Kentucky Department for Medicaid Services

Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the July 17, 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: Velphoro®	Place this product non preferred in the PDL class titled Phosphate Binders.
New Products to Market: Zohydro ER™	Place this product non preferred with appropriate quantity limits in the PDL class titled Narcotics: Long-Acting.
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: Otezla®	Place this product non preferred with appropriate quantity limits and similar criteria in the PDL class titled Immunomodulators.
New Products to Market: Luzu®	Place this product non preferred in the PDL class titled Topical Antifungal Agents.

Item	Options for Consideration
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.
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 one unique chemical entity 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.

Item	Options for Consideration
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.
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.

Item	Options for Consideration
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.
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.

Item	Options for Consideration
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.
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.

Item	Options for Consideration
Phenoxybenzamine (Dibenzyline®) Clinical Criteria	Phenoxybenzamine (Dibenzyline®) will be approved for a diagnosis of Pheochromocytoma only.
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
Palivizumab (Synagis®) Clinical Criteria	**Length of authorization:** Authorization should be granted during RSV season only; number of doses is specified below. 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 and child has Chronic Lung Disease (CLD) and required daily medical therapy (supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy) for CLD within 6 months before the start of the RSV season. If yes, approve for a maximum of 5 doses to be given during RSV season only. 2. Recipient is less than 24 months of age at the start of RSV season and child has hemodynamically significant cyanotic or acyanotic congenital heart disease and has one or more of the following risk factors: a. Receives medications to control CHF or cardiomyopathy; OR b. Has moderate to severe pulmonary hypertension; OR c. Has cyanotic heart disease. If yes, approve for a maximum of 5 doses to be given during RSV season only. 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 six days' gestation. If yes, approve for a maximum of 5 doses to be given during RSV season only. 4. Recipient is less than or equal to 12 months of age at the start of the RSV season **and** was born at less than 34 weeks six days' gestation **and** has either congenital abnormalities of the airway **or** a condition that compromises handling of respiratory secretions. If yes, approve for a maximum of 5 doses to be given during RSV season only. 5. Recipient is less than or equal to 6 months of age at the start of the RSV season **and** the infant was born between 29 weeks', 0 days' and 31 weeks', 6 days' gestation. If yes, approve for a maximum of 5 doses to be given during RSV season only. 6. Recipient is less than 3 months of age at the start of the RSV season or was born during the RSV season **and** was born at 32 weeks', 0 days' through 34 weeks', 6 days' 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; OR b. Has a sibling less than 5 years of age. If yes, approve for a maximum of 3 doses to be given during the RSV season only. Drug should be discontinued at 3 months of age regardless of number of doses given.

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.