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 18, 2014 meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration
New Products to Market: Adempas®	Place this product non preferred in the PDL class titled Agents for Pulmonary Hypertension; however, approve riociguat (Adempas®) if one of the following is true: • Diagnosis of PAH (WHO Group I) after trial and failure of two preferred products; OR • Diagnosis of CTEPH (WHO Group 4) functional class II or III deemed inoperable or with residual PH after undergoing pulmonary endarterectomy.
New Products to Market: Orenitram™	Place this product non preferred in the PDL class titled Agents for Pulmonary Hypertension.
New Products to Market: Zontivity™	Place this product non preferred in the PDL class titled Platelet Inhibitors; however, approve Zontivity™ for a diagnosis of history of myocardial infarction (MI) or peripheral artery disease (PAD) WITHOUT a history of stroke, transient ischemic attack (TIA), acute coronary syndrome (ACS), gastrointestinal (GI) bleed, or peptic ulcer. Patients must also be taking aspirin and/or clopidogrel concomitantly.
New Products to Market: Velphoro®	Place this product non preferred in the PDL class titled Phosphate Binders.
New Products to Market: Tanzeum™	Place this product non preferred in the PDL class titled GLP-1 Receptor Agonists.
New Products to Market: Otezla®	Place this product non preferred with appropriate quantity limits and similar criteria in the PDL class titled Immunomodulators.
New Products to Market: Entyvio™	Place this product non preferred with appropriate quantity limits and similar approval criteria in the PDL class titled Immunomodulators.
New Products to Market: Zykadia™	Place this product non preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.
New Products to Market: Zohydro ER™	Place this product non preferred with appropriate quantity limits in the PDL class titled Narcotics: Long-Acting.

Item	Options for Consideration
New Products to Market: Evzio™	Evzio™ will be limited to 4 auto injectors per prescription and will only be approved in the following circumstances: ▪ Patient or care-giver is administering medication outside of a healthcare facility (such as a personal residence or school); AND ▪ Patient or active care-giver is unable to manipulate vials/syringes due to issues related to poor eyesight, dexterity, or comprehension; AND ▪ The prescriber has completed and submitted with the prior approval request the Opioid Overdose Risk Assessment Checklist Form. The form can be found at: http://evzio.com/pdfs/Evzio-Opioid-Overdose-Risk-Assessment-Checklist.pdf; AND ▪ If the diagnosis is substance abuse, dependence and/or addition, the patient is receiving addiction counseling services; such as psychosocial therapy from a Substance Abuse provider. Documentation must be provided to include provider name, type of provider, and provider phone number.
New Products to Market: Aptiom®	Place this product non preferred in the PDL class titled Anticonvulsants: Carbamazepine Derivatives.
New Products to Market: Hetlioz®	Place this product non preferred with appropriate quantity limits in the PDL class titled Sedative Hypnotics; however, only approve tasimelteon (Hetlioz®) for a diagnosis of Non-24-hour sleep-wake disorder ("non-24") in patients who are totally blind.
New Products to Market: Anoro™ Ellipta™	Place this product non preferred with similar quantity limits in the PDL class titled COPD Agents; however, approve Anoro™ Ellipta™ for a diagnosis of COPD after trial and failure of an inhaled long-acting bronchodilator (a LABA or an anticholinergic).
New Products to Market: Sivextro™	Place this product non preferred with appropriate quantity limits and similar criteria in the PDL class titled Oxazolidinones.
New Products to Market: Luzu®	Place this product non preferred in the PDL class titled Topical Antifungal Agents.
New Products to Market: Jublia®	Place this product non preferred in the PDL class titled Topical Antifungal Agents; however, only approve efinaconazole (Jublia®) for a diagnosis of toenail onychomycosis after trial and failure of one other agent indicated for the treatment of onychomycosis.
Topical Antifungal Agents	1. DMS to select preferred agent(s) based on economic evaluation; however, at least agents representing multiple mechanisms of action as well as a combination product should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Before utilization, the combination product miconazole/zinc oxide should be subject to trial and failure of conventional therapies for diaper dermatitis. 4. For any new chemical entity in the Topical Antifungal Agents class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Topical Antiviral Agents	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 Topical Antiviral Agents class, require a PA until reviewed by the P&T Advisory Committee.
Topical Antibiotic Agents	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which should be mupirocin ointment, 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 Antibiotic Agents class, require a PA until reviewed by the P&T Advisory Committee.
Topical Antiparasitic Agents	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which should be permethrin 5% cream, 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 Antiparasitic Agents class, require a PA until reviewed by the P&T Advisory Committee.
Topical Psoriasis Agents	1. DMS to select preferred agent (s) based upon economic evaluation; however, at least two unique chemical entities 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 Topical Psoriasis Agents, require a PA until reviewed by the P&T Advisory Committee.
Oral Psoriasis Agents	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 prior authorization. 3. For any new chemical entity in the Oral Psoriasis Agents class, require a PA until reviewed by the P&T Advisory Committee.
Oral Acne Agents	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 prior authorization. 3. For any new chemical entity in the Oral Acne Agents class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Otic Antibiotics	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one single entity otic quinolone, one otic quinolone/steroid combination product and one non-quinolone combination product 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 Otic Antibiotics class, require a PA until reviewed by the P&T Advisory Committee.
Otic Anti-Infective/Anesthetics/Anti-Inflammatories	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 Otic Anti-Infective/Anesthetics/Anti-Inflammatories class, require a PA until reviewed by the P&T Advisory Committee.
Alpha Blockers for BPH	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two agents, one of which should be highly selective for the alpha receptors in the genitourinary tract, 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 Alpha Blockers for BPH class, require a PA until reviewed by the P&T Advisory Committee.
5-Alpha Reductase (5AR) Inhibitors	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one single-entity agent 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 5-Alpha Reductase Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.
5-Alpha Reductase (5AR) Inhibitors Clinical Criteria	5-Alpha Reductase (5AR) Inhibitors will be approved for a diagnosis of benign prostatic hyperplasia (BPH) via an ICD-9 override.
Tadalafil (Cialis®) Clinical Criteria	Tadalafil (Cialis®) will be approved for a diagnosis of benign prostatic hyperplasia (BPH) after trial and failure of both: • An alpha blocker for one month; AND • A 5-Alpha Reductase Inhibitor for four months. Cialis® should not be used in combination with an alpha blocker.
Bladder Relaxants	1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. 2. Only patients who are unable to swallow or tolerate oral medications should be approved for non-oral formulations of agents in this class. 3. Continue current quantity limits on all agents in this class. 4. Agents not selected as preferred will be considered non preferred and require PA. 5. For any new chemical entity in the Bladder Relaxants Class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Oral Oncology Agents	1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a first-line recommendation by the NCCN for each cancer type should be preferred. Due to new data on the treatment of CML, both imatinib and EITHER dasatinib OR nilotinib should be preferred. 2. Continue quantity limits based on FDA-approved maximum dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 5. For any new chemical entity in the Oral Oncology Agents class, require a PA until reviewed by the P&T Advisory Committee
Vaginal Antibiotics	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 Vaginal Antibiotics class, require a PA until reviewed by the P&T Advisory Committee.
Irritable Bowel Syndrome	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 Irritable Bowel Syndrome class, require a PA until reviewed by the P&T Advisory Committee.
Irritable Bowel Syndrome Clinical Criteria	Agents will be approved for the following diagnoses: • Irritable Bowel Syndrome with constipation (linaclotide and lubiprostone) or with diarrhea (alosetron); OR • Chronic Idiopathic Constipation after failure of one laxative (linaclotide and lubiprostone); OR • Opioid-Induced Constipation (lubiprostone) if the following are true: o Patient is experiencing chronic, non-cancer pain; and o Patient has tried and failed one laxative.
Topical Rosacea Agents	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 prior authorization. 3. For any new chemical entity in the Topical Rosacea Agents class, require a PA until reviewed by the P&T Advisory Committee.

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<tr><th>Item</th><th>Options for Consideration</th></tr>
<tr><td><u>Palivizumab (Synagis®) Clinical Criteria</u></td><td>
Length of authorization:

Authorization will be granted for a maximum of 5 doses during RSV reason (five monthly doses of 15 mg/kg IM). Despite differences in onset and offset of RSV infection in some states or regions, only a maximum of 5 doses will be approved during RSV season. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses. For eligible infants born during RSV season, fewer than 5 monthly doses may be needed.
For infants and children < 24 months of age, already on prophylaxis and eligible, one post-op dose can be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO).

Approval Criteria:
Palivizumab will be approved in the following scenarios:
<table>
<tr><th>Infant/Child Age at Start of RSV Season</th><th>Criteria</th></tr>
<tr><td><12 months
(1st year of life)</td><td>▪ GA <29 wks, 0 d (otherwise healthy); or
▪ CLD of prematurity (GA <32 wks, 0 d and >21% O_2 x first 28 d after birth); or
▪ Anatomic pulmonary abnormalities, or neuromuscular disorder, or congenital anomaly that impairs the ability to clear secretions; or
▪ Profoundly immunocompromised; or
▪ CF with CLD and/or nutritional compromise</td></tr>
<tr><td>≤ 12 months
(1st year of life)</td><td>▪ CHD (hemodynamically significant) with acyanotic HD on CHF medications and will require cardiac surgery or moderate to severe PH. For cyanotic heart defects consult a pediatric cardiologist</td></tr>
<tr><td>>12 months
(2nd year of life)</td><td>▪ CLD of prematurity (GA <32 wks, 0 d and >21% O_2 x first 28 d after birth) and medical support (chronic systemic steroids, diuretic therapy, or supplemental O_2) within 6 months before start of 2nd RSV season; or
▪ CF with severe lung disease* or weight for length <10th percentile</td></tr>
<tr><td><24 months
(2nd year of life)</td><td>▪ Cardiac transplant during RSV season; or
▪ Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO; or
▪ Profoundly immunocompromised during the RSV season</td></tr>
</table>
GA=gestational age; wks=weeks; d=day; CLD=chronic lung disease; CHD=congenital heart disease; O_2=oxygen; HD=heart disease; CHF=congestive heart failure; PH=pulmonary hypertension; CF=cystic fibrosis; ECMO=extracorporeal membrane oxygenation
*Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the 1st year of life, abnormalities on chest radiography [chest X-ray], or chest computed tomography [chest CT] that persist when stable
</td></tr>
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Item	Options for Consideration
Botulinum Toxins Clinical Criteria	AbobotulinumtoxinA (Dysport™) OR rimabotulinumtoxinB (Myobloc®) will be approved for a diagnosis of cervical dystonia. IncobotulinumtoxinA (Xeomin®) will be approved for the following diagnoses: • Cervical dystonia; OR • Blepharospasm after trial and failure of onabotulinumtoxinA (Botox®). OnabotulinumtoxinA (Botox®) will be approved for the following diagnoses: • Blepharospasm ; OR • Cervical dystonia; OR • Severe primary axillary hyperhidrosis ; OR • Strabismus; OR • Cerebral Palsy or other spasticity disorders as long as patient has tried ONE other option such as: o Muscle relaxants; or o Bracing; or o Splinting; or o Occupational therapy; or o Physical therapy; OR • Chronic migraines after trial and failure of ALL of the following (unless contraindication or intolerance): o Prophylactic therapy with at least two (2) of the following: ▪ Beta-blocker; or ▪ Amitriptyline; or ▪ Valproate; or ▪ Topiramate; AND o Tried and failed abortive therapy with two triptans; OR • Urinary incontinence due to detrusor overactivity associated with a neurologic condition (such as spinal cord injury or MS) after trial and failure of or contraindication to an anticholinergic medication; OR • Overactive bladder with symptoms of urge urinary incontinence, urgency and frequency after trial and failure of or contraindication to an anticholinergic medication.
Clonidine Patch Clinical Criteria	Clonidine patches will be approved if any one of the following is true: • Patient is <15 years old; OR • Patient cannot tolerate/absorb PO.
Phenoxybenzamine (Dibenzyline®) Clinical Criteria	Phenoxybenzamine (Dibenzyline®) will be approved for a diagnosis of Pheochromocytoma only.

Item	Options for Consideration
Lidocaine Patch (Lidoderm®) Clinical Criteria	Lidocaine patches (Lidoderm®) will be approved if any one of the following criteria is met: • Diagnosis of Post Herpetic Neuralgia via an ICD-9 override; OR • Diagnosis of neuropathic pain and history of one agent in any of the following medication classes in the past 90 days: o Tricyclic antidepressant; or o Anticonvulsant used for neuropathic pain (i.e. gabapentin, pregabalin); or o SNRI.
Capsaicin Patch (Qutenza®) Clinical Criteria	Capsaicin Patch (Qutenza®) will be approved for a diagnosis of postherpetic neuralgia after trial and failure of one of the following agents: • Tricyclic antidepressant; OR • Anticonvulsant used for neuropathic pain (i.e. gabapentin, pregabalin); OR • SNRI.
Prenatal Vitamins Clinical Criteria	Prenatal vitamins will be approved if one of the following is true: • Patient is female and currently pregnant; OR • Patient is female and actively nursing; OR • Patient suffers from a chronic condition associated with wasting (i.e., HIV) or malabsorption.
Becaplermin (Regranex®) Clinical Criteria	Becaplermin (Regranex®) will be approved for a diagnosis of lower extremity diabetic neuropathic ulcers.
Peginterferon Alfa 2b (Sylatron™) Clinical Criteria	Peginterferon Alfa 2b (Sylatron™) will be approved for a diagnosis of melanoma only.

Item	Options for Consideration
Omalizumab (Xolair®) Clinical Criteria	Initial Therapy (6 months): Xolair® (omalizumab) will be approved for the following diagnoses: • Moderate to severe asthma (step 5 or higher) if ALL of the following are true: o 12 years of age or older; AND o Positive skin test or in vitro reactivity to a perennial aeroallergen; AND o FEV1 of <80% while on asthma controller medication; AND o Has had failure of or contraindication to inhaled corticosteroid in combination with a second controller agent (such as a long-acting inhaled beta2-agonist, ipratropium, leukotriene modifier, or theophylline) for a 60-day trial. • Chronic idiopathic urticaria if ALL of the following are true: o 12 years of age or older; AND o The underlying cause of the patient's condition has been ruled out and is NOT considered to be any other allergic condition(s) or other form(s) of urticaria; AND o Documented baseline urticaria activity score (UAS7), renewals will require submission of current UAS7 (within previous 30 days); AND o One of the following: ▪ 3-month trial and failure of two (2) H1 antihistamines at maximally tolerated doses and patient has documented ongoing symptoms of chronic idiopathic urticaria; or ▪ 3-month trial and failure of one antihistamine products and one (1) of the following leukotriene antagonists: Singulair (montelukast) OR Accolate (zafirlukast) and patient has documented ongoing symptoms of chronic idiopathic urticaria. Continuation of Therapy: Xolair® (omalizumab) will be approved for continuation of therapy for the following diagnoses: • Moderate to severe asthma (step 5 or higher) if one of the following is true: o 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 o 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 o 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. • Chronic idiopathic urticaria if ALL of the following are true: o Treatment with Xolair® (omalizumab) has resulted in clinical improvement as documented by improvement (decrease) in urticaria activity score (UAS7) from baseline; AND o Submitted current UAS7 was recorded within the past 30 days.