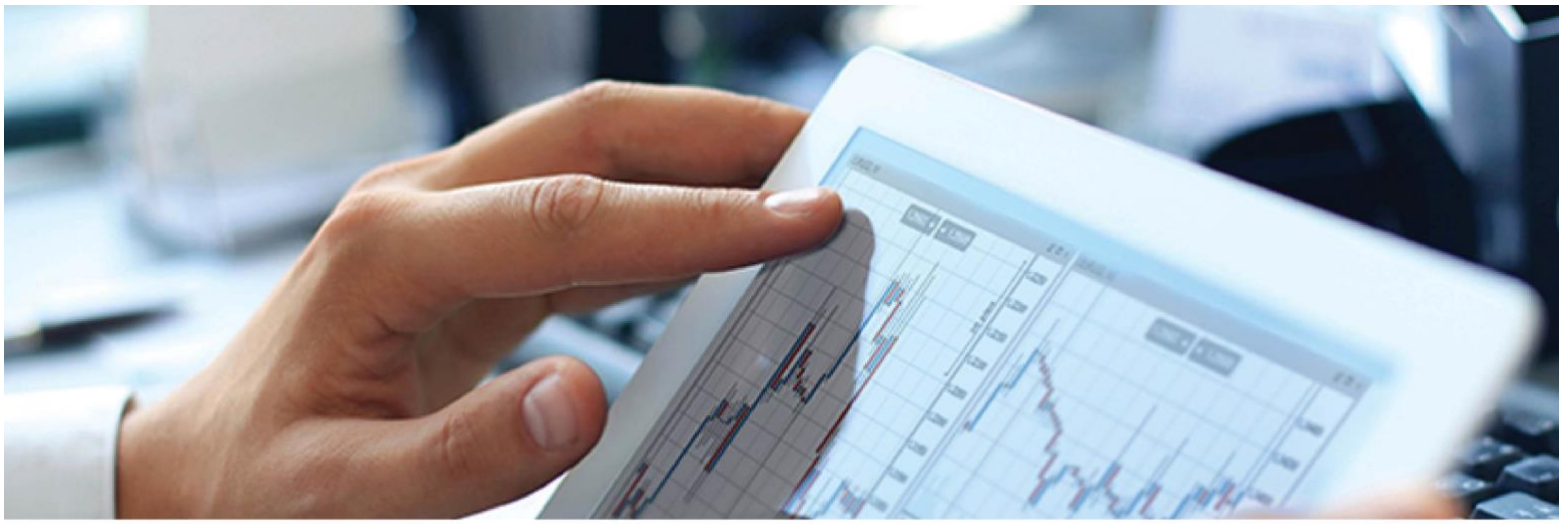
Health and Human Services

Drug Utilization Review Board

Drug Class Review

July 25, 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. Members:

- Alejandro D. Kudisch, M. D., D .F. A. P. A. (McAllen) (**Chair**)
- Jennifer Fix, Pharm. D (Burleson) (**Vice-chair**)
- Marlo Brawner, M. D. (Livingston)
- Dominique Brewster, Pharm.D, BCPS, BCGP, AAHIVP (Houston)
- 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)
- 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)
- 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
- David A. Valdez, M. D. (San Antonio); Molina Healthcare of Texas

Consumer advocate

- Vacant

Vacancies

- Drug Utilization Review Board vacancies

April 2025 Preferred Drug List Decisions Now Available

1. Call to order. The meeting was convened by Alejandro D. Kudisch. A quorum was present.

2. Consideration of April 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): All links and

comments from Gainwell Technologies: Public Health Services and Solutions unless otherwise noted.

Alzheimer's agents. Alzheimer's disease is a progressive, degenerative neurologic disorder that results in the irreversible loss of neurons, particularly in the cortex and hippocampus. Accounting for nearly two-thirds of all cases of dementia, Alzheimer's disease is the most common neurodegenerative disease in the world. A progressive impairment is seen in patients in the areas of memory, judgment, decision-making, orientation to physical surroundings, and language. While the exact etiology is unknown, treatment of the disease is based on the hypothesis that cognitive, functional, and behavioral dysfunction associated with Alzheimer's disease may be caused by an inability to transmit neurologic impulses across cholinergic synapses due to reduced functional capacity and loss of neurons. Theoretically, reversible acetylcholinesterase inhibitors prolong cholinergic transmission by slowing the hydrolysis and breakdown of acetylcholine. The efficacy of acetylcholinesterase inhibitors may lessen as Alzheimer's disease advances and fewer cholinergic neurons remain functionally intact.

Public Comment. No public comment

Antihistamines, minimally sedating. Oral antihistamines are well-established treatments for allergic rhinitis and urticaria. The first-generation antihistamines have been available since the 1940s but are generally no longer recommended for chronic use due to their sedative and anticholinergic effects which are minimized with newer agents known as the second-generation antihistamines or minimally sedating antihistamines. The minimally sedating antihistamines include cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine. All agents in this class work by blocking histamine, a key mediator in allergic response, at peripheral histamine H1 receptors. Allergic rhinitis symptoms typically include nasal congestion, rhinorrhea, postnasal drainage, sneezing, and itching of the nose, eyes, or throat. Allergic rhinitis may be seasonal or perennial and is estimated to occur in nearly one-third of adults in the US. First-line treatment recommended by the American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Asthma, Allergy, and Immunology (ACAAI) Joint Task Force includes intranasal corticosteroids; however, the second-generation antihistamines are considered to be an effective and established treatment. The guidelines state that a particular agent cannot be selected due to the lack of well-designed comparative trials. Second generation antihistamines are ineffective for nasal

congestion; thus, these agents are also available as combination formulations with the decongestant, pseudoephedrine.

Public Comment. No public comment

Antipsychotics. Since the 1950s, drug therapy has been the cornerstone of management for schizophrenia and its related conditions. The first agents available were known as "typical" or "conventional" antipsychotics. Typical antipsychotic medications such as haloperidol and perphenazine are effective; however, they have frequent adverse effects such as tardive dyskinesia, sedation and, rarely, neuroleptic malignant syndrome. In 1989, the Food and Drug Administration (FDA) approved clozapine (Clozaril®), the first in a new class of antipsychotic medications referred to as "atypical" or "second generation" antipsychotics. Clozapine demonstrated a lower incidence of extrapyramidal symptoms and greater efficacy in controlling the negative symptoms associated with schizophrenia, such as apathy, loss of motivation, and flat affect, than the typical antipsychotics. Currently available oral atypical antipsychotics include aripiprazole (Abilify®, Abilify MyCite®, Opipza®), asenapine (Saphris®, Secuado®), brexpiprazole (Rexulti®), cariprazine (Vraylar®), clozapine (Clozaril®, Versacloz®), iloperidone (Fanapt®), lumateperone (Caplyta®), lurasidone (Latuda®), olanzapine (Zyprexa®, Zyprexa Zydis®), paliperidone (Invega®), pimavanserin (Nuplazid®), quetiapine (Seroquel®, Seroquel XR®), risperidone (Risperdal®), and ziprasidone (Geodon®). There are 3 combination agents currently available. The first is comprised of an atypical antipsychotic and a selective serotonin reuptake inhibitor (SSRI): olanzapine/fluoxetine (Symbyax®). The second is comprised of an atypical antipsychotic and an opioid antagonist: olanzapine/samidorphan (Lybalvi®). The third is comprised of a muscarinic agonist in the central nervous system and antagonist in the periphery: xanomeline/trospium (Cobenfy™).

Public Comment

A company representative commented on CAPLYTA® (lumateperone).

A company representative commented on COBENFY™ (xanomeline and trospium chloride) for Schizophrenia.

Matthew Braums, MD, Psychiatrist spoke in support of ABILIFY ASIMTUFII® (aripiprazole) Bipolar

A company representative commented on ERZOFRI® (paliperidone palmitate)

A company representative commented on UZEDY® | Official Patient Site

A company representative commented on INVEGA

Greg Hensch, NAMI Texas (NAMI Texas - Support for Mental Health) requested that all safe and effective medications be made available to patients (Open Access)

A company representative commented on LYBALVI® (olanzapine and samidorphan)

Calcium channel blockers (oral). Calcium channel blockers (CCBs) inhibit the transmembrane influx of calcium ions into the vascular smooth muscle and the cardiac muscle, which dilates the coronary and systemic arteries. The CCBs are generally indicated for hypertension (HTN), angina, and arrhythmias, with specific indications varying by product. The CCBs are one of several first-line treatment options for HTN; however, guidelines generally reserve CCBs for certain patients with co-morbid indications. For the treatment of chronic angina, long-acting CCBs may be used if beta-blockers are contraindicated or if additional therapy is required. For vasospastic (Prinzmetal) angina, guidelines recommend CCBs alone or in combination with nitrates. Calcium channel blockers are generally categorized as dihydropyridines (DHPs) or non-DHPs.

Public Comment. No public comment

Cephalosporins and related antibiotics (oral). This review includes the oral cephalosporins and the penicillin/beta-lactamase inhibitor combination amoxicillin/clavulanate, which are antimicrobial agents indicated for numerous, distinct uses. Beta-lactams, such as cephalosporins and amoxicillin, act by binding to the penicillin-binding proteins which inhibit cell wall synthesis during bacterial growth. The clavulanate component of amoxicillin/clavulanate inactivates beta-lactamase enzymes produced by some bacteria and thus prevents the enzymatic destruction of amoxicillin. Oral cephalosporins are categorized into 3 generations of agents: a) first generation oral cephalosporins (cefadroxil, cephalexin), which have active coverage against gram-positive organisms; b) second generation oral cephalosporins (cefaclor, cefprozil, cefuroxime axetil), which are active against some gram-positive and gram-negative

organisms, and c) third generation oral cephalosporins (cefdinir, cefixime, cefpodoxime proxetil), which have extended gram-negative bacteria coverage and are more effective against many resistant bacteria. Many newer third generation oral cephalosporins are also active against gram-positive organisms. Amoxicillin/clavulanate products have similar spectrums of activity as the second and third generation oral cephalosporins.

Public Comment. No public comment

Fluoroquinolones, oral. Bacteria are organisms that help perform many beneficial activities in the body, including having roles in digestion and immunity. While many bacteria are helpful, infectious bacteria can lead to illness. Some bacteria can also release toxins that can damage tissue. Common types of bacterial infections include abdominal, lower respiratory, genitourinary, prostate, and skin infections. Common symptoms of bacterial infections include fever, chills, fatigue, and headache. Depending on the site of the infection, additional symptoms can include redness, blisters, ulcers, swollen or painful skin, diarrhea, stomach pain, nausea and vomiting, cough, shortness of breath, chest pain, phlegm, neck stiffness, weakness, low blood pressure, high fever, and burning or pain during urination.

The therapeutic landscape for bacterial infections includes many antibiotic drug classes, with selection based on suspected or confirmed pathogen involvement and the antibiotic's spectrum of activity. While antibiotic research and development continue, partly in response to antibiotic resistance, many of these antibiotic drug classes are indicated for various bacterial infections. This review focuses on a selection of oral fluroquinolones (ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, ofloxacin), among others. Oral fluoroquinolones have served as a widely used antibiotic class. Notably, ciprofloxacin (Cipro®, Cipro®XR, Proquin®XR) is FDA-approved for various bacterial infections, including genitourinary and abdominal infections. Delafloxacin (Baxdela®) is FDA-approved for pneumonia and skin infections; only the branded product is available. Levofloxacin (Levaquin®) is FDA-approved for approved for a variety of bacterial infections including genitourinary infections. Moxifloxacin (Avelox®) is FDA-approved for abdominal and lower respiratory infections. Ofloxacin (Floxin®) is also FDA-approved for a variety of bacterial infections. While some class similarities exist, safety and monitoring considerations vary by agent, emphasizing the need for tailored therapeutic approaches based on individual patient profiles.

Public Comment. No public comment

Glucocorticoids, oral. The adrenal glands create hormones known as corticosteroids which can be classified into 2 groups: mineralocorticoids and glucocorticoids. Glucocorticoids affect several metabolic pathways, such as glycogenesis, gluconeogenesis, lipolysis, and protein metabolism. Certain mineralocorticoid effects are also exerted by glucocorticoids. While cortisone and hydrocortisone have both glucocorticoid and mineralocorticoid characteristics, the oral corticosteroids covered in this review are classified as glucocorticoids. Oral glucocorticoids comprise a class of medications widely used in the management of various inflammatory and immune-mediated conditions. These medications have strong anti-inflammatory and immunosuppressive properties, which makes them useful in the treatment of a variety of illnesses, such as autoimmune diseases, endocrine disorders, and rare conditions like eosinophilic esophagitis and immunoglobulin A nephropathy (IgAN).

Public Comment. No public comment

Immunosuppressives. Immunosuppressive agents work by dampening abnormal immune responses and are used to treat autoimmune diseases, prevent organ rejection, and manage immune-mediated inflammatory conditions. This therapeutic class review includes agents from several categories—calcineurin inhibitors, antimetabolites, mammalian target of rapamycin (mTOR) inhibitors, and targeted immunomodulators—with FDA-approved uses across a range of chronic and often serious diseases.

Public Comment

A company representative commented on LUPKYNIS® (voclosporin)

Iron, oral. Iron supplements are taken to increase your iron levels. Common side effects include stomach pain or discomfort, nausea, constipation, diarrhea, or black poop. Accidental iron overdoses can lead to death, especially in children younger than 6 years old. Keep iron supplements out of the reach of children. Before taking an iron supplement, tell your health care provider about any prescription or over the counter (OTC) medicines, vitamins/minerals, herbal products, and other supplements you are

using. Iron Supplements (Ferosul, Slow Fe, and others): Uses, Side Effects, Interactions, Pictures, Warnings & Dosing - WebMD

Public Comment. No public comment

Leukotriene modifiers. Asthma and allergic rhinitis often coexist; it is unclear whether rhinitis and asthma result from the same allergic process (one-airway hypothesis) or whether rhinitis is a discrete asthma trigger. Asthma is a disease of diffuse airway inflammation caused by various triggering stimuli resulting in partially or completely reversible bronchoconstriction. Common asthma symptoms include dyspnea, chest tightness, wheezing, and coughing. Common asthma triggers include environmental and occupational allergens, cold and dry air, infections, exercise, inhaled irritants, emotion, aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs), and gastroesophageal reflux disease (GERD). Allergic rhinitis (AR) is seasonal or perennial itching, sneezing, rhinorrhea, nasal congestion, and sometimes conjunctivitis caused by exposure to pollens or other allergens. Common AR allergens include tree pollens, grass pollens, weed pollens, fungal spores, dust mite feces, cockroach components, and animal dander. The therapeutic landscape for asthma and allergic rhinitis includes multiple drug classes, with selection based on preventing exacerbations and minimizing chronic symptoms. This review focuses on leukotriene receptor modifiers (montelukast, zafirlukast, zileuton). Leukotriene receptor modifiers have been widely used for asthma and allergic rhinitis. Notably, montelukast (Singulair®) is FDA-approved for prophylaxis and chronic treatment of asthma, acute prevention of exercise-induced bronchoconstriction (EIB), and relief of symptoms of allergic rhinitis. Zafirlukast (Accolate®) is FDA-approved for prophylaxis and chronic treatment of asthma. Zileuton (Zyflo®, Zyflo CR®) is FDA-approved for prophylaxis and chronic treatment of asthma. While some class similarities exist, safety and monitoring considerations vary by agent, emphasizing the need for tailored therapeutic approaches based on individual patient profiles.

Public Comment. No public comment

Non-narcotic analgesics. Non-narcotic analgesics include nonsteroidal anti-inflammatory drugs (NSAIDs), cyclooxygenase-2 (COX-2) inhibitors, and sodium channel blockers. NSAIDS are a drug class that is FDA-approved for use as antipyretic, anti-inflammatory, and analgesic agents. The mechanism of action of NSAIDs is the inhibition of the enzyme cyclooxygenase (COX). Physiologically, COX turns arachidonic

acid into prostaglandins in the inflammatory signal cascade, and it is these chemicals cause pain, inflammation, and fever during injury. NSAIDs target COX to reduce pain and inflammation. These effects make NSAIDs useful for treating muscle pain, dysmenorrhea, arthritic conditions, pyrexia, gout, and migraines and they are used as opioid-sparing agents in certain acute trauma cases. NSAIDs are available in various dosage forms for oral, topical, ophthalmic, rectal, and parenteral administration, and the choice of NSAID formulation will depend on the specific condition being treated and the individual's needs. The advantages of NSAIDs include their efficacy in relieving pain and inflammation, relatively rapid onset of action, and availability in multiple formulations for various routes of administration. However, NSAIDs are associated with an increased risk of gastrointestinal adverse effects such as ulcers and bleeding, as well as cardiovascular events, including myocardial infarction and stroke. Selective COX-2 inhibitors were developed to mitigate gastrointestinal complications but may still pose cardiovascular risks. Suzetrigine (Journavx™) is a sodium channel blocker, a non-opioid, non-NSAID analgesic that is FDA-approved for the use of moderate to severe acute pain in adults. It reduces pain by blocking selective sodium channels in the peripheral nervous system, thus preventing pain signals from reaching the brain.

Public Comment. No public comment

Ophthalmic antibiotics. Ophthalmic infections, such as bacterial conjunctivitis, keratitis, and blepharitis, are common conditions that can lead to significant discomfort, visual disturbances, and in severe cases, vision loss. These infections are caused by various bacterial pathogens, including Staphylococcus aureus, Streptococcus pneumoniae, and Haemophilus influenzae. Prompt and effective treatment with antibiotics is necessary to prevent complications and ensure rapid resolution of symptoms. Ophthalmic antibiotics work by targeting various bacterial processes. The selection of an appropriate agent should be guided by the specific pathogen, patient population, and safety profile. Fluoroquinolones and macrolides are commonly preferred for their efficacy and broad-spectrum coverage, while erythromycin remains a mainstay for neonatal prophylaxis. FDA has approved using ophthalmic antibiotics for conditions such as bacterial conjunctivitis, keratitis, blepharitis, corneal ulcers, and post-surgical prophylaxis to prevent infection in patients undergoing ocular surgery. The benefits of ophthalmic antibiotics are the rapid onset and direct application for local drug concentrations, minimal systemic absorption, reducing the risk of systemic side effects, and there are a variety of agents available in multiple drug classes that allow for targeted therapy-based on specific pathogens and resistance patterns. Some limitations

of therapies include discomfort, redness, and burning upon application, the development of resistance from overuse and misuse, and some agents may not cover all potential pathogens, requiring combination therapy or alternative agents. According to The American Academy of Ophthalmology (AAO) guidelines, first-line agents for bacterial conjunctivitis are fluoroquinolones or macrolides; these agents are often preferred due to their broad-spectrum activity and efficacy. Aminoglycosides and sulfacetamide can be used in cases of specific bacterial resistance or patient intolerance to first-line agents. Bacitracin and erythromycin ointments are commonly used in neonates to prevent ophthalmia neonatorum, a severe form of conjunctivitis. Common Adverse Effects of ophthalmic antibiotics are local irritation, burning, stinging, redness of the eye, and blurred vision.

Public Comment. No public comment

Ophthalmics antibiotic – steroid combinations. Bacterial infections and inflammatory ocular conditions may rapidly damage important ocular structures and lead to permanent vision loss or blindness if not treated appropriately. The agents included in this therapeutic class review (TCR) are U.S. Food and Drug Administration (FDA)approved and indicated for steroid-responsive inflammatory ocular conditions (such as bacterial conjunctivitis, corneal abrasion, and uveitis) for which a corticosteroid is indicated and where bacterial infection or risk of bacterial infection exists. All agents in the TCR contain an antimicrobial agent and steroid. Although there is no generally accepted mechanism of ocular corticosteroids, corticosteroids inhibit inflammatory responses to a variety of inciting agents. They can also delay or slow wound healing and can cause an increase in intraocular pressure (IOP). The relative potency of the corticosteroid depends on the molecular structure, drug concentration, and release from the vehicle. The antimicrobial component is included to provide action against susceptible organisms.

Public Comment. No public comment

Ophthalmics for allergic conjunctivitis. Allergic conjunctivitis (AC) is a class type I immunoglobulin E (IgE)-mediated hypersensitivity and can be divided into three conditions: acute allergic conjunctivitis, seasonal allergic conjunctivitis (SAC), and perennial allergic conjunctivitis (PAC). Acute AC is a sudden-onset hypersensitivity reaction caused by a known environmental allergen (e.g., cat dander). This form of AC is characterized by intense itching, tearing, and eyelid edema. SAC is typically associated

with outdoor airborne pollens (e.g., tree, grass, and weed) and can have a slower onset than acute AC (i.e., over days to weeks). PAC is a mild but chronic AC related to year-round environmental exposure to indoor allergens (e.g., dust mites, animal dander, and molds).

Public Comment. No public comment

Ophthalmics, anti-inflammatories. Ophthalmic conditions such as postoperative inflammation and pain following cataract surgery, seasonal allergic conjunctivitis, and discomfort associated with corneal refractive surgery significantly affect patient quality of life. Cataract surgery, one of the most common surgical procedures worldwide, often results in postoperative inflammation, impacting visual recovery and comfort. Corneal refractive surgery, aimed at vision correction, also presents challenges like postoperative pain and photophobia, necessitating effective management for patient comfort and optimal healing. Seasonal allergic conjunctivitis, marked by ocular itching, redness, and watering, affects a considerable population, especially during peak pollen seasons, requiring efficacious treatments. Additionally, inhibiting intraoperative miosis, or preventing pupil constriction during ocular surgery, is crucial for surgical success and minimizing postoperative complications. Each condition demands precise management to alleviate symptoms and prevent long-term sequelae that could impair vision or lead to further ocular discomfort.

The introduction of ophthalmic nonsteroidal anti-inflammatory drugs (NSAIDs) has revolutionized the management of these conditions. Ophthalmic NSAIDs, including bromfenac (BromSite™, Prolensa®), diclofenac, flurbiprofen, ketorolac (Acular®, Acular LS®, Acuvail®), and nepafenac (Ilevro™, Nevanac®), offer targeted relief by addressing both symptoms and underlying inflammatory processes. These drugs effectively manage inflammation at the heart of these conditions by inhibiting cyclooxygenase and reducing prostaglandin production. Notably, nepafenac and bromfenac are preferred for their improved dosing regimens. However, common adverse events like ocular burning and stinging and a higher incidence of corneal adverse effects with diclofenac are noted. Safety and efficacy concerns for pediatric use and potential adverse effects on the fetal cardiovascular system limit the use of these drugs in specific populations.

Public Comment. No public comment

Ophthalmics, anti-inflammatory immunomodulators. Dry eye disease (DED), also known as keratoconjunctivitis sicca, is characterized by a loss of homeostasis of the tear film with ocular symptoms including dryness, red eyes, general irritation, burning, light sensitivity, and blurred vision. Symptoms of DED result from activation of sensory nerves of the ocular surface, which can be due to tear hyperosmolarity, the presence of inflammatory mediators, or hypersensitivity of the sensory nerves. The current management of DED focuses on symptom improvement by increasing or supplementing tear production, slowing tear evaporation, reducing tear resorption, or reducing ocular surface inflammation. Treatment with artificial tears may improve vision and prevent ocular damage and is thus considered a first-line therapy in patients diagnosed with DED. Vernal keratoconjunctivitis (VKC), a seasonally recurring, severe form of allergic inflammation, has many overlapping symptoms and treatment strategies with DED (e.g., nonpharmacologic strategies, artificial tears, immunomodulators). This relatively uncommon allergic eye disease occurs predominantly in male children between ages 4 and 7 years and can cause severe damage to the ocular surface, leading to corneal scarring and vision loss if not treated. The ophthalmic therapies used in the treatment of DED and VKC discussed in this therapeutic class review are the anti-inflammatory immunomodulators: cyclosporine (Cequa™, Restasis®, Verkazia®, Vevye™), lifitegrast (Xiidra®), loteprednol etabonate (Eysuvis®), perfluorohexyloctane (Miebo™), and varenicline (Tryvaya™).

Public Comment. No public comment

Ophthalmics, glaucoma agents. Glaucoma is a group of eye conditions that cause damage to the optic nerve, often due to increased intraocular pressure (IOP), leading to vision loss if untreated. The most common form, open-angle glaucoma (OAG), occurs when the drainage angle formed by the cornea and iris remains open, but the trabecular meshwork is partially blocked, causing a gradual increase in IOP and optic nerve damage. Ocular hypertension (OHT) is characterized by elevated IOP without detectable changes in vision or optic nerve damage, but it poses a risk of developing glaucoma and requires regular monitoring. Angle-closure glaucoma happens when the drainage angle formed by the cornea and iris becomes blocked or closed, leading to a rapid increase in IOP. This can be acute, presenting as a medical emergency with severe pain and blurred vision, or chronic, leading to gradual vision loss. Normal-tension glaucoma (NTG) occurs despite normal IOP levels, potentially due to poor blood flow to the optic nerve, and requires careful monitoring and management. Congenital glaucoma, a rare form in infants and young children, results from developmental issues

in the eye's drainage system. Lowering the IOP can help reduce the progression of optic nerve damage in patients diagnosed with OAG and prevent or delay the onset of OAG in patients with OHT. Management of glaucoma generally aims to lower IOP through medications, laser therapy, or surgical procedures; medical intervention is usually used first line before laser or surgical intervention. Beta-blockers reduce aqueous humor production in the eye, lowering IOP. Some formulations, including timolol maleate, are available as extendedrelease (ER) and in a unit-dose preservative-free form known as Timoptic in Ocudose®. These agents effectively manage glaucoma but may have systemic side effects (e.g., worsening of heart failure, bradycardia, heart block, and increased airway resistance) due to beta-blockade. For this reason, topical beta-blockers are contraindicated in patients with pulmonary or cardiac disease.

Public Comment. No public comment

Otic antibiotics. Otitis externa (OE) is a common bacterial infection of the external auditory canal that results in ear canal inflammation, otalgia, itching, and canal erythema. The most common pathogens involved are Pseudomonas aeruginosa and Staphylococcus aureus. The currently available otic preparations approved for the treatment of acute otitis externa (AOE) in pediatric and adult patients are ciprofloxacin, ciprofloxacin/dexamethasone, and ciprofloxacin/hydrocortisone (Cirpo HC Otic®). Acute otitis media with tympanostomy tubes (AOMT) is a short-term, sudden-onset bacterial infection of the middle ear that often occurs at some point after ear tube insertion. This infection typically involves discharge draining to the outer ear (otorrhea); purulent otorrhea lasting longer than six weeks despite treatment is called chronic suppurative otitis media (CSOM). Ciprofloxacin/dexamethasone, ciprofloxacin/fluocinolone, and ofloxacin are indicated for the treatment of AOMT, and only ofloxacin carries an indication for the treatment of CSOM. Guidelines by the American Academy of Otolaryngology recommend otic antibiotics (including fluoroquinolones) for first-line treatment of both AOE and AOMT.

Public Comment. No public comment

Otic anti-infectives/anesthetics. Acute otitis externa (AOE) is an acute inflammation of the external auditory canal. Commonly referred to as “swimmer’s ear” or “tropical ear,” this condition is often precipitated by water exposure or trauma. The etiology is typically bacterial; the most common pathogens implicated are Pseudomonas aeruginosa and Staphylococcus aureus, often occurring as a

polymicrobial infection. Patients typically complain of otalgia and otorrhea; the ear canal may appear erythematous and swollen. It is imperative that the ear canal be cleared of any discharge or debris that can occlude the canal since the presence of such material can keep the canal moist and interfere with topical treatment. All ages are affected, with a peak incidence in children aged 7 to 12 years. Acetic acid and acetic acid/hydrocortisone are low-pH antibacterial and antifungal topical otic solutions indicated for superficial infections of the external auditory canal. Hydrocortisone is an anti-inflammatory agent. These agents are contraindicated if an individual has hypersensitivity to any of the ingredients in the solution or has a perforated tympanic membrane. Stinging or burning may occur, and local irritation has occurred very rarely. Both agents are only available generically. The safety and effectiveness of acetic acid-containing products in pediatric patients younger than 3 years of age have not been established.

Public Comment. No public comment

Penicillins. Penicillins are a group of antibiotics commonly used to treat various bacterial infections. These infections can affect different parts of the body, including the respiratory tract infections, infections of the skin, ear infections , throat infections, and urinary tract infections. Penicillins are particularly effective against Gram-positive bacteria, though some formulations have extended activity against Gram-negative bacteria. Penicillins exert their bactericidal effect by inhibiting the synthesis of bacterial cell walls. They specifically target penicillin-binding proteins located inside the bacterial cell wall. By binding to these binding proteins, the penicillins inhibit the cell wall synthesis, which eventually causes cell lysis and death of the bacterium. Penicillins are approved by the FDA for the treatment of a variety of bacterial infections, including but not limited to streptococcal pharyngitis, pneumonia, otitis media, skin and soft tissue infections, syphilis, urinary tract infections, bacterial endocarditis, etc. Benefits of this drug class is their broad spectrum of activity mainly effective against many gram-positive and some gram-negative bacteria, generally well-tolerated with a long history of use, and cost-effective, many penicillins are available as generic formulations, thus making them affordable. Limitations of use the development of bacterial resistance, including penicillinase-producing organisms, limits their effectiveness, A significant proportion of patients may have hypersensitivity reactions ranging from mild rashes to severe anaphylaxis, and the penicillin have a short half-life which requires frequent dosing, which can impact patient adherence. Per clinical guidelines, penicillins remain a first-line treatment for many infections: streptococcal pharyngitis: Penicillin V is

recommended as the first-line treatment, syphilis: Penicillin G remains the drug of choice, bacterial endocarditis prophylaxis: Penicillins are used in specific populations for prophylaxis, pneumonia and Other Respiratory Infections: Amoxicillin, often in combination with clavulanic acid, is recommended for community-acquired pneumonia and other respiratory infections. In the presence of penicillin allergies, alternative antibiotics such as cephalosporins, macrolides, or clindamycin may be used, depending on the severity of the allergy and the infection being treated. Penicillins are generally well-tolerated, but adverse reactions can occur. Common adverse effects include Hypersensitivity Reactions: Rash, urticaria, fever, serum sickness, and anaphylaxis and Gastrointestinal Effects: Nausea, vomiting, diarrhea, and, in some cases, antibiotic-associated colitis. Penicillins continue to be a cornerstone in the treatment of various bacterial infections due to their efficacy, safety, and cost-effectiveness. While their use is sometimes limited by bacterial resistance and potential for allergic reactions, they remain indispensable in the antimicrobial arsenal. Vigilant monitoring for adverse effects and adherence to clinical guidelines ensure their optimal use in therapy.

Public Comment. No public comment

Rosacea agents, topical. Rosacea is a chronic inflammatory disorder of the facial skin, typically characterized by remissions and exacerbations. It primarily affects the cheeks, nose, chin, forehead, and eyes; manifestations may include persistent facial erythema, papules, pustules, and flushing. There are no curative therapies for rosacea, but various topical and oral treatments may be used to reduce or control disease manifestations. Selecting a specific therapy or combination of therapies will depend on the severity and type of symptoms present. Topical therapies for inflammatory lesions of rosacea include azelaic acid, benzoyl peroxide, ivermectin, metronidazole, and minocycline; the mechanisms of action for these therapies in rosacea are unclear but may be related to anti-inflammatory and/or antimicrobial effects. Topical therapies for persistent facial erythema associated with rosacea include the alpha-adrenergic agonists brimonidine and oxymetazoline.

Public Comment. No public comment

Skeletal muscle relaxants. Pain is one of the most common reasons for emergency department and primary care visits. Musculoskeletal pain affects bones, joints, ligaments, muscles, and tendons. Neck and low back pain are two of the most common musculoskeletal conditions causing tenderness and muscle spasms. Pain

associated with these conditions is usually the result of local factors involving muscle groups. Spasticity is disordered sensory-motor control caused by an upper motor neuron lesion that manifests as intermittent or prolonged involuntary muscle contractions. This manifestation is seen in a variety of neurological conditions, including cerebral palsy (CP), multiple sclerosis (MS), spinal cord injuries (SCI), and brain injuries. In many patients with these conditions, spasticity can be disabling and painful, profoundly affecting functional ability and quality of life. Skeletal muscle relaxants are indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. They are also indicated for the treatment of chronic spasticity associated with upper motor neuron disorders. They include baclofen, carisoprodol, chlorzoxazone, cyclobenzaprine, dantrolene, metaxalone, methocarbamol, orphenadrine, and tizanidine. Only baclofen, dantrolene, and tizanidine are FDA-approved for treating spasticity. These three act by different mechanisms: baclofen exerts its effects by stimulation of the GABA-B receptor subtype, tizanidine is a centrally acting agonist of α2 receptors, and dantrolene directly inhibits muscle contraction by decreasing the release of calcium from skeletal muscle sarcoplasmic reticulum. The other agents have heterogenous mechanisms of action that are less understood but may be related to their sedative effects.

Public Comment. No public comment

Steroids, topical. Topical corticosteroids have a long history of effectiveness in a wide spectrum of dermatologic conditions, including dermatitis, atopic dermatitis, eczema, psoriasis, pruritus, insect bites, and localized burns. The usefulness and side effects of topical corticosteroids directly result from their anti-inflammatory properties, and currently available products differ widely in potency and formulation. They are available in various dosage forms, most commonly creams and ointments. The dosage form choice depends on the lesion's area and the condition being treated. Topical corticosteroids are classified according to potency, from very high to low, based on the ability of the formulations to cause cutaneous vasoconstriction. Systemic effects from topical corticosteroids are most likely to occur when large skin areas are involved, prolonged use, or occlusive dressings are used. Reversible suppression of the hypothalamic-pituitary-adrenal axis may occur, and pediatric patients are more susceptible due to greater body weight to surface area ratio. Chronic use in children may impact growth and development. Low-potency topical corticosteroids are the safest for chronic use, application over large surface areas, use on the face, genitals, and axilla, and in children. Guidelines generally recommend topical corticosteroids as a

first line for treating various steroid-responsive dermatoses, including atopic dermatitis and psoriasis. Lower potency agents are typically recommended for the treatment of children and when applied to areas of thin skin, such as the face. Selection of an agent for the Preferred Drug List should be based on clinical efficacy, side effect profile, generic availability, and cost; the preferred list should include at least 1 agent from each potency group.

Public Comment. No public comment

Transthyretin-related amyloidosis. Hereditary transthyretin amyloidosis (ATTR), also referred to as variant ATTR, is a life-threatening disease caused by mutations in the TTR gene. In patients with hereditary ATTR, genetic variants lead to the misfolding of transthyretin (TTR) proteins. The misfolded proteins aggregate and form amyloid deposits in the heart and peripheral or autonomic nerves (along with other major organs); these amyloid deposits lead to progressive organ dysfunction. Misfolding and aggregation of TTR can also occur as part of the aging process in patients with normal TTR genes; ATTR not associated with a genetic mutation is generally referred to as wild-type ATTR. Disease-modifying agents for ATTR are generally classified as TTR stabilizers (tafamidis, acoramidis) or TTR silencers (eplontersen, inotersen, patisiran, vutrisiran). The TTR stabilizers bind to the TTR tetramer and slow its dissociation into monomers, thereby preventing TTR misfolding and deposition. The TTR silencers target TTR messenger ribonucleic acid (mRNA) and reduce TTR synthesis; antisense oligonucleotide TTR silencers (eplontersen and inotersen) bind directly to TTR mRNA, leading to mRNA degradation, while small interfering RNA TTR silencers (patisiran and vutrisiran) cause mRNA degradation through RNA interference.

Public Comment.

A company representative commented on ATTRUBY™ (acoramidis) . The UGT inducers triggers an automatic denial, and they requested this step be modified and allow prescribers to review this issues case by case. There is no evidence of a clinical interaction.

Ulcerative colitis. Inflammatory Bowel Disease (IBD) comprises a spectrum of chronic inflammatory conditions of the gastrointestinal tract, with ulcerative colitis (UC) and Crohn's disease (CD) being the primary entities. These diseases are marked by intermittent episodes of inflammation leading to a broad range of symptoms such as

abdominal pain, diarrhea, rectal bleeding, weight loss, and fatigue, as well as complications. UC is localized to the colon, manifesting as recurrent mucosal inflammation that typically causes symptoms, including bloody diarrhea and abdominal cramping. The therapeutic landscape for UC has evolved with the introduction of various oral agents aimed at inducing and maintaining remission. Initial treatment strategies depend on disease severity, often starting with 5-aminosalicylic acid (5-ASA) agents, possibly accompanied by an induction course of oral glucocorticoids. This review focuses on a selection of oral and rectal 5-ASAs (balsalazide, mesalamine, olsalazine, sulfasalazine), the oral glucocorticoid budesonide, and the sphingosine 1-phosphate (S1P) receptor modulators, etrasimod (Velsipity™) and ozanimod (Zeposia®). Notably, balsalazide, most mesalamine formulations, budesonide (Uceris®), and sulfasalazine (Azulfidine®) are FDA-approved for inducing remission in mild to moderately active UC. Most 5-ASAs are also approved for remission maintenance, with sulfasalazine serving as an adjunct in severe active UC. Safety and monitoring considerations vary by agent, emphasizing the need for tailored therapeutic approaches based on individual patient profiles.

Public Comment. No public comment

Uterine disorder treatment. Endogenous gonadotropin-releasing hormone (GnRH), also known as luteinizing hormone-releasing hormone (LHRH), is produced in the hypothalamus and targets GnRH receptors on gonadotropin cells in the pituitary gland. This action triggers the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), which regulate ovarian function and are influenced by negative feedback from estradiol and progesterone. GnRH agonists and antagonists, short peptide analogues of GnRH, profoundly inhibit estrogen and androgen synthesis, making them effective in treating hormone-responsive conditions such as endometriosis, uterine fibroids, and advanced prostate cancer.

Public Comment. No public comment

4. Public comment and discussion on single new drugs to be reviewed for the Medicaid PDL:

Gomekli capsule and tablet for susp / Oncology, other- oral.

Company Website: SpringWorks CareConnections™ Patient Support Program | HCP

Public Comment.

A company representative commented on Gomekli.

Onapgo cartridge / Antiparkinson's agents.

Company Website: ONAPGO™ - Official Patient Website

Public Comment. No public comment

Raldesy solution / Antidepressants, other

Company Website: Raldesy

Public Comment. No public comment

Romvinza capsule / Oncology, other- oral

Company Website: ROMVIMZA™ (vimseltinib) | TGCT (PVNS) Treatment

Public Comment. No public comment

Symbravo tablet / Antimigraine agents

Company Website: SYMBRAVO® (meloxicam and rizatriptan) | For Patients

Public Comment.

A company representative commented on Symbravo.

Tryngolza autoinjector / Lipotropics, others

Company Website: First & Only FDA-Approved Medicine for FCS | TRYNGOLZA™

Public Comment. No public comment

Xromi solution / Sickle cell anemia treatments

Company Website: Home | XROMI (hydroxyurea) Oral solution

Public Comment. No public comment

5. Therapeutic and clinical drug reviews and updates, were provided by Gainwell Technologies.

6. Executive work session

Pursuant to Texas Government Code, Section 531.071, 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 recommended changes are noted)

Alzheimer's Agents:

Zunveyl	Nonpreferred
Namenda	PDL
Memantine	Nonpreferred

Calcium Channel Blockers

Katerzia	Nonpreferred
Norliqva	PDL

Fluoroquinolones, oral

Levofloxacin	PDL

Immunosuppressives

Prograf	PDL

Non-narcotic Analgesics

Journavx	PDL

Ophthalmic Antibiotics

Ocuflox	PDL

Ophthalmic Antibiotic-Steroid

Tobradex	PDL

Ophthalmics for allergic conjunctivitis

Alrex	PDL
Lastacaf OTC	PDL
Olopatadine	PDL

Ophthalmics Anti-inflammatories

Acular Drops	PDL
Acular LS Drops	PDL
Acuvail Droperette	PDL
Flurbiprofen Sodium Drops	PDL
Nevanac Drops Susp	PDL
Prolensa Drops	PDL
Flarex Drops Susp	PDL
Flourometholone Drops Susp	PDL
FML Drops Susp	PDL
FML Forte Drops Susp	PDL
Maxidex Drops Susp	PDL
Pred Forte Drops Susp	PDL
Pred Mild Drops Susp	PDL

Ophthalmics, Glaucoma Agents

Alphagan P Drops	PDL
Betoptic S Drops	PDL
Timoptic Sol	PDL
Timoptic Droperette	PDL
Timoptic-XE Drops	PDL
Lumigan Drops	PDL
Zioptan Droperette	PDL
Phospholine Iodide Drops	PDL

Otic Antibiotics

Cipro HC Drops Susp	PDL
CortisporinTC Drops Susp	PDL

Rosacea Agents Topical

Metronidazol Gel w/ pump	Nonpreferred

Skeletal Muscle Relaxants

Tanlor Tablet	Nonpreferred
Cyclobenzaprine HCL	Nonpreferred
Amrix Cap	PDL
Tizanidine HCL	PDL

Steroids Topical

Anusol HC	Nonpreferred
Pandel Cream	PDL
Vanos Cream	PDL

Transthyretin-related Amyloidosis

Attruby Tablet	Nonpreferred
Vyndamax Capsule	PDL
Vyndaqel Capsule	Nonpreferred
Wainua Auto inject	Nonpreferred

Ulcerative Colitis

Azulfidine Tablet	PDL
Azulfidine EN Tablet	PDL

Single Drug Reviews

Raldesy solution	Nonpreferred
Symbravo	Nonpreferred
Onapgo	Nonpreferred
Tryngolza	Nonpreferred
Gomekli	PDL
Romvinza	PDL
Xromi solution	PDL

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