cefpodoxime, cefprozil, cefotaxime, ceftriaxone); OR o Macrolide (e.g., azithromycin, clarithromycin, erythromycin); OR o Fluoroquinolone (e.g., levofloxacin, gatifloxacin, moxifloxacin) ; OR o Tetracycline (e.g., doxycycline); OR o Trimethoprim/sulfamethoxazole (e.g., Bactrim); AND • Request is NOT for more than a 10-day supply **If Ketek was initiated in the hospital, approve to complete the course of antibiotic therapy
Macrolides	1. DMS to select preferred agent(s) based on economic evaluation; however, at least three unique chemical entities 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 Antibiotics: Macrolides class, require a PA until reviewed by the P&T Advisory Committee.
Oxazolidinones	1. DMS to select preferred agent(s) based on economic evaluation; however, at least linezolid should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 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.

Item	Options for Consideration
Zyvox® Clinical Criteria	Diagnoses to approve: • Vancomycin-Resistant Gram Positive Infections (VRE) via current culture and sensitivity testing for Enterococcus faecium or Enterococcus faecalis • Methicillin-Resistant S. 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: o Previously documented MRSA infection; OR o Previous cellulitis caused by documented MRSA; OR o Skin and soft tissue infection with abscess; OR o Patient has: ▪ Failed antibiotic therapy within the past month with any of the following: • Tetracycline, or • Sulfamethoxazole/trimethoprim, or • Fluoroquinolone, or • Clindamycin; AND ▪ Presents with any of the following risk factors: • Health facility stay/visit (current or within the past month); or • Surgery in the past month; or • Participation in team sports (current or past month); or • Jail/Prison (current or in past month); or • Military (current or in past month); or • History of "spider bite" within the past month; or • Pediatrics enrolled in daycare or school (current or in past month); or • Multiple areas of induration; or • HIV; or • Permanent indwelling catheters; or • Percutaneous implanted device; or • Previously colonized with multi-drug resistant pathogens including MRSA; or • Diabetic foot ulcer; or • End stage renal disease.