Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations

May 19, 2016

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the May 19, 2016 meeting.

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

	Description of Recommendation	P & T Vote
1	**New Products to Market: Zembrace™ SymTouch™** Non-prefer in PDL class: *Antimigraines, Triptans* **Length of Authorization:** 1 year Zembrace™ SymTouch™ (sumatriptan succinate) Injection, for subcutaneous use, is a serotonin (5-HT1B/1D) receptor agonist (triptan) indicated for: Acute treatment of migraine with or without aura in adults. • Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include: – Adverse reaction to all preferred drugs; – Allergy to all preferred drugs; or – Contraindication to all preferred drugs. • Has the patient had a documented therapeutic trial and treatment failure with ALL preferred drugs? If so, document the details • Sumatriptan generic products are covered without PA; document clinical reason as to why sumatriptan generic products cannot be used. **Quantity Limit** = 8 units per month (to match all other pens/cartridges)	**Passed** 8 For 0 Against
2	**New Products to Market: Vraylar™** Non-prefer in the PDL class: *Antipsychotics* **Length of Authorization:** 1 year Vraylar™ (cariprazine) capsules, for oral use, indicated for: Acute treatment of manic or mixed episodes associated with bipolar I disorder OR treatment of schizophrenia. • Has a diagnosis of schizophrenia or acute treatment of manic or mixed episodes associated with bipolar I disorder. • Had a failed 14-day trial of BOTH risperidone and 1 other atypical antipsychotic (i.e., Seroquel, Abilify, Clozaril, Invega, Zyprexa, Geodon, HIC3 H7T or H7X) OR medical justification why a trial is not appropriate. **Minimum Age =** 18 years of age or older **Quantity Limit** = 1 per day	**Passed** 8 For 0 Against

	Description of Recommendation	P & T Vote
3	**New Products to Market: Zepatier™** Non-prefer in PDL class: *Hepatitis C* **Length of Authorization:** depends upon regimen Zepatier™ (elbasvir and grazoprevir) tablets, for oral use, is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated with or without ribavirin for treatment of chronic HCV genotypes 1 or 4 infection in adults. • Indicated with or without ribavirin for treatment of chronic HCV genotypes 1 or 4 infection in adults. • Must supply proof of genotypes 1 or 4 along with documentation of F3 or F4 fibrosis score. • Documentation of *Readiness to Treat* is also required. • Test patients with HCV genotype 1a infection for the presence of virus with NS5A resistance associated polymorphisms prior to initiation of treatment with Zepatier to determine dosage regimen and duration. • Zepatier is contraindicated in patients with moderate hepatic impairment (Child-Pugh B) and in patients with severe hepatic impairment (Child-Pugh C). Must supply documentation of Child-Pugh classification. **Minimum age** = 18 years **Maximum Quantity Limit** = 1 per day	**Passed** 9 For 0 Against
4	**New Products to Market: Adzenys XR-ODT™** Non-prefer in PDL class: *Stimulants & Related* **Length of Authorization:** 1 year Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablets), CII, is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older. • Is there any reason that the patient cannot be switched to a preferred medication? Document the details: – Adverse reaction to preferred drugs – Allergy to preferred drugs – Contraindication to preferred drugs • Has the patient had a therapeutic trial and treatment failure with **TWO** preferred drugs? Document the details. • Patient has a swallowing disorder and cannot be given tablets or capsules. **Minimum age** = 6 years **Quantity Limit** = 1 per day	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
5	**New Products to Market: Dyanavel™ XR** Non-prefer in PDL class: *Stimulants & Related* **Length of Authorization:** 1 year Dyanavel XR (amphetamine) extended-release oral suspension, CII, is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). • Is there any reason that the patient cannot be switched to a preferred medication? Document the details: – Adverse reaction to preferred drugs – Allergy to preferred drugs – Contraindication to preferred drugs • Has the patient had a therapeutic trial and treatment failure with **TWO** preferred drugs? Document the details. • Patient has a swallowing disorder and cannot be given tablets or capsules. **Minimum age** = 6 years **Quantity Limit** = 20 mg/d (2.5 mg/mL)	**Passed** 9 For 0 Against
6	**New Products to Market: QuilliChew ER™** Non-prefer in the PDL class: *Stimulants & Related* **Length of Authorization:** 1 year QuilliChew ER™ (methylphenidate hydrochloride) extended-release chewable tablets, for oral use, CII: QuilliChew ER is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). • Is there any reason that the patient cannot be switched to a preferred medication? Document the details: – Adverse reaction to preferred drugs – Allergy to preferred drugs – Contraindication to preferred drugs • Has the patient had a therapeutic trial and treatment failure with **TWO** preferred drugs? Document the details. • Quillivant XR and Methylin Chewable Tablets are covered as preferred; clinical reason as to why Quillivant XR and Methylin Chewable Tablets cannot be used. **Minimum age** = 6 years **Quantity Limit** = 1 per day (1QAM)	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
7	**Acne Agents, Topical:** • DMS to select preferred agent(s) based on economic evaluation; however, at least multiple generic formulations of benzoyl peroxide, 1 topical antibiotic agent for acne, and tretinoin should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Acne Agents, Topical class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
8	**Antivirals, Oral:** **HSV:** • DMS to select preferred agent(s) based on economic evaluation; however, at least acyclovir and either valacyclovir or famciclovir should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Antivirals, Oral class, require a PA until reviewed by the P&T Advisory Committee. **Influenza:** • DMS to select preferred agent(s) based on economic evaluation; however, oseltamivir, and zanamivir should be preferred. (removed amantadine) • Agents not selected as preferred will be considered non-preferred and require PA. • DMS to consider CDC recommendation updates regarding antiviral therapy for the treatment of influenza. The Medical Director, with Commissioner approval, may make changes to the PDL listing based on the CDC recommendations until this class can be considered at the next scheduled review. • For any new chemical entity in the Antivirals, Oral class, require a PA until reviewed by the P&T Advisory Committee	**Passed** 9 For 0 Against
9	**Bone Resorption Suppression and Related:** • DMS to select preferred agent(s) based on economic evaluation; however, at least alendronate, calcitonin-salmon, and raloxifene should be preferred on the PDL. Additionally, at least 1 bisphosphonate with a once-weekly dosing formulation should be preferred on the PDL. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Bone Resorption Suppression and Related Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
10	**Cytokine and CAM Antagonists:** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 self-administrable **products should be preferred.** • Agents not selected as preferred will be considered non-preferred and require trial and failure of preferred product (s) with an FDA-approved indication for the requested diagnosis. • All agents in the category should be approved for their FDA-approved indications only. • Allow continuation of therapy for non-preferred single-source branded products. • Maintain quantity limits on agents within the category according to their maximum recommended dose, taking into consideration any escalating doses needed during initial therapy. • For any new chemical entity in the Cytokine and CAM Antagonists class, require a PA until reviewed by the P&T Advisory Committee. • **Note:** Taltz as non-preferred (NPD) will have length of authorization of 1 year with standard NPD product criteria of - document why a preferred agent cannot be used.	**Passed** 9 For 0 Against
11	**Glucocorticoids, Inhaled:** • DMS to select preferred agent(s) based on economic evaluation; however, at least 3 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • Continue quantity limits on agents in this class. • Continue to allow budesonide respules without PA for patients less than 8 years of age. • For any new chemical entity in the Glucocorticoids, Inhaled class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
12	**Glucocorticoids, Oral:** • 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. • The orally-disintegrating formulation of prednisolone should be available for children < 12 years of age. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Glucocorticoids, Oral class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
13	**Growth Hormone:** • DMS to select preferred agents based upon economic evaluation; however, 1 preferred agent should be supplied in a pediatric convenient dosing form. • Continue to require clinical PA for all agents, preferred or non-preferred. • For any new chemical entity in the Growth Hormone class, require a PA until reviewed by the P & T Advisory Committee.	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
14	**Hepatitis B Agents:** • DMS to select preferred agent(s) based on economic evaluation; however, at least entecavir and lamivudine should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Hepatitis B Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
15	**Immunomodulators, Atopic Dermatitis:** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 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 Immunomodulators, Atopic Dermatitis class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
16	**Immunosuppressants, Oral:** • DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • DMS to allow continuation of therapy if there is a paid claim in the past 90 days. • For any new chemical entity in the Immunosuppressants, Oral class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
17	**Multiple Sclerosis Agents:** • DMS to select preferred agent(s) based on economic evaluation; however, at least glatiramer, 1 interferon ß-1b, and 1 interferon ß-1a product should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • Place quantity limits on these products based on maximum recommended dose. • For any new chemical entity in the Multiple Sclerosis Agents class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
18	**Pancreatic Enzymes:** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 pancreatic enzyme product should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Pancreatic Enzymes class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
19	**Progestins for Cachexia:** • DMS to select preferred agent(s) based upon economic evaluation; however, at least 1 unique chemical entity must be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Progestins for Cachexia class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
20	**Steroids Topical, High, Medium, Low, Very High:** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 agent in each of the potency categories (i.e., low, medium, high, and very high) should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the Steroids, Topical class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
21	**Viberzi Clinical Criteria Review – Clarification of criteria regarding covered antidiarrheals:** This agent was initially reviewed as a new product to market during the March 17, 2016 P&T meeting. The Committee voted at that time to table discussion over to the May 19, 2016 agenda and to include step therapy in the revised criteria. Below is the criteria as reviewed at the May 19, 2016 P&T meeting: Non-prefer in the PDL class: *GI Motility, Chronic* **Length of Authorization:** 1 Year • The safety and effectiveness of Viberzi have not been established in pediatric patients. • Indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D). • Trial and failure of two (2) covered antidiarrheals. (RX: loperamide or diphenoxylate/atropine. OTC: loperamide) **Quantity Limit** = 2 tablets per day.	**Passed** 8 For 0 Against