The following tables list the agenda items as well as the Options for Consideration that are scheduled to be presented and reviewed at the October 14, 2025 meeting of the Pharmacy and Therapeutics Advisory Committee.

SINGLE AGENT REVIEWS

Agent	Options for Consideration

New Product to Market
Zelsuvmi™ (berdazimer)
	Dermatologics – Topical Antiviral Agents: Non-Preferred
	
	Approval Duration: 3 months
	
	• *Berdazimer is a nitric oxide releasing agent. Although the exact mechanism of action is unknown, nitric oxide release may interfere with viral replication, inhibiting the molluscum contagiosum virus (MCV) by disrupting viral DNA synthesis and assembly.*
	
	Approval Criteria:
	• Diagnosis of molluscum contagiosum (MC); **AND**
	• Prescribed by, or in consultation with, a dermatologist; **AND**
	• Patient has had a trial and failure (at least 3 months) of ≥ 1 of the following conventional therapies:
	  ○ Cantharidin,
	  ○ Silver nitrate,
	  ○ Cryotherapy,
	  ○ Curettage; **AND**
	• Patient meets one of the following:
	  ○ Patient has atopic dermatitis (AD); **OR**
	  ○ Patient is immunocompromised; **OR**
	  ○ Patient has concomitant bacterial infection; **AND**
	• Patient is not on concurrent treatment for MC; **AND**
	• Patient meets the minimum age recommended by the package insert for the provided indication.
	
	Age Limit: 1 year of age or older
	
	Quantity Limit: 1 kit (31 grams) per month

New Product to Market **Vykat™ XR (diazoxide choline)**	**Non-PDL** **Approval Duration:** 12 months initial, renewal • *The mechanism of action of diazoxide choline in the treatment of hyperphagia in patients with Prader-Willi syndrome is unknown.* **Approval Criteria:** • Diagnosis of hyperphagia; **AND**

Agent	Options for Consideration

	• Clinical confirmation of Prader-Willi Syndrome (PWS) documented by a genetic test identifying abnormal DNA methylation of chromosome 15q11.2Q13 region; **AND**
	• Prescribed by, or in consultation with, an endocrinologist, geneticist, or other specialist in the treatment of PWS; **AND**
	• Patient has had a baseline fasting plasma glucose (FPG) and HbA1c performed; **AND**
	• Prescriber attests to monitoring the following during treatment:
	  ○ FPG as clinically indicated; **AND**
	  ○ HbA1c as clinically indicated; **AND**
	  ○ Signs or symptoms of edema; **AND**
	• Patient meets the minimum age recommended by the package insert for the provided indication.
	
	Quantity Limit:
	• 150 mg tablets: 3 per day
	• 75 mg tablets: 3 per day
	• 25 mg tablets: 2 per day

New Product to Market
Tryptyr® (acoltremon)
	Ophthalmic – Immunomodulators: Non-Preferred
	
	Approval Duration: 3 months initial, 1 year renewal
	
	• *Acoltremon is an agonist of transient receptor potential melastatin 8 (TRPM8) thermoreceptors. TRPM8 thermoreceptor stimulation has been shown to activate trigeminal nerve signaling leading to increased basal tear production.*
	
	Initial Approval Criteria:
	• Patient has diagnosis of dry eye disease (DED); **AND**
	• Prescribed by or in consultation with an ophthalmologist or optometrist; **AND**
	• Patient has had a trial and failure of preservative-free, nonprescription lubricating eye drops (e.g., artificial tears); **AND**
	• Patient has had ≥ 1 month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 2 preferred agents; **AND**
	• Prescriber has documented at least 1 of the following signs of DED:
	  ○ Corneal fluorescein staining (CFS) score of ≥ 2 points in any field on a 0-to-4-point scale; **OR**
	  ○ Schirmer tear test (STT) of 1 to 10 mm in 5 minutes.
	• Patient meets the minimum age recommended by the package insert for the provided indication.

Agent	Options for Consideration

	Renewal Criteria:
	• Patient continues to meet the above criteria; **AND**
	• Patient has improvement in signs of DED, as measured by at least 1 of the following:
	  ○ Decrease in corneal fluorescein staining score; **OR**
	  ○ Increase in number of mm per 5 minutes using Schirmer tear test.
	
	Age Limit: 18 years of age or older
	
	Quantity Limit: 60 vials per 30 days

New Product to Market
Andembry® (garadacimab-gxii)
	Non-PDL
	
	Approval Duration: 6 months initial, 12 months renewal
	
	• *Garadacimab-gxii is a monoclonal antibody that blocks the function of activated factor XII (7), which prevents the overactivation of the kallikrein-kinin system and overproduction of bradykinin reducing or preventing hereditary angioedema (HAE) attacks. It is indicated for prophylactic treatment of C1-INH HAE in patients aged 12 years and older.*
	
	Initial Approval Criteria:
	• Diagnosis of hereditary angioedema (HAE); **AND**
	• Documentation of confirmed diagnosis of HAE by one of the following tests:
	  ○ Complement testing, **OR**
	  ○ C1 Inhibitor protein and functional tests; **AND**
	• Prescribed for prophylactic use; **AND**
	• Prescribed by, or in consultation with, an immunologist, hematologist, or other specialist in the diagnosis and treatment of HAE; **AND**
	• Patient is not on concurrent treatment with alternative prophylactic agent for HAE (e.g., Takhzyro, Haegarda, Cinryze, Dawnzera, Orladeyo); **AND**
	• Patient meets the minimum age recommended by the package insert for this FDA-approved indication.
	
	Renewal Criteria:
	• Prescriber attestation of improvement compared to baseline in hereditary angioedema attacks (i.e., reductions in attack frequency or attack severity).
	
	Quantity Limit: 1.2 mL (200 mg) per month

Agent	Options for Consideration
New Product to Market **Sephience™ (sepiapterin)**	**Non-PDL** **Approval Duration:** 1 month initial, 1 year renewal • *Sepiapterin acts as a precursor to enzymatic co-factor tetrahydrobiopterin (BH4), a natural cofactor that enhances the activity of phenylalanine hydroxylase (PAH), thereby reducing Phe levels.* **Initial Approval Criteria:** • Confirmed diagnosis of phenylketonuria (PKU) with elevated blood phenylalanine (Phe) levels; **AND** • Prescribed by, or in consultation with, a metabolic disease expert or other specialist in the management of PKU; **AND** • Provider attests that that the patient is on, and will continue, a phenylalanine-restricted diet supervised by a metabolic disease specialist or knowledgeable healthcare provider; **AND** • Provider attests to the presence of a monitoring plan for dietary intake; **AND** • Provider attests that the patient will have regular blood Phe level assessments as clinically indicated; **AND** • The requested dose does not exceed the maximum FDA-approved dose for this condition based on patient weight. **Renewal Criteria:** • Patient must continue to meet initial approval criteria; **AND** • Prescriber provides documentation (e.g., chart notes or summary) confirming sustained biochemical response, defined as continued ≥ 30% reduction in blood phenylalanine (Phe) levels. **Age Limit:** 1 month of age or older
New Product to Market **Anzupgo® (delgocitinib)**	**Immunomodulators – Atopic Dermatitis: Non-Preferred** • *Delgocitinib is a Janus kinase (JAK) inhibitor that specifically targets JAK1, JAK2, JAK3, and tyrosine kinase 2 (TYK2) to offer broad JAK inhibition. Thereby preventing downstream signaling and subsequent inflammation at the site of action.* **Initial Approval Criteria** • Diagnosis of moderate to severe chronic hand eczema (CHE); **AND** • Documentation of Investigator's Global Assessment for Chronic Hand Eczema (IGACHE) with a score ≥ 3; **AND**

Agent	Options for Consideration

	• Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of chronic hand eczema; **AND**
	• Trial and failure, contraindication, or intolerance to ≥ 1 agent in 2 or more of the following categories (total prior agent use of ≥ 90 days):
	  ○ Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone); **AND**
	  ○ Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); **OR**
	  ○ Immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil); **AND**
	• Trial and failure, contraindication, or intolerance to preferred JAK inhibitor (e.g., Opzelura); **AND**
	• No concurrent use of other biologics or JAK inhibitors or immunosuppressants; **AND**
	• Patient must meet the minimum age recommended by the package insert for the provided indication.
	
	Renewal Criteria
	• Patient must continue to meet initial approval criteria; **AND**
	• Patient must have disease improvement and/or stabilization based on an objective measure.
	
	Quantity Limit: 30 grams per month

New Product to Market
Ekterly® (sebetralstat)
	Non-PDL
	
	Approval Duration: 6 months initial, renewal
	
	• *Sebetralstat is a competitive, reversible inhibitor of plasma kallikrein that reduces production of bradykinin to treat acute, episodic attack of HAE.*
	
	Approval Criteria
	• Diagnosis of hereditary angioedema (HAE); **AND**
	• Documentation of confirmed diagnosis of HAE by one of the following tests:
	  ○ Complement testing, **OR**
	  ○ C1 Inhibitor protein and functional tests; **AND**
	• Prescribed by, or in consultation with, an immunologist, hematologist, or other specialist in the diagnosis and treatment of HAE; **AND**
	• Patient is not on concurrent acute treatment for HAE (e.g., Ruconest, Berinert, Kalbitor, Firazyr); **AND**
	• Patient meets the minimum age recommended by the package insert for this FDA-approved indication.

Agent	Options for Consideration
	Renewal Criteria • Prescriber attestation of improvement compared to baseline in hereditary angioedema attacks (i.e., reductions in attack frequency or attack severity). **Quantity Limit:** 4 tablets per day

FULL CLASS REVIEWS

PDL Class	Options for Consideration
Acne Agents, Oral	• 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 will require PA. • For any new chemical entity in the Acne Agents, Oral class, require PA until reviewed by the P&T Committee.
Antiemetics and Antivertigo Agents	• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Antiemetics and Antivertigo Agents class, require PA until reviewed by the P&T Committee.
Cytokine and Cell-Adhesion Molecule (CAM) Antagonists	• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Cytokine and Cell-Adhesion Molecule (CAM) Antagonists class, require PA until reviewed by the P&T Committee.
Immunomodulators, Atopic Dermatitis	• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Immunomodulators, Atopic Dermatitis class, require PA until reviewed by the P&T Committee.
Stimulants and Related Agents	• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA.

PDL Class	Options for Consideration
	• For any new chemical entity in the Stimulants & Related Agents class, require PA until reviewed by the P&T Committee.
Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists	• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists class, require PA until reviewed by the P&T Committee.
Antivirals, Oral	• 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 will require PA. • For any new chemical entity in the Antivirals, Oral class, require PA until reviewed by the P&T Committee.
Chronic Obstructive Pulmonary Disease (COPD) Agents	• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Chronic Obstructive Pulmonary (COPD) Agents class, require PA until reviewed by the P&T Committee.

CONSENT AGENDA ITEMS

Consent Agenda	Options for Consideration
For the following therapeutic classes, there are **no recommended changes to the Preferred Drug List (PDL) status**; these may be voted on as a group	
• **Acne Agents, Topical** • **Antibiotics, Topical** • **Antifungals, Topical** • **Antiparasitics, Topical** • **Antipsoriatics, Oral** • **Antipsoriatics, Topical** • **Antivirals, Topical** • **Rosacea Agents, Topical** • **Steroids, Topical** • **Anticholinergics/Antispasmodics** • **Antidiarrheals** • **Anti-Ulcer Protectants** • **Bile Salts** • **GI Motility, Chronic** • **H. Pylori Treatment**	• **Ophthalmics, Antibiotics** • **Ophthalmics, Antibiotic-Steroid Combinations** • **Ophthalmics, Antihistamines** • **Ophthalmics, Anti-Inflammatory Steroids** • **Ophthalmics, Antivirals** • **Ophthalmics, Beta Blockers** • **Ophthalmics, Carbonic Anhydrase Inhibitors** • **Ophthalmics, Combinations for Glaucoma** • **Ophthalmics, Glaucoma Agents (Other)** • **Ophthalmics, Immunomodulators**

Consent Agenda	Options for Consideration
• Histamine II Receptor Blockers • Laxatives and Cathartics • Proton Pump Inhibitors • Ulcerative Colitis Agents • Immunomodulators, Asthma • Immunosuppressives, Oral • Multiple Sclerosis Agents • Muscular Dystrophy Agents • Spinal Muscular Atrophy	• Ophthalmics, Mast Cell Stabilizers • Ophthalmics, Mydriatic • Ophthalmics, NSAIDs • Ophthalmics, Prostaglandin Agonists • Ophthalmics, Sympathomimetics • Otics, Anesthetics and Anti-Inflammatories • Otic Antibiotics