Health and Human Services

Drug Utilization Review Board

Drug Class and New Drug Review Only

October 24, 2025

This summary contains supplemental information from reliable sources where that information provides clarity to the issues being discussed. Power Point tables used in the presentations may also be used in this summary. Names of individuals may be misspelled but every attempt has been made to ensure accuracy. Tables and Text have been used from executive and legislative agencies and departments' presentations and publications.

Drug Utilization Review Board develops and submits recommendations for the preferred drug list, suggests clinical prior authorizations on outpatient prescription drugs, recommends education interventions for Medicaid providers, and reviews drug usage across Medicaid programs.

Membership

Physicians and pharmacists

- Alejandro D. Kudisch, M. D., D .F. A. P. A. (McAllen) (**Chair**)
- Jennifer Fix, Pharm. D (Burleson) (**Vice-chair**)
- Marlo Brawner, M. D. (Livingston)
  - *Term ends Aug. 31, 2025*
- Dominique Brewster, Pharm.D, BCPS, BCGP, AAHIVP (Houston)
  - *Term ends Aug. 31, 2025*
- Manuel Cano Rivera, M. D., F. A. A. P. (Corpus Christi)
- Heather Holmes, M. D. (Amarillo)
  - *Term ends Aug. 31, 2024*
- Sarah E. Kubes, Pharm. D. (San Antonio)
  - *Term ends Aug. 31, 2024*
- Jill N. Lester, Pharm. D. (Dallas)
  - *Term ends Aug. 31, 2025*
- Jia Lin, M.D., M. P. H. (Houston)
- Brigetta Martinez, Pharm. D., BCPPS, MASPHM (Edinburg)
- Richard Noel, M. D. (Spring)
- Joshua R. Tonche-Johns, Pharm. D. (Richardson)
  - *Term ends Aug. 31, 2024*
- Natalie N. Vanek, M. D. (Houston)
- Kathryn L. Velasquez, Pharm. D. (Houston)
  - *Term ends Aug. 31, 2025*
- Carlos Viesca, M. D. (El Paso)
- Vacant
- Vacant

Managed care representatives

- Salil V. Deshpande, M. D., M. B. A. (Sugar Land); UnitedHealthcare
- Lisa Sprenger, Pharm. D., BCPS (Kingsville); Driscoll Children's Health Plan
  - *Term ends Aug. 31, 2025*
- David A. Valdez, M. D. (San Antonio); Molina Healthcare of Texas

Consumer advocate

- Vacant

Resources:

- Drug Utilization Review Board Handbook
- Bylaws
- Conflict of Interest Policy
- Member information
- Meeting location
- Testimony information
- Form usage and instructions

- Contacts
- Retrospective Drug Use Criteria Handbook

Meeting

1. Call to order. Alejandro D. Kudisch, Chair called the meeting to order. A Quorum was present.

2. Consideration of July 25, 2025, draft meeting minutes. The minutes were approved as drafted

3. Public comment and discussion on the drug classes to be reviewed for the Medicaid Preferred Drug List (PDL):

Androgenic agents, topical Hypogonadism in males is a clinical syndrome characterized by low serum testosterone levels in combination with symptoms such as reduced libido, fatigue, impaired mood, and decreased muscle mass or bone density. It may be classified as primary hypogonadism (testicular failure, resulting in low testosterone with elevated gonadotropins) or secondary/hypogonadotropic hypogonadism (pituitary or hypothalamic dysfunction, leading to low testosterone with inappropriately low or normal gonadotropins). The prevalence of hypogonadism increases with age, with higher incidence in those with comorbidities such as obesity, type 2 diabetes, and metabolic syndrome. This review includes the topical androgenic agents, including testosterone gel, solution, transdermal system (patch), and intranasal gel. All these agents are Food and Drug Administration (FDA)-approved for the management of hypogonadism in males, including primary hypogonadism and hypogonadotropic hypogonadism that is congenital or acquired.

Public Comment. No comment

Antibiotics, gastrointestinal (GI) The gastrointestinal (GI) antibiotics class comprises a diverse range of drugs, each with different mechanisms of action and uses. This therapeutic class review includes two nitroimidazoles that damage DNA by causing strand breakage, two rifamycins that block RNA synthesis, two aminoglycosides (AGs) and one macrolide, which disrupt bacterial protein synthesis by binding to ribosomal subunits (AGs) or RNA polymerase (macrolide), a glycopeptide that inhibits bacterial cell wall synthesis, an antiprotozoal, thought to interfere with anaerobic metabolism, and

two live fecal microbiota agents, which are believed to help in the colonization of beneficial bacteria. While most of these drugs are used to treat infections in the GI tract, some are used for conditions outside the GI tract, like extraintestinal amebiasis and sexually transmitted infections (STIs). Additionally, some are used for non-infectious conditions like irritable bowel syndrome (IBS), hepatic coma, and hepatic encephalopathy (HE).

Public Comment.

A representative from Nesle Pharmaceuticals spoke in support of VOWST™ | Official Patient Website.

Antibiotics, topical Topical antibiotic products such as bacitracin, gentamicin, and combination agents such as bacitracin/polymyxin b, neomycin/bacitracin/polymyxin b, and neomycin/polymyxin b/pramoxine exert their antibiotic effects either through prevention of mucopeptide transfer to inhibit bacterial cell wall production, inhibition of bacterial protein synthesis by binding to the 30s ribosomal subunit, or alterations in the bacterial cytoplasmic membrane. Mupirocin exerts its activity by binding to RNA synthetase, and ozenoxacin, a quinolone antibiotic, acts to inhibit bacterial DNA replication enzymes. All topical antibiotic products are available generically, except for ozenoxacin, and several products are available over the counter (OTC).

Public Comment. No comment

Antibiotics, vaginal Two common vaginal infections are bacterial vaginosis (BV) and trichomoniasis. Symptoms of these infections can range from pruritis, vaginal soreness, dyspareunia, and abnormal vaginal discharge to minimal or no symptoms. Treatment is important to prevent serious health risks, including acquiring other sexually transmitted diseases (STDs), complications during pregnancy, or infecting others. The vaginal anti-infectives discussed in this therapeutic class review (TCR) are clindamycin (vaginal cream, gel, and suppository formulations), metronidazole (vaginal gel), and secnidazole (oral granules).

Public Comment. No comment

Anticonvulsants A number of anticonvulsant drugs are available for the treatment of various seizure disorders; these drugs are diverse in terms of their mechanisms of action, indicated populations, and warnings. Barbiturates (phenobarbital and primidone) and phenytoin are older agents used for the treatment of partial onset and tonic-clonic seizures. Partial (focal) seizures originate in one specific area of the brain and can cause symptoms like muscle twitching, unusual sensations, or confusion. The succinimides (ethosuximide and methsuximide) are used for absence seizures, a type of seizure that causes brief lapses in consciousness, often appearing as staring spells. Oral benzodiazepines are indicated for seizure disorders; however, only clonazepam, clobazam, and diazepam buccal film are specifically discussed within this review. Additional benzodiazepine formulations used for the acute outpatient treatment of seizures include intranasal formulations of diazepam and midazolam. The carbamazepine derivatives (carbamazepine, eslicarbazepine, and oxcarbazepine) and valproic acid derivatives (divalproex and valproic acid) can be used for a variety of seizure types; these agents have additional indications that include neuropathic pain (carbamazepine), bipolar disorder (carbamazepine and divalproex), and migraine prophylaxis (divalproex). Finally, there are a number of newer anticonvulsant therapies indicated for a wide variety of seizure types and seizure disorders,

Public Comment. No comment

Antiemetic-antivertigo agents (excludes injectables). Nausea and vomiting (N/V) are the most common presenting complaints in primary care and emergency settings. Management of N/V generally involves addressing the underlying etiology if one can be identified; this may include prophylactic approaches in patients with known or anticipated risk factors. Some of the most common conditions and therapies associated with N/V include certain anticancer treatments, surgery and surgical anesthesia, pregnancy, infection (eg, gastroenteritis), motion sickness, and vertigo. This review includes non-injectable (mostly oral) agents with labeled and off-label indications for N/V of various etiologies. Notably, several of these agents have other approved injectable formulations that are not reviewed in detail in this document, including aprepitant, dimenhydrinate, dolasetron, granisetron, ondansetron, prochlorperazine, promethazine, and trimethobenzamide.

Public Comment. No comment

Pediatric Neurologist testified on vertigo and its impact on quality of life. Four agents are approved for children but have their drawbacks like drowsiness, Has asked future consideration of anticelalucine

Antifungals, oral The oral antifungal agents vary in their spectrum of activity and are FDA-approved for treating a range of fungal infections, including aspergillosis, blastomycosis, candidiasis, histoplasmosis, onychomycosis, and ringworm (tinea) infections. Different types of fungi cause these infections and can affect various parts of the body. For example, aspergillosis can cause severe respiratory symptoms, including hemoptysis, wheezing, and shortness of breath, while candidiasis often affects mucosal areas such as the mouth or genitals, leading to discomfort and pain. Onychomycosis affects the nails, causing thickening, discoloration, and brittleness. Few comparative trials exist regarding the safety and efficacy of these drugs, and some agents have significant adverse effects. For instance, ketoconazole is associated with severe hepatotoxicity, limiting its use to salvage therapy.

Public Comment. No comment

Antifungals, topical . Topical antifungals treat dermatophytes belonging to 3 genera, Trichophyton, Epidermophyton, and Microsporum , which cause fungal infections of keratinized tissue such as the skin, hair, and nails. Dermatomycoses were ranked second to acne as the most frequent skin disease in the United States. Treatment (topical or systemic) of dermatophyte infections is generally indicated to alleviate symptoms (e.g., pruritis), reduce the risk for secondary bacterial infection, and decrease the spread of infection to other parts of the body. Topical antifungal agents have decreased potential for serious adverse side effects often experienced with oral medications; most cutaneous dermatophyte infections are limited to the epidermis and can be managed with topical antifungal therapy.

Public Comment.

A representative from Puretek Pharmaceuticals spoke in support of Personal Care to Prescription. their products

Antihistamines, first generation. Antihistamine drugs block histamine release from histamine-1 receptors and are mostly used to treat allergies or cold and flu

symptoms, although some first-generation antihistamines (also called sedating antihistamines) may be used for other conditions, such as nausea or motion sickness. Histamine-1 receptors are located in your airways (breathing tubes), blood vessels, stomach, and esophagus (throat area). Allergens, such as pollen or pet fur can stimulate these receptors, causing the release of histamine, which results in symptoms such as a rash, sneezing, a runny nose, or a narrowing of the airways (also called bronchoconstriction). Histamine-1 receptors are also found in the brain and spinal cord and first-generation antihistamines (sedating antihistamines) can cross through the blood/brain barrier into the brain and act on these receptors, causing sleepiness (sedation), and drowsiness.

Public Comment. No public

Antiparasitics, topical. Topical antiparasitic agents are utilized for the treatment of head lice, body lice, pubic lice, and scabies. Spinosad and permethrin both have indications for lice and scabies; the prescription strength permethrin indication is limited to scabies and the over the counter (OTC) indication is limited to lice. Crotamiton is only indicated in the treatment of scabies. The remaining drugs – pyrethrins/piperonyl, ivermectin, malathion, and lindane – are indicated for various types of lice treatment. Most of these topical agents are parasiticidal activity by way of effects on the neuronal membrane. Most agents are available generically. Pyrethrins/piperonyl butoxide, permethrin (1%), and ivermectin are available OTC. In general, the topical antiparasitic agents are well-tolerated when applied according to product label recommendations. The most common adverse events are related to skin irritation and include pruritus, itching, tingling, rash, and irritation. Serious adverse events can occur with malathion and lindane. Malathion can cause chemical burns and is flammable; use in neonates and infants is contraindicated due to potential increased absorption. Lindane is contraindicated in premature infants, patients with uncontrolled seizure disorders, and patients with skin conditions that may increase absorption; lindane can also cause neurologic toxicity.

Public Comment. No public comment

Antivirals, topical. Herpes simplex virus (HSV) is a common, lifelong infection that is frequently asymptomatic or unrecognized. When present, symptoms of HSV include painful blisters or sores at the site of the infection that can recur over time.

Transmission of HSV occurs through contact with an infected individual's lesion, mucosal surface, or genital or oral secretions. Once antibodies are produced, the infection remains latent unless triggered. Herpes labialis, also known as cold sores or fever blisters, is an infection of the lips or perioral area. It can be caused by either HSV type 1 (HSV-1) or HSV type 2 (HSV-2). The primary infection can be caused by either HSV-1 or HSV-2, but recurrences are generally caused by HSV-1, as oral recurrences with HSV-2 are very rare. Genital herpes is more commonly caused by HSV-2. During 2017 to 2018, approximately 51.3% of individuals ages 20 to 49 years in the United States (US) had HSV-1, and 14.6% of individuals in the same age range in the US had HSV-2. Prevalence of both types of HSV were higher in females than males. Generally, HSV can be reactivated after exposure to certain stimuli, including fever, other infection, physical or emotional stress, or ultraviolet light exposure. A prodromic phase, which can last up to 24 hours before lesion development, typically precedes recurrent episodes of cold sores and may consist of tingling, itching, or redness. Recurrent infections are generally less severe than primary infections due to existing immunity from prior exposures.

Public Comment. No public comment.

Bone resorption suppression and related agents. Bone resorption suppression and related agents are used for various bone diseases (e.g., osteoporosis, Paget's disease) in ambulatory populations. Osteoporosis is characterized by the deterioration of bone tissue and low bone mass, and may be postmenopausal, age-related, or secondary osteoporosis (e.g., from glucocorticoid use). Paget's disease is a chronic condition characterized by excessive breakdown and regrowth in the affected bones. Patients with hypoparathyroidism may have suppressed bone turnover and impaired calcium homeostasis due to reduced parathyroid hormone (PTH) activity. The agents in the review include bisphosphonates and other agents with varying mechanisms and specific indications.

Public Comment.

A representative from Amgen Pharmaceuticals spoke in support of Evenity Treatment for Postmenopausal Osteoporosis | EVENITY® (romosozumab-aqqg)

Colony stimulating factors. Colony-stimulating factor (CSF) agents serve a vital role in oncology, particularly for patients undergoing treatments that impact the immune system. These agents are pivotal in treating and preventing neutropenia, a

condition characterized by a dangerously low level of neutrophils. Neutropenia often affects patients receiving myelosuppressive chemotherapy or those undergoing bone marrow transplantation (BMT), both of which can significantly reduce the body's ability to fight infections. In addition to managing neutropenia, CSF agents are also employed to mobilize peripheral blood stem cells. This process is crucial for collecting these cells from the blood for use in autologous stem cell transplantation, offering an alternative to traditional BMT. Furthermore, certain CSF agents have a role in treating the effects of acute radiation syndrome, a serious condition that occurs after a high dose of radiation exposure, impacting bone marrow function and, consequently, blood cell production. Through these diverse applications, CSF agents provide essential support in mitigating the side effects of cancer treatments and enhancing patient outcomes. The CSF agents discussed in this therapeutic class review are the granulocyte(G)-CSFs (i.e., efbemalenograstim alfa, eflapegrastim, filgrastim, tbofilgrastim, pegfilgrastim, and corresponding biosimilars) and the granulocyte/macrophage (GM)-CSF, sargramostim. G-CSFs specifically promote neutrophil proliferation and maturation, whereas GM-CSF shows much broader effects on multiple cell lineages, particularly on macrophages and eosinophils

Public Comment. No comment

Epinephrine, self-injected. Anaphylaxis is the most severe sequelae of an allergic reaction to unknown (idiopathic) or known exposures to foods, insect stings/bites, medications, and exercise. It is characterized by a sudden onset of skin and/or mucosal tissue symptoms that can include generalized hives, pruritis or flushing, swollen lips, tongue, or uvula along with reduced blood pressure, respiratory difficulties, or severe gastrointestinal symptoms. Skin involvement may or may not be present in all cases of anaphylaxis. The most common pathway leading to anaphylaxis is the interaction of an allergen with the immunoglobulin E (IgE) receptor on mast cells and basophils. Intramuscular epinephrine using an auto-injector is the first-line emergency treatment for anaphylaxis. It reduces vasodilation and vascular permeability through action at alpha-adrenergic receptors and relaxes bronchial smooth muscle alleviating bronchospasm through action at betaadrenergic receptors. If injected into areas other than the anterolateral thigh, serious reactions such as skin and soft tissue infections and reduced blood flow to the affected area. Although not a contraindication for use, closer monitoring is warranted when epinephrine is used in patients with concomitant cardiac disease due to potential exacerbation of arrhythmias, angina, and increased blood pressure.

Public Comment.

HEB Pharmacist commented on two generic alternatives on the PDL and have rebates. The cost is more than Teva's version of the drug. They requested lifting the prior authorization restriction on Teva products. Teva's Epinephrine Auto-Injector

Texas Pharmacy Association stated there are two products and one is preferred and the second is restricted. This decision was based on the rebate provided. She supported removing restriction on Teva's product.

GI motility, chronic. Agents in this class are used to treat a variety of gastrointestinal (GI) motility disorders, including constipation of various etiologies and diarrhea associated with irritable bowel syndrome (IBS). Linaclotide and plecanatide (guanylate cyclase stimulators), lubiprostone (a chloride channel activator), and prucalopride (a selective serotonin 5-HT 4 receptor agonist) are used for the treatment of chronic idiopathic constipation (CIC) in adults; linaclotide is additionally indicated for functional constipation (FC) in pediatric patients 6 to 17 years of age. Only lubiprostone is available generically. Plecanatide and linaclotide can cause significant diarrhea and are specifically contraindicated in young patients (age <2 years for linaclotide and age <6 years for plecanatide) due to the risk of serious dehydration. Lubiprostone carries warnings for nausea, diarrhea, syncope/hypotension, dyspnea, and bowel obstruction, while prucalopride carries a warning for suicidal ideation and behavior. Current guidelines for CIC state that secretagogues (lubiprostone, linaclotide, plecanatide) and prucalopride are recommended options for patients who do not respond to over-the-counter laxatives; lubiprostone is conditionally recommended, while linaclotide, plecanatide, and prucalopride are strongly recommended. Guidelines for pediatric FC have not been updated since 2014 and therefore do not include a place in therapy for linaclotide.

Public Comment. No comment

Growth hormone. Growth hormone deficiency (GHD) is a rare disorder characterized by the inadequate secretion of growth hormone from the pituitary gland and presents as short stature and slow growth. GHD can be present at birth (congenital), acquired (as a result of trauma, infection, or radiation), or idiopathic. GHD

is treated by injections of synthetic growth hormones for several years to increase the chance the child will attain near-normal adult height. Other conditions that utilize synthetic growth hormones to treat short statue include Turner syndrome, Prader-Willi syndrome (PWS), Noonan syndrome, short stature homeobox-containing gene (SHOX) deficiency, idiopathic short stature (ISS), children born small for gestational age (SGA) and chronic renal insufficiency.

Public Comment.

A representative from Ascendis Pharma spoke in support of Skytrofa Once-weekly SKYTROFA® (lonapegsomatropin-tcgd) | HCP Website

A representative from Pfizer spoke in support of Ngenla NGENLA™ (somatrogon-ghla) Injection for Pediatric GHD | Safety Info

Hepatitis C agents. Hepatitis C is a liver infection caused by the hepatitis C virus (HCV) characterized by liver inflammation. While most patients with acute HCV are asymptomatic, there are symptoms of HCV that may surface during the acute episode including jaundice, dark urine, white stool, nausea, and right upper quadrant pain. This disease is associated with a high risk of viral spread, particularly among patients sharing needles or other drug-use paraphernalia and those with high-risk sexual practices. For this reason, antiviral therapy during acute infection is typically initiated. The recommended regimens and durations are the same for patients with chronic HCV infection. The standard of treatment for infection with HCV involves use of a combination of direct-acting oral antivirals (DAAs) with or without ribavirin. Previously, patients were treated with either interferon monotherapy or dual therapy with peginterferon + ribavirin; however, side effects were substantial (e.g., flu-like symptoms, fatigue, neuropsychiatric symptoms, and hematologic side effects). A greater understanding of HCV has resulted in the development of DAAs in effort to improve efficacy and tolerability. Direct-acting oral antivirals inhibit non-structural (NS) proteins that subsequently interfere with virus replication

Public Comment.

A representative from Gilliad spoke in support of Epclusa Common EPCLUSA® Side Effects | Patient Site

A representative from Abbvie spoke in support of Mavyret
MAVYRET Hep C Treatment Information - Official Site

HIV/AIDS. Infection with Human Immunodeficiency Virus (HIV) is characterized by a progressive decline in CD4 cell count, leading to the development of severe immunosuppression, which increases the risk for infectious diseases caused by opportunistic pathogens. The most common type of HIV is HIV-1. The goal of antiretroviral therapy (ART) for HIV infection is multifaceted. Treatment should be continued to maximally suppress plasma HIV, restore and preserve immunologic function, prevent transmission, reduce HIV-associated morbidity and mortality, and prolong the duration or quality of survival. Individual antiretroviral (ARV) medications spanning 8 drug classes are Food and Drug Administration (FDA)-approved for the treatment of HIV-1 infection, including nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), non-nucleoside/nucleotide reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), integrase strand transfer inhibitors (INSTIs), and the entry inhibitors (including a fusion inhibitor, CC chemokine receptor 5 (CCR5) inhibitor, post-attachment inhibitors, and a recently approved capsid inhibitor. In addition, 2 drugs, ritonavir and cobicistat, are used as pharmacokinetic (PK) enhancers (i.e., boosters) to improve the PK profiles of some ARV drugs. Fixed-dose combination products containing 2 or 3 active ARV agents are also available as full ART regimens and for use with other ARV therapies. For organizational clarity, the ART agents evaluated in this TCR are classified into 3 categories. This classification differentiates between combination therapy, single tablet, and non-single-tablet regimens.

Public Comment.

A representative from Gilead spoke in support of Yeztugo Yeztugo Lenacapavir Is Now the First and Only FDA Approved HIV Prevention Option Offering 6 Months of Protection

Hypoglycemics, incretin mimetics/enhancers. Diabetes is a chronic illness that requires continuous medical care and risk-reduction strategies to prevent short- and long-term complications. The hallmark of type 1 diabetes mellitus (T1DM) is b-cell dysfunction that results in the cessation of endogenous insulin production; for this reason, insulin treatment is essential. Type 2 diabetes (T2DM) is characterized by progressive reductions in pancreatic β-cell production of insulin coupled with broad insulin resistance, leading to permanent disturbances in glucose homeostasis. Persistent elevations in plasma glucose and associated perturbations in lipid

metabolism have the potential for far-reaching microvascular and macrovascular complications, such as neuropathy, cardiovascular disease, and chronic kidney disease (CKD). Lifestyle interventions, weight loss, and medication improve glycemic control, reducing the risk of long-term complications. Guidelines for pharmacologic management of T2DM initially stratify recommendations based on cardiorenal risk; in patients at high risk, agents associated with cardiorenal benefit (including certain sodium-glucose cotransporter 2 [SGLT2] inhibitors and glucagon-like peptide 1 [GLP-1] receptor agonists) are generally recommended as earlier-line therapy. In such patients whose glucose-lowering regimens have been optimized for cardiorenal risk reduction and require additional glycemic control, or in patients who do not have a specific indication for cardiorenal risk reduction, agent selection is based on the likelihood of achieving glycemic control, efficacy for weight loss, and safety considerations.

Public Comment.

Jordan Smelley representing himself requested GLP1 access without PA for all conditions that involve **Polyphagia**,

Hypoglycemics, insulin and related. Diabetes is a chronic illness that requires continuous medical care and risk-reduction strategies to prevent short- and long-term complications. The hallmark of type 1 diabetes mellitus (T1DM) is β-cell dysfunction that results in the cessation of endogenous insulin production; therefore, insulin treatment is essential. Type 2 diabetes mellitus (T2DM) is a progressive disease in many patients that ultimately requires maintenance of glycemic targets with combination therapy that may include insulin. Insulin regulates glucose metabolism by stimulating glucose uptake in skeletal muscle and fat and inhibiting hepatic glucose production.

Public Comment. No comment

Hypoglycemics, meglitinides. Diabetes Mellitus is a chronic condition associated with elevated blood glucose levels in the body that affects more than 34 million Americans and over 463 million people worldwide. Diabetes occurs when the body cannot produce or effectively produce enough insulin to help regulate the amount of glucose in the bloodstream. The two main types of diabetes are type 1 (T1DM) and type 2 (T2DM), with T2DM being the most common. Symptoms often develop over time and are not always apparent; these may include increased thirst, increased urination, unexplained weight loss, extreme hunger, weakness or fatigue, irritability, and vision

disturbances. Nonpharmacologic therapies aim for lifestyle modifications such as diet, exercise, and weight loss. When these approaches fail, medication therapy must be initiated.

Public Comment. No comment

Hypoglycemics, metformin. The biguanide therapeutic class is indicated for the treatment of type 2 diabetes mellitus (T2DM). Diabetes is a common, chronic disease among Americans, with an estimated 37.3 million individuals affected. Approximately 90% to 95% of diabetes cases in the United States are type 2. Type 2 diabetes initially results from insulin resistance in peripheral tissues; however, as the disease progresses, the pancreas cannot keep pace, and elevated blood glucose results. The complications of T2DM include cardiovascular disease, retinopathy, nephropathy, and neuropathy. The biguanides work through various mechanisms including decreased hepatic gluconeogenesis production, decreased glucose absorption in the intestine, and increased insulin sensitivity through improved peripheral glucose uptake and utilization. Metformin is the only agent in the biguanide class; however, it is available in several formulations and combination with other agents.

Public Comment. No comment

Hypoglycemics, sodium-glucose cotransporter-2 (SGLT2). Type 2 diabetes (T2DM) is a metabolic disease characterized by progressive reductions in pancreatic β-cell production of insulin coupled with broad insulin resistance, leading to permanent disturbances in glucose homeostasis. Persistent elevations in plasma glucose and associated perturbations in lipid metabolism have the potential for microvascular and macrovascular complications, such as neuropathy, cardiovascular disease, and chronic kidney disease (CKD). Lifestyle interventions, weight loss, and medication improve glycemic control, reducing the risk of long-term complications. Guidelines for pharmacologic management of T2DM initially stratify recommendations based on cardiorenal risk; in patients at high risk, agents associated with cardiorenal benefit (including certain sodium-glucose co-transporter 2 [SGLT2] inhibitors and glucagon-like peptide 1 [GLP-1] receptor agonists) are generally recommended as earlier-line therapy. In such patients whose glucose-lowering regimens have been optimized for cardiorenal risk reduction and require additional glycemic control, or in patients who do not have a specific indication for cardiorenal risk reduction, agent

selection is based on the likelihood of achieving glycemic control, efficacy for weight loss, and safety considerations.

Public Comment.

A representative from Boehringer Ingelheim Pharmaceutical spoke in support of Jardiance T2D & eCVD | HF | CKD | Jardiance® (empagliflozin) tablets

Hypoglycemics, thiazolidinediones (TZDs). Type 2 diabetes mellitus (T2DM) is a metabolic disease characterized by insulin resistance followed by a decline in the ability of pancreatic β-cells to produce insulin, resulting in persistently elevated blood glucose levels. If left untreated, persistent hyperglycemia can increase the risk of microvascular complications, such as retinopathy and neuropathy, and macrovascular complications, such as cardiovascular disease and chronic kidney disease (CKD). The Centers for Disease Control and Prevention report that more than 11% of the United States (US) population lives with diabetes. Management of T2DM requires glycemic control and risk reduction of cardiorenal complications. Lifestyle modifications are critical to any treatment regimen. Pharmacologic therapy may be necessary to improve glycemic control and reduce the risk of long-term complications. Thiazolidinediones (TZDs) are peroxisome proliferator-activated receptor-β (PPARβ) agonists that depend on the presence of insulin for its mechanism of action but do not act as insulin secretagogues.

Public Comment. No comment

Macrolides-ketolides. Macrolides are active against a broad spectrum of bacteria including gram-positive, gram-negative, mycobacteria, Legionella pneumophila, Chlamydia species, Mycoplasma pneumoniae, and Helicobacter pylori. Spectrum of activity is similar among the macrolides for the more common organisms, with the exception of Haemophilus influenzae, which is more susceptible to azithromycin than the other agents. Erythromycin is less favored in practice than azithromycin or clarithromycin due to its shorter half-life/frequency of administration and gastrointestinal tolerability issues. Azithromycin has fewer drug interactions than clarithromycin and erythromycin. All 3 macrolides can cause QT prolongation. All 3 macrolides have been studied in children for a variety of indications but data for extended-release formulations in children is limited. Selection of an agent for inclusion

on the Preferred Drug List should be based on the approved indication, efficacy, cost, available routes of administration, and guideline preference to steer utilization to more clinically supported and cost-effective treatments.

Public Comment. No comment

Opiate dependence treatments. Opioid Use Disorder (OUD) is a chronic condition marked by compulsive opioid use despite harmful consequences and is commonly treated with a combination of medications and psychosocial support. Medications like buprenorphine, buprenorphine/naloxone, and naltrexone play key roles in both induction and maintenance therapy, as well as in preventing relapse after detoxification. Buprenorphine, a partial opioid agonist, is used for both induction and maintenance and is available as a monoproduct or combined with naloxone. The combination with naloxone is intended to reduce misuse potential by causing withdrawal symptoms if injected. Sublingual buprenorphine tablets and extended-release subcutaneous injections, such as Brixadi ® and Sublocade ® , are primarily used in patients with moderate to severe OUD. These extended-release formulations are particularly beneficial for patients who struggle with adherence but carry boxed warnings regarding potential harm, including death, if administered intravenously. As of December 29, 2022, providers that prescribe buprenorphine for OUD are no longer required to have a waiver (DATA-Waiver); any provider with valid DEA registration with prescribing authority for Schedule III medications may prescribe buprenorphine. Naltrexone, an opioid antagonist, is used to maintain abstinence once a patient has completed opioid detoxification. Available as both an extendedrelease injection and an oral tablet, naltrexone is not recommended for patients currently using opioids or those in withdrawal, as it can precipitate severe withdrawal symptoms. It is commonly prescribed in patients who have completed detoxification and are committed to avoiding opioid use.

Public Comment.

A company representative spoke in support of Vivitrol VIVITROL® - Injectable Naltrexone | HCP

A representative from Purdue Pharma spoke in support of Nalmefene hydrochloride Nalmefene HCl injection | Official HCP Website and Zurnai ZURNAI™ (nalmefene injection)—Opioid Antagonist Auto-Injector

Tetracyclines. This review covers agents in the tetracycline antibiotic class, which inhibit bacterial protein synthesis by binding primarily to the 30S ribosomal subunit. This prevents aminoacyl transfer-RNA from attaching to the ribosome and interferes with bacterial growth. These agents have a broad spectrum of activity and are used for a variety of infections, including respiratory tract infections, sexually transmitted infections, rickettsial diseases, ophthalmic infections, and certain zoonotic infections.

Public Comment. No comment

4. Public comment and discussion on single new drugs to be reviewed for the Medicaid PDL: (Links to the company website are provided when available).

Andembry / Hereditary angioedema treatments. **Company Website:** ANDEMBRY® (garadacimab-gxii) | Breaking New Ground In HAE Protection. ANDEMBRY® (garadacimab-gxii) injection, for subcutaneous use, is a prescription medication used to prevent attacks of hereditary angioedema (HAE) in people 12 years and older. It is not known if ANDEMBRY is safe and effective in children under 12 years of age.

Public Comment. No comment

Avmapki / Oncology, oral - other. Cancer encompasses a broad range of organ systems, many of which are treated with oral therapies targeting specific molecular pathways. These agents are particularly valuable in advanced or metastatic settings, offering a non-invasive alternative to traditional chemotherapy. This review focuses on oral oncology therapies, including kinase inhibitors, poly (ADP-ribose) polymerase (PARP) inhibitors, and other targeted treatments. Kinase inhibitors act by targeting specific tyrosine kinases which are crucial in tumor growth and angiogenesis. Examples include cabozantinib, vandetanib, and fruquintinib. PARP inhibitors, including olaparib, niraparib, and rucaparib, prevent DNA repair in cancer cells with mutations, leading to cell death. Miscellaneous agents also play a role in niche applications, such as nirogacestat, which inhibits Notch signaling in desmoid tumors, and tazemetostat, which targets EZH2 to influence chromatin remodeling in follicular lymphoma and epithelioid sarcoma. BRCA These agents are FDA-approved for various indications.

Kinase inhibitors like cabozantinib and vandetanib are recommended for thyroid cancer, while ripretinib is effective in gastrointestinal stromal tumors. PARP inhibitors are used for maintenance or therapeutic intervention in ovarian, breast, and prostate cancers, particularly in BRCA-mutated cases. Other specialized agents include tovorafenib for pediatric gliomas with BRAF alterations, nirogacestat for desmoid tumors, selumetinib for pediatric neurofibromas, and avutometinib copackaged with defactinib (avutometinib/defactinib) for the treatment of recurrent low-grade serious ovarian cancer (LGSOC). Oral oncology agents offer significant advantages, including targeted actions that minimize off-target effects, convenience of oral administration, and efficacy in refractory cancers. However, limitations include the development of resistance, high costs, and toxicities such as hypertension with kinase inhibitors, myelosuppression with PARP inhibitors, and gastrointestinal side effects.

Public Comment. No comment

Avmapki-Fakzynja Co-Pack / Oncology, oral - other. **Company Website:** AVMAPKI™ FAKZYNJA™ CO-PACK | Patient Information. AVMAPKI FAKZYNJA CO-PACK is a prescription medicine used to treat adults who have low-grade serous ovarian cancer (LGSOC) that has come back (recurrent), **and** LGSOC with an abnormal *KRAS* gene, **and** previously been treated with medicine for their cancer. It is not known if AVMAPKI FAKZYNJA CO-PACK is safe and effective in children.

Public Comment. No comment

Fakzynja / Oncology, oral - other. Cancer encompasses a broad range of organ systems, many of which are treated with oral therapies targeting specific molecular pathways. These agents are particularly valuable in advanced or metastatic settings, offering a non-invasive alternative to traditional chemotherapy. This review focuses on oral oncology therapies, including kinase inhibitors, poly (ADP-ribose) polymerase (PARP) inhibitors, and other targeted treatments. Kinase inhibitors act by targeting specific tyrosine kinases which are crucial in tumor growth and angiogenesis. Examples include cabozantinib, vandetanib, and fruquintinib. PARP inhibitors, including olaparib, niraparib, and rucaparib, prevent DNA repair in cancer cells with mutations, leading to cell death. Miscellaneous agents also play a role in niche applications, such as nirogacestat, which inhibits Notch signaling in desmoid tumors, and tazemetostat, which targets EZH2 to influence chromatin remodeling in follicular lymphoma and epithelioid sarcoma. BRCA These agents are FDA-approved for various indications.

Kinase inhibitors like cabozantinib and vandetanib are recommended for thyroid cancer, while ripretinib is effective in gastrointestinal stromal tumors. PARP inhibitors are used for maintenance or therapeutic intervention in ovarian, breast, and prostate cancers, particularly in BRCA-mutated cases. Other specialized agents include tovorafenib for pediatric gliomas with BRAF alterations, nirogacestat for desmoid tumors, selumetinib for pediatric neurofibromas, and avutometinib copackaged with defactinib (avutometinib/defactinib) for the treatment of recurrent low-grade serious ovarian cancer (LGSOC). The agents in this review are not available generically with the exception of temozolomide. Only a few agents have been shown safe and effective in pediatric patients such as eflornithine, selumetinib, tovorafenib, tazemetostat, larotrectinib, repotrectinib, and vorasidenib. Selection of an agent for inclusion on the Preferred Drug List should be based on the approved indication, efficacy, safety, dosing schedule, cost, and guideline preference to steer utilization to more cost-effective treatments.

Public Comment. No comment

Ibtrozi / Oncology, oral - lung. **Company Website:** ROS1+ NSCLC Therapy | IBTROZI™ (taletrectinib). IBTROZI™ (taletrectinib) is indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer (NSCLC).

Public Comment. No comment

Imuldosa / Cytokine and CAM antagonists. **Company Website:** Imuldosa® - Vivo Infusion. Imuldosa® (ustekinumab-srlf) is an FDA-approved biosimilar to Stelara® (ustekinumab), indicated for the treatment of chronic inflammatory conditions including moderate to severe plaque psoriasis, active psoriatic arthritis, moderately to severely active Crohn's disease, and ulcerative colitis. It targets interleukin-12 and interleukin-23 (IL-12/23), key cytokines involved in immune-mediated inflammation, helping to reduce immune system overactivity. Imuldosa® offers a biosimilar alternative to its reference product, with no clinically meaningful differences in safety, efficacy, or pharmacokinetics. It is administered via subcutaneous injection for all indications, with intravenous infusion used only for induction therapy in Crohn's disease and ulcerative colitis.

Public Comment. No comment

Khindivi / Glucocorticoids, oral. **Company Website:** Khindivi (hydrocortisone).
KHINDIVI is a prescription medicine used in children 5 years of age and older as replacement therapy when the adrenal gland is not making enough cortisol.
Limitation of Use: KHINDIVI is not approved for increased dosing during periods of stress or acute events. Use a different hydrocortisone-containing drug product for stress dosing.

Public Comment. No comment

Leqselvi / Cytokine and CAM antagonists. **Company Website:**Learn About LEQSELVI™ for Managing Severe Alopecia Areata. LEQSELVI is used to treat adults with severe hair loss (alopecia areata). It is not known if LEQSELVI is safe and effective in children.
Public Comment. No comment

nilotinib tartrate capsules / Oncology, oral - hematologic. **Company Website:** Nilotinib. NILOTINIB is a prescription medicine used to treat:

- Adults and children 1 year old or older with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).
- Adults with CP and accelerated phase (AP) Ph+ CML resistant or intolerant to prior therapy that included imatinib.
- Children 1 year old or older with CP and AP Ph+ CML with resistance or intolerance to prior tyrosine kinase inhibitor (TKI) therapy.

It is not known if NILOTINIB is safe and effective in children younger than 1 year of age with newly diagnosed, resistant, or intolerant Ph+ CML in chronic phase.
The long-term effects of treating children with NILOTINIB for a long period of time are not known.

Public Comment. No comment

Pyzchiva 45mg/0.5ml vial / Cytokine and CAM antagonists, **Company Website:** PYZCHIVA® (ustekinumab-ttwe) | PYZCHIVA® Patient Website. PYZCHIVA is an FDA-approved biosimilar to Stelara® (ustekinumab). This means **PYZCHIVA has been thoroughly studied and proven to be as safe and effective as Stelara®**. It also means PYZCHIVA can be used in place of Stelara®. PYZCHIVA is FDA approved to treat

Crohn's disease, ulcerative colitis, plaque psoriasis, and psoriatic arthritis. Please see full uses for PYZCHIVA below.

Public Comment. No comment

Qfitlia / Hemophilia treatments. **Company Website**: QFITLIA® (fitusiran) | For US HCPs. Qfitlia™ (fitusiran) is an antithrombin (AT)-directed small interfering ribonucleic acid (siRNA) indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without Factor VIII or IX inhibitors.

Public Comment.

A company representative presented support for their product Qfitlia, speaking from information available on the company website.

Tezruly / Benign prostatic hyperplasia (BPH) treatments. Benign prostatic hyperplasia (BPH) results from overgrowth of the prostate gland's epithelial tissue, smooth muscle, and connective tissue. The enlarged gland causes direct bladder outlet obstruction and increases smooth muscle tone/resistance, contributing to lower urinary tract symptoms (LUTS) of voiding difficulties and urinary incontinence. Most men with BPH experience only mild or moderate symptoms of obstruction; severe BPH is more likely to occur beyond the sixth decade of life and can result in serious complications such as acute renal failure. The International Prostate Symptom Score (IPSS) is a recommended tool to assess and monitor the degree of LUTS. Options for managing LUTS secondary to BPH include lifestyle modifications, pharmacological agents, and procedural intervention.

Public Comment. No comment

Tryptyr / Ophthalmics, anti-inflammatory immunomodulators. **Company Website**: TRYPTYR (acoltremon ophthalmic solution) 0.003% eye drops | Alcon US. TRYPTYR (acoltremon ophthalmic solution) 0.003% is a prescription eye drop used for the treatment of the signs and symptoms of dry eye disease (DED).

Public Comment. No comment

5. Therapeutic and clinical drug reviews and updates, discussion, and recommendations: Gainwell Technologies and DURB members

(Given the absurd nature of the spelling of most pharmaceutical products, no effort has been made to ensure spelling in this section is accurate. Accessing your "Hooked on Phonics" memory may be helpful when reading this section). The information below is a summary of this presentation.

Updates were provided on multiple drug classes, with pauses for questions after each:

- Androgenic Agents Topical, Antibiotics (topical/vaginal), Antiemetics, Antifungals (oral/topical), Antihistamines, Antiparasitics, Bone Resorption Agents, Epinephrine, GI Motility, Hepatitis C, Macrolides/Ketolides, Opiate Dependence Treatments, Tetracyclines, Hypoglycemics (TZD, Metformin, Meglitinides): No updates.
- Antibiotics Gastrointestinal: Generic Deficit tablets now available.
- Anticonvulsants: Generic Actium and Fycompa now available.
- Antivirals Topical: FDA approved ZELSUVMI 10.3% gel for molluscum contagiosum, a novel home-use nitric oxide gel.
- Colony Stimulating Factors: FDA approved Resnuda, a non-pegylated long-acting G-CSF (no demonstrated clinical superiority over Neulasta).
- HIV and AIDS:
    - New pediatric formulation of rilpivirine (Edurant Ped) for children 2+ years (14-25kg).
    - New Biktarvy indication for specific patient groups.
    - Generic Complera now available.
- Growth Hormone: Speaker for Skytrofa noted brief discussion about Engenvo.
- Hypoglycemics (Incretin Mimetics/Enhancers):
    - FDA approved Brinovene (sitagliptin oral solution) for type 2 diabetes.
    - Generic extended-release Zetuvimab available.
    - Rybelsus approved for reducing cardiovascular risk in high-risk adults with type 2 diabetes.
    - Discussion on whether any drugs in this class are studied for Bardet-Biedl syndrome (follow-up needed).
    - Questions about process for rare disease medication access; clarified that prior authorization and exception processes exist, though approvals for off-label, rare disease use are handled case-by-case, often resulting in denials due to lack of FDA-approved indication. Request made for statistics on approval/denial rates for process improvement.

- Hypoglycemics Insulin & Related: FDA approved Merelog, the first Novolog biosimilar (pen/vial).
- Hypoglycemics SGLT2: Invokana/Invokamet expanded to ages 10+; details on pediatric approval criteria to be followed up.

Single Product Updates

- **Andembry:** First-in-class monoclonal antibody for hereditary angioedema prophylaxis (12+ years).
- **Avmapki/Fakzynja Co-Pak:** Accelerated approval for KRAS-mutated recurrent low-grade serous ovarian cancer.
- **Ibtrozi:** Oral tyrosine kinase inhibitor for ROS1+ non-small cell lung cancer.
- **Imuldosa:** Stelara biosimilar (various dosage forms).
- **Khindivi:** Pediatric hydrocortisone solution for adrenocortical insufficiency.
- **Leqselvi:** Oral JAK inhibitor for severe alopecia areata, with CYP2C9 genotyping requirement.
- **Nilotinib Tartrate Capsules:** For Philadelphia chromosome positive chronic myeloid leukemia; generic referencing Tasigna.
- **Pyzchiva 45mg Vial:** New vial formulation for previously syringe-only product.
- **Qfitlia:** Speaker presentation covered use and value; no additional clinical updates.
- **Tezruly:** Oral terazosin solution for BPH and hypertension.
- **Tryptyr:** Ophthalmic solution for dry eye disease, new mechanism of action (TRPM8 agonist).

6. Executive work session

Pursuant to Texas Government Code, Section 549.0151, and in accordance with Texas Administrative Code, Title 1, Part 15, Subchapter F, Section 354.1941(c)(2), the DURB may meet in executive session on one or more items listed under public comment on the drug classes to be reviewed for the Medicaid PDL, and as permitted by the Texas Open Meetings Act.

7. Announcements of drugs recommended for the Medicaid PDL: OptumRx.

Only changes to the PDL are presented

Pharmaceutical Product	New Status
Antibiotics, Gastrointestinal	
Fidaxomcin Oral	Nonpreferred
Metronidazole Oral	Nonpreferred
Dificid Oral	Preferred
Anticonvulsants	
Eslicarbazepine Acetate	Preferred
Perampanel Oral	Preferrd
Antiemetic-Antivertigo Agents	
Scopolamine (transdermal) patch	Nonpreferred
Antifungals, Oral	
Posaconazole Oral Suspension	Nonpreferred
Posaconazole Oral Tablet	Nonpreferred
Antifungals, Oral	
Griseofulvin	Preferred
Griseofulvin Ultramicrosize	Preferred
Noxafil Oral Suspension	Preferred
Noxafil Tablet	Preferred
Sopranox oral solution	Preferred
Vfend tablet	Preferred
Antifungals, Topical	
Clotrimazole Solution	Preferred
Econazole Cream	Preferred
Klayesta Cream	Preferred
Antiparasitics Topical	
Natroba Suspension	Nonpreferred
Piperonyl Butoxide/Pyrethrins Shampoo	Preferred
Piperonyl Butoxide/Pyrethrins Topical Kit	Preferred

Sklice Lotion	Preferred
Spinosad Suspension	Preferred
Antivirals, Topical	
Zelsuvmi Gel	Nonpreferred
Acyclovir Cream	Preferred
Acyclovir Ointment	Preferred
Acyclovir Ointment(g)(ag)	Preferred
Bone Resorption Suppression	
Bonsity Pen Injector	Nonpreferred
Evista Tablet	Nonpreferred
Calcitonin-Salmon Nasal Spray	Preferred
Raloxifene Tablet	Preferred
Ibandronate Tablet	Preferred
Colony Stimulating Factors	
Ryzneuta Syringe	Nonpreferred
Granix Vial	Nonpreferred
Neupogen injection syringe	Nonpreferred
Neupogen injection Vial	Nonpreferred
Fulphila Syringe	Preferred
Granix Syringe	Preferred
Nyvestim Vial	Preferred
Nyvestim Syringe	Preferred
Epinephrine, Self-Injected	
Epinephrine Epipen Jr	Preferred
Epinephrine Epipen	Preferred
GI Motility, Chronic	
Symproic Tablet	Preferred
Hepatitis C Agents	
Epclusa Tablet	Preferred
Sofosbuvir-Velpatasvir Tablet	Preferred

HIV-AIDS	
Edurant Ped Tab for Oral Suspension	Preferred
Yeztugo Tablet	Preferred
Emtricitabine-Rilpivirne-Tenof Tablet	Preferred
Hypoglycemics, Incretin Mimetics-Enhancers	
Brynovin Oral Solution	Nonpreferred
Sitagliptin-Metformin ER (oral) TBMP 24HR	Nonpreferred
Hypoglycemics, Insulin and Related	
Merilog (subcut) Vial	Nonpreferred
Merilog Solostar Insulin Pen	Nonpreferred
Hypoglycemics, Metformin	
Metformin HCL Tablet	Nonpreferred
Macrolides-Ketolides	
Eryped 400 Susp Recon	Nonpreferred
Erythromycin Capsule Dr Base	Nonpreferred
Ery-Tab Tablet	Preferred
Erythromycin Ethylsuccinate (oral) 400 Susp Recon	Preferred
Opiate Dependence Treatments	
Nalmefene (injection) Vial	Preferred
Tetracyclines	
Doxycycline Hyclate Tablet	Preferred
Doxycycline Monohydrate Tablet	Preferred
Oracea Capsule	Preferred

SINGLE NEW DRUG REVIEW

PDL Category	Brand Name (Route)	Current PDL Status	Gainwell/OptumRx Recommendations
BPH TREATMENTS	TEZRULY (ORAL) SOLUTION	NR	NPD
CYTOKINE AND CAM ANTAGONISTS	IMULDOSA (SUBCUT) SYRINGE	NR	NPD
CYTOKINE AND CAM ANTAGONISTS	LEQSELVI (ORAL) TABLET	NR	NPD
CYTOKINE AND CAM ANTAGONISTS	PYZCHIVA (SUBCUT) VIAL	NR	PDL
GLUCOCORTICOIDS, ORAL	KHINDIVI (ORAL) SOLUTION	NR	NPD
HEMOPHILIA TREATMENT	QFITLIA (SUBCUT) PEN	NR	PDL
HEMOPHILIA TREATMENT	QFITLIA (SUBCUT) VIAL	NR	PDL
HEREDITARY ANGIOEDEMA (HAE) TREATMENTS	ANDEMBRY (SUBCUT) PEN	NR	NPD
ONCOLOGY, ORAL - HEMATOLOGIC	NILOTINIB TARTRATE (ORAL) CAPSULE	NR	PDL
ONCOLOGY, ORAL - LUNG	IBTROZI (ORAL) CAPSULE	NR	PDL
ONCOLOGY, ORAL - OTHER	AVMAPKI-FAKZYNJA (ORAL) CO-PACK	NR	PDL
OPHTHALMICS, ANTI-INFLAMMATORY	TRYPTYR (OPHTHALMIC) SINGLE DOSE VIALS	NR	NPD

MOTION: Approve the recommendations above prevailed

Adjourn—Future Meetings Friday, Jan. 23, 2026; Friday, April 24, 2026.