Kentucky Department for Medicaid Services

Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the January 19, 2012 meeting of the Pharmacy and Therapeutics Advisory Committee

Item	Options for Consideration
New Products to Market: Zelboraf™	Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Zelboraf™ after confirmation that the serine-threonine protein kinase BRAF **(**BRAF) V600E mutation has been detected by an FDA-approved test.
New Products to Market: Xalkori®	Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Xalkori® after confirmation of non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
New Products to Market: Xarelto®	Place this product non preferred in the PDL class titled Anticoagulants. Only approve Xarelto® for a diagnosis of prophylaxis against deep vein thrombosis in patients scheduled to undergo elective hip or knee replacement surgery or for stroke prevention in patients with nonvalvular atrial fibrillation.
New Products to Market: Dificid™	Place this product non preferred in the PDL class titled Macrolides; however, approve Dificid™ after trial and failure of oral vancomycin or metronidazole.
New Products to Market: Arcapta™	Place this product non preferred with appropriate quantity limits in the PDL class titled Beta Agonist, Long-Acting.
New Products to Market: Brilinta™	Place this product non preferred in the PDL class titled Platelet Inhibitors.
New Products to Market: Duexis®	Place this product non preferred in the PDL class titled Non-Steroidal Anti-Inflammatory Drugs; however, only approve Duexis® for patients who cannot take ibuprofen and famotidine as individual components.
New Products to Market: Juvisync™	Place this product non preferred with similar quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.
Hepatitis C: Oral Protease 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. 3. PDL selected agents will apply for any new courses of therapy only. 4. Place clinical prior authorization around the entire class to ensure appropriate utilization. 5. Continue quantity and duration limitations based on approved maximum dose and duration. 6. For any new chemical entity in the Hepatitis C: Oral Protease Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.
Hepatitis C: Incivek™ Clinical Criteria	Incivek™ should be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection if the patient is receiving concurrent therapy with ribavirin and peginterferon.

Item	Options for Consideration
Hepatitis C: Victrelis™ Clinical Criteria	Victrelis™ should be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection after the patient has received 4 weeks of ribavirin and peginterferon therapy if they are receiving concurrent therapy with ribavirin and peginterferon. Durations of therapy should be based on the following: • Cirrhosis or previous treatment with peginterferon / ribavirin with documented lack of achievement of > 2 log reduction at week 12 with previous treatment: o Approve for 14 weeks o After 14 weeks of therapy: ▪ If HCV-RNA level is ≤ 100 IU/mL at week 12 of therapy, approve for 12 more weeks • If HCV-RNA results at week 24 of therapy are undetectable, approve for an additional 18 weeks (44 weeks total therapy) • If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin). • If none of the above: o Approve for 14 weeks o If HCV-RNA level is ≤ 100 IU/mL at week 12 of therapy, approve for 12 more weeks ▪ After 26 weeks, continuation of therapy should be approved based on the following: • Treatment naïve patients: o If HCV-RNA results at week 8 and 24 are both undetectable – 2 more weeks then discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin) – total duration of Victrelis™ therapy = 28 weeks o If HCV-RNA results at week 8 are detectable and week 24 are undetectable – 10 more weeks – total duration of Victrelis™ therapy = 36 weeks o If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ ribavirin). ▪ Previously treated or relapsed patients: o If HCV-RNA results at week 8 and 24 are both undetectable – 10 more weeks (then discontinue all 3) – total duration of Victrelis™ therapy = 36 weeks o If HCV-RNA results at week 8 are detectable and week 24 results are undetectable 10 more weeks – total duration of Victrelis™ therapy = 36 weeks o If HCV-RNA results at week 24 are detectable, discontinue all 3 therapies (Victrelis™ and peginterferon/ribavirin).

Item	Options for Consideration
Hepatitis C: Interferons	1. DMS to select preferred agent (s) based on economic evaluation; however, at least peginterferon alfa-2a and peginterferon alfa-2b 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 to ensure appropriate utilization. 5. Continue current quantity limits based on maximum approved dose. 6. For any new chemical entity in the Hepatitis C: Interferons class, require a PA until reviewed by the P&T Advisory Committee.
Hepatitis C: Interferons Clinical Criteria	After the initial 18 weeks of therapy, interferons should be approved if there is at least a 2 logarithmic unit decrease in HCV RNA levels at treatment week 12. ***LIMITATION ON LENGTH OF THERAPY IS BASED ON PRODUCT*** 1. Interferon alfacon-1 a. IFN naïve – 24 weeks total therapy b. INF relapse – 48 weeks total therapy 2. Peginterferon alfa-2a OR 2b a. Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy b. Genotype 2, 3 – 24 weeks total therapy
Hepatitis C: Ribavirins	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.
Hepatitis C: Ribavirins Clinical Criteria	Ribavirins should pay at point-of-sale if there is concurrent interferon therapy in history.
Beta Agonists, Short-Acting	1. DMS to select preferred agent (s) based on economic evaluation; however, at least a nebulized and metered dose inhaler formulation of albuterol must be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on inhaled versions of Short-Acting $Beta_2$ Adrenergic Agents. 4. For any new chemical entity in the Short-Acting $Beta_2$ Adrenergic Agents class, require a PA until reviewed by the P&T Advisory Committee.
Beta Agonists, Long-Acting	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity available in a metered dose inhaler should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. For any new chemical entity in the Long-Acting $Beta_2$ Adrenergic Agents class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Corticosteroids, Inhaled	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 will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. Continue to allow budesonide respules without PA for patients less than 8 years of age. 5. For any new chemical entity in the Inhaled Corticosteroid class, require a PA until reviewed by the P&T Advisory Committee.
Beta Agonists: Combination Products	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity FDA-approved for COPD should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. For any new chemical entity in the Beta Agonist: Combination class, require a PA until reviewed by the P&T Advisory Committee.
Leukotriene Modifiers	1. DMS to select preferred agent (s) based on economic evaluation; however, at least montelukast should be preferred. 2. Continue to require Prior Authorization for all agents in this class. 3. Continue quantity limits on agents in this class based on maximum approved dose. 4. For any new chemical entity in the Leukotriene Modifiers class, require a PA until reviewed by the P&T Advisory Committee.
COPD Agents	1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. At least one combination product and tiotropium should be among the preferred products. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. For any new chemical entity in the COPD Agents class, require a PA until reviewed by the P&T Advisory Committee.
Corticosteroids, Intranasal	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.
Antihistamines, Intranasal	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.

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Anticholinergics, Intranasal	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 Anticholinergics class, require a PA until reviewed by the P&T Advisory Committee.
Antihistamines, Non-Sedating	1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Non-Sedating Antihistamines class, require a PA until reviewed by the P&T Advisory Committee.
Antibiotics, Inhaled	1. DMS to select preferred agent (s) based on economic evaluation; however, at least tobramycin should be preferred. 2. Aztreonam should be reserved for patients who have documented resistance or contraindication to tobramycin. 3. For any new chemical entity in the Inhaled Antibiotics class, require a PA until reviewed by the P&T Advisory Committee.
Self Injectable Epinephrine	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one product available in an adult and pediatric dose 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 Self-Injectable Epinephrine Agents class, require a PA until reviewed by the P&T Advisory Committee.
Cialis® Clinical Criteria	Cialis® will be approved for a diagnosis of benign prostatic hyperplasia (BPH), without a diagnosis of erectile dysfunction (ED) in the past five (5) years, after trial and failure of both: • An alpha blocker; AND • A 5-Alpha Reductase Inhibitor. Cialis® should not be used in combination with an alpha blocker.
BOTOX™ Clinical Criteria	**Diagnosis to approve:** • Blepharospasm • Cervical dystonia • Severe primary axillary hyperhidrosis • Strabismus • Cerebral Palsy or other spasticity disorders as long as patient has tried ONE other option such as: o Muscle relaxants o Bracing o Splinting o Occupational Therapy o Physician Therapy • Chronic migraines after trial and failure of ALL of the following (unless contraindication or intolerance): o Prophylactic therapy with at least three (3) of the following: ▪ Beta-blocker ▪ Amitriptyline ▪ Valproate ▪ Topiramate o Tried and failed abortive therapy with two triptans.

Item	Options for Consideration
Synagis® Clinical Criteria	Approval should be granted if the recipient has at least **one** of the following indications: 1. Recipient is less than 24 months of age at the start of RSV season (i.e., November 1st) and has chronic lung disease that has required medical treatment (supplemental oxygen, bronchodilators, diuretics or chronic corticosteroids) in the preceding 6 months. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 2. Recipient is less than 24 months of age at the start of RSV season and has one of the following: a. Hemodynamically significant cyanotic or acyanotic congenital heart disease. b. Receives medications to control CHF or cardiomyopathy. c. Has moderate to severe pulmonary hypertension. d. Has undergone cardio-pulmonary bypass surgery. For this patient population, the dose should be given as soon as the patient is medically stable, even if sooner than a month from the previous dose] If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 3. Recipient is less than or equal to 12 months of age at the start of the RSV season **and** was born at less than or equal to 28 weeks' gestation. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 4. Recipient is less than or equal to 6 months of age at the start of the RSV season **and** was born at 29 to 32 (31 weeks, 6 days or less) weeks' gestation. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31. 5. Recipient is less than or equal to 3 months of age at the start of the RSV season **and** was born between 32 and <35 (32 weeks, 0 days to 34 weeks, 6 days) weeks' gestation **and** has one of the following other risk factors: a. Attends child care, defined as a home or facility where care is provided for any number of infants or young toddlers. b. Has a sibling less than 5 years of age. If yes, approve for a maximum of 3 doses to be given between November 1 and March 31. Drug should be discontinued at 3 months of age regardless of number of doses given. 6. Recipient is less than or equal to 12 months of age at onset of RSV season and was born before 35 weeks' (34 weeks, 6 days) gestation who have either congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions. If yes, approve for a maximum of 5 doses to be given between November 1 and March 31.

Item	Options for Consideration
Xolair® Clinical Criteria	Xolair® (omalizumab) should be approved for a diagnosis of moderate to severe asthma (step 5 or higher) if ALL of the following are true: • Positive skin test to perennial aeroallergen; AND • FEV_1 of <80% while on asthma controller medication; AND • Has had failure of or contraindication to inhaled corticosteroid in combination with a second controller agent (such as a long-acting inhaled $beta_2$-agonist, ipratropium, leukotriene modifier, or theophylline) for a 60-day trial. Xolair® (omalizumab) should be approved for continuation of therapy for a diagnosis of moderate to severe asthma (step 5 or higher) if on of the following are true: • During previous treatment with Xolair®, the patient experienced a reduction in asthma exacerbations (e.g., hospitalizations, urgent or emergent care visits, use of rescue medications, etc.) from their pre-Xolair® baseline, OR • The patient was receiving maintenance therapy with an oral corticosteroid prior to initiation of Xolair® and the patient has been able to reduce their oral corticosteroid dose to less than their pre-Xolair® baseline or to ≤ 5 mg daily, OR • The patient was receiving maintenance therapy with an inhaled corticosteroid prior to initiation of Xolair® and the patient has been able to reduce their inhaled corticosteroid dose to less than their pre-Xolair® baseline.