HHSC: Drug Utilization Review Board
Part One

November 12, 2021

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

- Robert L. Hogue, M.D., F.A.A.F.M. (Brownwood) (**Chair**)
- Alejandro D. Kudisch, M.D., D.F. A.P.A. (McAllen) (**Vice-chair**)
- Scott Blaszczyk, Pharm.D., BCGP (Dallas)
- Deborah E. Briggs, M.D. (Austin)
- Marlo Brawner, M.D. (Livingston) - *term ending Aug. 31, 2021*
- Deeatra S. Craddock, Pharm. D, BCACP (Carrollton)
- Jennifer Fix, Pharm. D (Burleson)
- Heather Holmes, M.D. (Amarillo)
- Joshua R. Johns, Pharm. D. (Richardson)
- Sarah E. Kubes, Pharm. D. (San Antonio)
- Jill N. Lester, Pharm. D. (Dallas) - *term ending Aug. 31, 2021*
- Thanhhao T. Ngo, Pharm. D. (Austin) - *term ending Aug. 31, 2021*
- Richard Noel, M.D. (Spring)
- Kim Pham, D.O. (Dallas)
- Kathryn L. Velasquez, Pharm. D. (Houston)

Managed care representatives

- Salil V. Deshpande, M.D., M.B.A. (Sugar Land), UnitedHealthcare
- Joseph J. Vazhappilly, Pharm. D., M.B.A. (Irving), Molina Healthcare of Texas - *term ending Aug. 31, 2021*

Consumer advocate

- Dennis A. Borel (Austin)

Vacancies

- One pharmacist, managed care representative
  - Term ends Aug. 31, 2025
- One physician, pediatrician, non-managed care representative
  - Term ends Aug. 31, 2025
- Two pharmacists, non-managed care representative
  - Term ends Aug. 31, 2025
- Two physicians, any specialty, non-managed care representative
  - Term ends Aug. 31, 2022

Call to order. The meeting was called to order by the Chair, Robert L. Hogue. A quorum was not established. PDL recommendations from July were approved by the Executive Commissioner

Consideration of minutes from July 23, 2021 The minutes were approved as drafted.

Public comment on the drug classes to be reviewed for the Medicaid Preferred Drug List (PDL). References are from Drugs.com unless otherwise noted.

Androgenic agents Androgens and anabolic steroids include the male sex hormone testosterone and dihydrotestosterone, and other agents that behave like these sex hormones. They stimulate the

development of male sexual characteristics (such as deepening of voice and growth of beard) and development of male sex organs.
Anabolic steroids stimulate growth in many types of tissues, especially bone and muscle. Anabolic effects also include increased production of red blood cells.

Androgens and anabolic steroids are used as replacement therapy to treat delayed puberty in adolescent boys, hypogonadism and impotence in men, and to treat breast cancer in women. They are also used to treat anemia, osteoporosis, weight loss and other conditions with hormonal imbalance.

No Public Comment

Antibiotics. Antibiotics are specific for the type of bacteria being treated and, in general, cannot be interchanged from one infection to another. When antibiotics are used correctly, they are usually safe with few side effects. Health care providers can assess each patient individually to determine the correct antibiotic, dose and length of treatment.
However, as with most drugs, antibiotics can lead to side effects that may range from being a nuisance to serious or life-threatening. In infants and the elderly, in patients with kidney or liver disease, in pregnant or breastfeeding women, and in many other patient groups, antibiotic doses may need to be adjusted based upon the individual patient. Drug interactions can also be common with antibiotics. Follow the links for more detailed and specific information

Antibiotics, gastrointestinal (GI)

Public Comment

Gregory Kauffman, Lupin Pharmaceuticals commented on Bacterial Vaginosis & Trichomoniasis Treatment | Solosec®. He provided information from the company website. Follow the link for this information. It has been on the market since 2018.

Antibiotics, topical **No public comment was offered**

Antibiotics, vaginal **No public comment was offered**

Anticonvulsants Anticonvulsants (antiepileptics or AEDs) helps to normalize the way nerve impulses travel along the nerve cells which helps prevent or treat seizures. When the brain is

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working normally the nerve cells talk to each other using controlled electrical signals from one nerve cell to another. This tells the body to do everything it needs or wants to do.
During a seizure there is a change in the level of nerve cell electrical signals from a normal level to an excessive or abnormal amount of nerve signals. This increased nerve activity is responsible for the signs and symptoms of a seizure. What causes the change is nerve impulses can be the result of an injury to part of the brain, stroke, brain tumor, genetic causes, metabolic problems or toxicity issues. Anticonvulsants can also be used to treat nerve pain and bipolar disorder.

Public Comment

Kristin Herd, Neurelis requested that VALTOCO® (diazepam nasal spray), CIV remain on the PDL with no restriction. She presented information from the company website. Follow the link for this information.

Michelle Shinover, UCB presented on BRIVIACT® (brivaracetam) CV | Patient Information on information on the company website. Please follow the link.

Hallie Scurry, UCB presented on Patient Information for VIMPAT® (lacosamide) CV from information on the company website. Please follow the link.

Anna Plosch, Sogenix spoke on FINTEPLA® (fenfluramine) oral solution, CIV | For Dravet Syndrome Seizures from information on the company website. Please follow the link.

Herbert Peoples, UCB spoke on Information for Patients | NAYZILAM® (midazolam) nasal spray, CIV from information on the company website. Please follow the link.

Antiemetics/Antivertigo agents Vomiting is controlled by the vomiting center in the medulla. Vomiting center is activated by either one of four trigger zones: chemoreceptor trigger zone, vestibular nuclei, cerebral cortex and gastrointestinal tract. Vomiting center is controlled by serotonin (5-HT3), muscarinic and histamine (H1) receptors.

Chemoreceptor trigger zone is sensitive to chemical stimuli, such as opioids and cytotoxic drugs. It is under the control of dopamine, serotonin (5-HT3) and opioid receptors.
Vestibular nuclei is controlled by muscarinic and histamine (H1) receptors. This is activated in vertigo or motion sickness.

Cerebral cortex activates vomiting from smell, thought and so on. Gastrointestinal tract has serotonin (5-HT3) receptors, which are affected by chemotherapeutic drugs.
Different classes of drugs work on different receptors and act as antiemetics and antivertigo agents.

Public Comment

Chris Molo, Viking Health Care spoke on Home - Bonjesta® from information found on the company website. Please follow the link.

Antifungals. Antifungal agents are also called antimycotic agents. They kill or inactivate fungi and are used to treat fungal infections (including yeast infections).

Polyene antifungals are not absorbed when given orally, so are used to treat fungal infections of the gastrointestinal tract, such as oral thrush. It can be given intravenously for treatment of systemic fungal infections.

Azole antifungals are synthetic, fungistatic agents with broad-spectrum activity.

- azole antifungals
- echinocandins
- miscellaneous antifungals
- polyenes

Antifungals, oral

Public Comment

Brian Burke, Scynexis spoke on BREXAFEMME® (ibrexafungerp, 150 mg per tablet) from information found on the company website. Please follow the link.

Antifungals, topical No public comment was offered

Antihistamines - first generation Antihistamines are a class of agents that block histamine release from histamine-1 receptors and are mostly used to treat allergies or cold and flu symptoms, although some first-generation antihistamines may also be used for other conditions.
Histamine-1 receptors are located in the airways, blood vessels and gastrointestinal tract (stomach and esophagus). Stimulation of these receptors can lead to conditions such as a skin rash or

inflammation, a narrowing of the airways (bronchoconstriction), hay fever, or motion sickness. Histamine-1 receptors are also found in the brain and spinal cord, and stimulation of these receptors makes you more awake and alert. Sedating antihistamines oppose the effects of histamine on H1 receptors in your brain, which is why they cause sedation and drowsiness.

Public Comment

A Pharmacist spoke on behalf of GNP Pharmaceuticals on PediaClear-8 Oral: Uses, Side Effects, Interactions, Pictures, Warnings & Dosing – and another Pediaclear product stating they have an excellent safety profile.

Antiparasitics, topical Antiparasitics/Anthelmintics are a type of medicine that kills helminths. Helminths are worm-like parasites such as flukes, roundworms, and tapeworms.

It is important that anthelmintics are selectively toxic to the parasite and not the host. Some work by inhibiting metabolic processes that are vital to the parasite but absent or not vital in the host. Other anthelmintics are poorly absorbed through the gut, which means the parasite is exposed to much higher concentrations of the anthelmintic than the host. Starvation or paralysis or the parasite result, followed by subsequent expulsion or digestion.

Public Comment.

Mr. Garcia, spoke on VANALICE- piperonyl butoxide, pyrethrum gel (nih.gov) stating it is up for renewal and a high efficacy profile.

Antipsychotics Antipsychotics are drugs that are used to treat symptoms of psychosis such as delusions (for example, hearing voices), hallucinations, paranoia, or confused thoughts. They are used in the treatment of schizophrenia, severe depression and severe anxiety. Antipsychotics are also useful at stabilizing episodes of mania in people with Bipolar Disorder.

Their main action is on dopamine receptors, reducing levels of excess dopamine. They may also affect levels of other neurotransmitters, namely acetylcholine, noradrenaline, and serotonin. Older antipsychotics tend to be called typical antipsychotics, and antipsychotics that have been developed more recently are called atypical antipsychotics. Atypical antipsychotics are less likely to produce extrapyramidal side effects (such as tremor and Parkinson's-like symptoms) and tardive dyskinesia (abnormal, repetitive facial movements). Atypical antipsychotics are also more likely to

improve cognitive function. Clozapine (classed as an atypical antipsychotic even though it is quite an old drug) also improves delusions and hallucinations and reduces the risk of suicide.

Public Comment

Brian Wentzel Sunovion Pharmaceuticals spoke on Bipolar Depression | Latuda® (lurasidone HCl). from information found on the company website. Please follow the link.

William Rowe, Intra-cellular Therapies spoke on CAPLYTA® (lumateperone) | Patient Information from information found on the company website. Please follow the link.

Kenneth Barry, Alkermes spoke on ARISTADA® (aripiprazole lauroxil) | HCP | Coverage (aristadahcp.com) from information found on the company website. Please follow the link. He requested it remain on preferred status.

Tara McKinley, Otsuka Pharmaceutical was available for questions related to The ABILIFY MYCITE® System - Official HCP Site (abilifymycitehcp.com), ABILIFY® (aripiprazole) | Official Site, REXULTI® (brexpiprazole) | Efficacy (rexultihcp.com), Efficacy in Bipolar I Disorder | ABILIFY MAINTENA® (aripiprazole) (abilifymaintenahcp.com).

Laura Hill, AbbVie spoke on Treatment for Bipolar 1 Disorder | VRAYLAR® (cariprazine) (vraylarhcp.com) from information found on the company website. Please follow the link. Requested preferred status.

Brent Malavak, Indivior spoke on Healthcare Professional Information | PERSERIS® (risperidone) HCP (perserishcp.com) from information found on the company website. Please follow the link. The speaker asked for preferred status.

Chris Molo, Noven Pharmaceuticals, spoke on Secuado Film - FDA prescribing information, side effects and uses (drugs.com). Follow the link for additional information. (Not a company website link). Requested it be added to the preferred drug list.

Matthew Lovett, NAMI Texas supports open access to all medications in this class with no restrictions. He cited the passage of 87(R) HB 2822 - Enrolled version (texas.gov)

H.B. 2822 seeks to streamline the prior authorization process in Medicaid to reduce barriers to care and decreases adverse events for patients experiencing certain serious and persistent mental illnesses (SMI), including schizophrenia, schizo-affective disorders, bipolar disorders, major depressive disorders, paranoia, and other psychotic disorders. Successful management of SMI symptoms typically depends on reliable access to prescribed medications, which can help maintain a stable home life and employment and avoid hospitalization or incarceration. Well-managed medication reduces the symptoms of SMI and allows individuals to focus on recovery, which improves quality of life and reduces costs of care. However, concerned parties contend that certain regulations in the Texas Medicaid program limit access to these medications while producing minimal savings to the system. Moreover, individuals with SMI who incur access challenges face a considerably higher number of adverse events that dramatically increase state expenditures and reduce quality of life. These adverse events include emergency room visits, hospitalization, homelessness, suicidal ideation, and incarceration. H.B. 2822 addresses these problems within the current structure of the Medicaid PA policies, chiefly by automating and streamlining the Medicaid prior authorization process.

The bill only applies to adults with SMI, for example bipolar disorder or schizophrenia. Under this bill, managed care organizations (MCOs) will update the PBM pharmacy claims update system to recognize that a patient has failed a 14-day trial of a preferred antipsychotic within the previous year, after which the system will automatically approve a non-preferred prescription. The system will also recognize when dosage levels are being changed for titration, provided they are below FDA maximum levels. The clinical edits for safety are clearly preserved. Importantly, the MCOs agreed to update their systems to notify a pharmacist at the point of sale about how to resolve a prior authorization and to dispense a 72-hour supply for continuity of care. In doing so,

H.B. 2822 will result in improved health outcomes, significant savings to the state budget, and improved quality of life. H.B. 2822 amends current law relating to the availability of antipsychotic prescription drugs under the vendor drug program and Medicaid managed care.

This has not been implemented because of the need for a CMS amendment according to the Vendor Drug Program.

Kevin Simmons, Director of Pharmacy at a West Oaks Hospital requested open access for long acting injectables.

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Antivirals, topical Topical antiviral agents are applied locally to treat viral infections. Different antiviral agents have different mechanisms of action, but they all inhibit production of viruses that cause disease. Topical agents are used to treat viral conditions such as cold sores (facial herpes simplex). Medical conditions associated with topical antivirals:

- Cold Sores
- Herpes Simplex

No public comment was offered.

Bone resorption suppression and related agents

From Wikipedia. Bone resorption is resorption of bone tissue, that is, the process by which osteoclasts break down the tissue in bones and release the minerals, resulting in a transfer of calcium from bone tissue to the blood.

The osteoclasts are multi-nucleated cells that contain numerous mitochondria and lysosomes. These are the cells responsible for the resorption of bone. Osteoclasts are generally present on the outer layer of bone, just beneath the periosteum. Attachment of the osteoclast to the osteon begins the process. The osteoclast then induces an infolding of its cell membrane and secretes collagenase and other enzymes important in the resorption process.

High levels of calcium, magnesium, phosphate and products of collagen will be released into the extracellular fluid as the osteoclasts tunnel into the mineralized bone. Osteoclasts are prominent in the tissue destruction found in psoriatic arthritis and rheumatological disorders.

The human body is in a constant state of bone remodeling Bone remodeling is a process which maintains bone strength and ion homeostasis by replacing discrete parts of old bone with newly synthesized packets of proteinaceous matrix. Bone is resorbed by osteoclasts, and is deposited by osteoblasts in a process called ossification. Osteocyte activity plays a key role in this process. Conditions that result in a decrease in bone mass can either be caused by an increase in resorption or by a decrease in ossification. During childhood, bone formation exceeds resorption. As the aging process occurs, resorption exceeds formation.

Bone resorption rates are much higher in post-menopausal older women due to estrogen deficiency related with menopause. Common treatments include drugs that increase bone mineral density. Bisphosphonates, RANKL inhibitors, SERMs—selective oestrogen receptor modulators, hormone replacement therapy and calcitonin are some of the common treatments. Light weight bearing exercise tends to eliminate the negative effects of bone resorption.

No public comment was offered.

Colony stimulating factors Colony stimulating factors are glycoproteins that promote production of white blood cells (mainly granulocytes such as neutrophils), in response to infection. Administration of exogenous colony stimulating factors stimulates the stem cells in the bone marrow to produce more of the particular white blood cells. The new white blood cells migrate into the blood and fight the infection.

Colony stimulating factors are used in patients who are undergoing cancer treatment that causes low white blood cell counts (neutropenia) and puts the patient at risk of infection. Colony stimulating factors tend to reduce the time where patients are neutropenic.

No public comment was offered.

Epinephrine, self-injected Epinephrine injection is used to treat severe allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs, and other allergens. Epinephrine auto-injectors may be kept on hand for self-injection by a person with a history of severe allergic reaction. Epinephrine is also used to treat exercise-induced anaphylaxis, or to treat low blood pressure that is caused by septic shock. Epinephrine injection may also be used for purposes not listed in the medication guide.

No public comment was offered.

GI Motility, chronic Gastrointestinal stimulants are drugs that increase motility of the gastrointestinal smooth muscle, without acting as a purgative. These drugs have different mechanisms of action, but they all work to move the contents of the gastrointestinal tract faster. Gastrointestinal stimulants are used to treat gastroesophageal reflux disease and other gastrointestinal conditions where gastrointestinal movement is slowed.

No public comment was offered.

Growth hormone The first report of human growth hormone use for treatment of short stature or growth hormone deficiency was in 1958. Early growth hormone preparations were derived or extracted from human cadaver pituitaries for therapeutic use. The biochemical structure was

determined in 1972. Production of some early preparations was discontinued due to the potential increased risk for Creutzfeldt-Jakob disease, an incurable, often fatal neurodegenerative condition. In 1985, the US Food and Drug Administration (FDA) approved the commercial use of a recombinant human growth hormone product. Commercial preparations now have the identical 191 amino acid sequence of native human pituitary hormone. Human growth hormone injection is FDA-approved for long-term use in the treatment of children with growth failure. However, homeopathic formulations of human growth hormone have not been evaluated for this use.

Public Comment

Courtney Walker, Novo Nordisk spoke on Growth Hormone Therapy | Norditropin® (somatropin) Injection from information found on the company website. Please follow the link

Hepatitis C HCV is carried in the blood and other body fluids, such as semen or vaginal fluids. The following are some ways HCV is spread:

- A stick from an infected needle, including for illegal drugs and for procedures such as tattooing
- An object with infected blood or body fluids on it touches your wound
- Sharing personal items, such as razors, toothbrushes, or nail clippers with someone who has hepatitis C
- Travel to areas in the world where HCV is common
- Unprotected sex with someone who has hepatitis C, sex with more than one partner, or you are a man who has sex with men
- Rarely, a blood, organ, or tissue transplant from an infected donor, or long-term kidney dialysis

Public Comment

Portia Showers, Gilead Sciences spoke on sovaldi_pi.pdf (gilead.com) from information found on the company website. Please follow the link

Laura Hill, Abbvie Medical Affairs provided updates to MAVYRET (glecaprevir/pibrentasvir) for Hepatitis C | Official Site from information found on the company website. Please follow the link. Requested preferred status.

HIV / AIDS The human immunodeficiency virus (HIV) weakens the body's immune defenses by destroying CD4 (T-cell) lymphocytes, a type of white blood cell. T-cells normally help guard the body against attacks by bacteria, viruses and other germs.

When HIV destroys CD4 cells, the body becomes vulnerable to many different types of infections. These infections are called "opportunistic" because usually they only can invade the body when the immune defenses are weak. HIV infection also increases the risk of certain cancers, illnesses of the brain and nerves, body wasting, and death.

The range of symptoms and illnesses that can happen when HIV infection severely weakens the body's immune defenses is called acquired immunodeficiency syndrome or AIDS.
Since 1981, when doctors first recognized HIV/AIDS as a new illness, scientists have learned much about how a person becomes infected with HIV. The virus is spread through contact with an infected person's body fluids, especially through blood, semen and vaginal fluids.

Once inside the body, HIV particles invade CD4 cells and use the cells' own building machinery and materials to produce billions of new HIV particles. These new particles cause the infected CD4 cells to burst (lyse). The new particles can then enter the bloodstream and infect other cells.
Once someone is infected with HIV, the number of their CD4 cells continues to decrease. HIV is actively copying itself and killing CD4 cells from the time the infection starts. Eventually, the number of CD4 cells drops below the threshold level needed to defend the body against infections, and the person develops AIDS.

In its early stages, HIV infection often causes transient flu-like symptoms, such as fever, sore throat, rash, nausea and vomiting, diarrhea, fatigue, swollen lymph nodes, muscle aches, headaches, and joint pain. Doctors call this acute HIV infection.
The symptoms of acute HIV can be mild. So, the person or doctor may attribute the symptoms to a routine cold or flu. In a small number of cases, this early stage of infection may progress to meningitis (inflammation of membranes covering the brain) or severe flulike symptoms that require hospitalization.

Without treatment, the number of CD4 cells almost always declines. During this time, the person may begin to develop swollen lymph nodes and skin problems, such as varicella-zoster (shingles), seborrheic dermatitis (dandruff), new or worsening psoriasis, and minor infections. Ulcers can develop around the mouth and herpes outbreaks (oral or genital) may become more frequent.

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Over the next few years, as more CD4 cells continue to die, skin problems and mouth ulcers develop more often. Many people develop diarrhea, fever, unexplained weight loss, joint and muscle pain, and fatigue. Old tuberculosis infections may reactivate even before AIDS develops. (Tuberculosis is one of the most common HIV/AIDS-related infections in the developing world.)
Finally, with further decreases in the levels of CD4 cells, the person develops AIDS. According to the CDC, for an HIV-infected person, some signs that AIDS has developed (known as AIDS-defining conditions) are:

- The CD4 cell count has decreased to fewer than 200 cells per cubic milliliter of blood.
- An opportunistic infection has developed, indicating that the immune system is severely weakened. These types of infections include specific causes of pneumonia, diarrhea, eye infections and meningitis. Some of the causes of these opportunistic infections include Cryptococcus, reactivation of cytomegalovirus, reactivation of toxoplasma in the brain, wide-spread infection with Mycobacterium avium complex and Pneumocystis jiroveci (formerly called Pneumocystis carinii) in the lungs.
- A type of cancer has developed that shows that the immune system is severely weakened. For those who are infected with HIV, these cancers can include advanced cervical cancer, Kaposi's sarcoma (a cancer causing round, reddish spots in the skin and mouth), certain types of non-Hodgkin's lymphoma and brain lymphoma.
- An AIDS-related brain illness has developed, including HIV encephalopathy (AIDS dementia) or progressive multifocal leukoencephalopathy (PML) that is caused by the JC virus.
- There is severe body wasting (HIV wasting syndrome).
- There is an AIDS-related lung illness, such as pulmonary lymphoid hyperplasia or lymphoid interstitial pneumonia (usually seen only in children).

No public comment was offered.

Hypoglycemics Hypoglycemia, also known as low blood sugar, is a fall in blood sugar to levels below normal.[1] This may result in a variety of symptoms, including clumsiness, trouble talking, confusion, loss of consciousness, seizures, or death. Feelings of hunger, sweating, shakiness, or weakness may also be present. Symptoms typically come on quickly.

The most common cause of hypoglycemia is medications used to treat diabetes such as insulin and sulfonylureas. Risk is greater in diabetics who have eaten less than usual, recently exercised,[4] or drunk alcohol Other causes of hypoglycemia include kidney failure, certain tumors (such as insulinoma), liver disease, hypothyroidism, starvation, inborn error of

metabolism, severe infections, reactive hypoglycemia, and a number of drugs, including alcohol. Low blood sugar may occur in otherwise healthy babies who have not eaten for a few hours.[1]
The glucose level that defines hypoglycemia is variable. In people with diabetes, levels below 3.9 mmol/l (70 mg/dl) are diagnostic. In adults without diabetes, symptoms related to low blood sugar, low blood sugar at the time of symptoms, and improvement when blood sugar is restored to normal confirm the diagnosis. Otherwise, a level below 2.8 mmol/l (50 mg/dl) after not eating or following exercise may be used. In newborns, a level below 2.2 mmol/l (40 mg/dl), or less than 3.3 mmol/l (60 mg/dl) if symptoms are present, indicates hypoglycemia. Other tests that may be useful in determining the cause include insulin and C peptide levels in the blood.

Among people with diabetes, prevention is by matching the foods eaten with the amount of exercise and the medications used. When people feel their blood sugar is low, testing with a glucose monitor is recommended. Some people have few initial symptoms of low blood sugar, and frequent routine testing in this group is recommended. Treatment of hypoglycemia is by eating foods high in simple sugars or taking dextrose. If a person is not able to take food by mouth, glucagon by injection or in the nose may help. The treatment of hypoglycemia unrelated to diabetes includes treating the underlying problem and a healthy diet. The term "hypoglycemia" is sometimes incorrectly used to refer to idiopathic postprandial syndrome, a controversial condition with similar symptoms that occurs following eating, but with normal blood sugar levels

Hypoglycemics, insulin and related agents

Public Comment

Courtney Walker, Nova Nordisk commented on Tresiba® Benefits | Tresiba® (insulin degludec injection) 100 U/mL, 200 U/mL U/mL (novomedlink.com) from information found on the company website. Please follow the link.

Stephen Ponder, Pediatric Endocrinologist spoke on a product that was unclear (A new for of Glucagon)

Hypoglycemics, meglitinides **No public comment was offered.**

Hypoglycemics, metformin **No public comment was offered.**

Hypoglycemics, sodium-glucose cotransporter-2 (SGLT2) inhibitors **No public comment was offered.**

Hypoglycemics, thiazolidinediones (TZDs) **No public comment was offered.**

Macrolides-Ketolides Macrolides are a class of antibiotics derived from *Saccharopolyspora erythraea* (originally called *Streptomyces erythreus*), a type of soil-borne bacteria.

Macrolides inhibit protein synthesis in bacteria by reversibly binding to the P site of the 50S unit of the ribosome. Macrolides mainly affect gram-positive cocci and intracellular pathogens such as mycoplasma, chlamydia, and legionella. Erythromycin was the first macrolide discovered; other macrolides include azithromycin, clarithromycin, and roxithromycin.

Their action is primarily bacteriostatic but may be bactericidal at high concentrations or depending on the type of microorganism.

Ketolides are a new generation of macrolide antibiotics designed to overcome issues with bacterial resistance to macrolides. They are semi-synthetic antibiotics derived from erythromycin (macrolide antibiotic) and the changes give ketolides a broader spectrum of activity.

Ketolides bind to the bacterial 50S ribosomal subunit and inhibit RNA-dependent protein synthesis. They are bacteriostatic at low concentrations and bactericidal at high concentration, so basically exhibit concentration dependent killing.

Ketolides have good antibacterial activity against Gram-positive bacteria such as those that cause respiratory tract infections.

No public comment was offered.

Opiate dependence treatments Opiate Dependence means that a person needs an opiate drug to function normally. Abruptly stopping the drug leads to withdrawal symptoms. Opiate drugs include heroin, fentanyl, hydrocodone, morphine, codeine, oxycodone and methadone.

Public Comment

Did not state name, spoke on VIVITROL.com | Alcohol Dependence from information found on the company website. Please follow the link.

Brent Malavak, Indivior spoke on SUBLOCADE® (buprenorphine extended-release) injection, for subcutaneous use (CIII) requesting it be addressed in the PDL in conjunction with being already available on the medical side.

Tetracyclines Tetracyclines are a class of antibiotics that may be used to treat infections caused by susceptible microorganisms such as gram positive and gram negative bacteria, chlamydia, mycoplasmata, protozoans, or rickettsiae.

They were discovered in the 1940s and the first tetracyclines were obtained or derived from *Streptomyces* bacteria.

Tetracyclines inhibit protein synthesis in the microbial RNA (an important molecule that acts as a messenger for DNA). They are primarily bacteriostatic which means that they prevent bacteria from multiplying but don't necessarily kill them.

Although tetracyclines are still widely used in human and veterinary medicine, the emergence of bacterial resistance has limited their effectiveness and is of major concern.

No public comment was offered.

Public comment on single new drugs to be reviewed for the Medicaid PDL:

Benlysta Autoinjector (subcutane) / Immunosuppressives

> **Beverly Franklin Thompson Glaxo Smith Kline** spoke in support of inclusion of the product on the PDL. The link provides access to the presentation materials. Why BENLYSTA? | BENLYSTA (belimumab)

Benlysta Syringe (subcutane) / Immunosuppressives

Beverly Franklin Thompson Glaxo Smith Kline spoke in support of inclusion of the product on the PDL. The link provides access to the presentation materials Why BENLYSTA? | BENLYSTA (belimumab)

Lumakras (oral) / Oncology, oral – lung

Gia McClean, Amgen Medical Affairs spoke in support of inclusion of the product on the PDL. The link provides access to the presentation materials. Metastatic Non-Small Cell Lung Cancer Treatment | LUMAKRAS™ (sotorasib) (lumakrashcp.com)

Lupkynis (oral) / Immunosuppressives

German Hernandez, Nephrologist spoke in support of the product being included on the PDL.

Albert Stone, company representative spoke in support of the product being included on the PDL. An Option for Lupus Nephritis | Lupkynis™ (voclosporin)

Truseltiq (oral) / Oncology, oral - other

No public comment was provided

Zegalogue Autoinjector (subcutaneous) / Glucagon agents

Stephen Ponder, Pediatric Endocrinologist requested that this product be included on the PDL.

Emily Smith company representative spoke in support of the product being included on the PDL. ZEGALOGUE® | Very Low Blood Sugar Treatment by Injection

Frenald Ruani Zydus Pharmaceuticals spoke in support of using Glucagon and asked to support Gvoke® (glucagon injection) | Patient Information (gvokeglucagon.com)

Jill Johannson, Patient spoke in support of Zegalogue and shared a personal story.

Zegalogue Syringe (subcutaneous) / Glucagon agents

Stephen Ponder, Pediatric Endocrinologist requested that this product be included on the PDL.

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ZEGALOGUE® | Very Low Blood Sugar Treatment by Injection

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Therapeutic and clinical drug reviews and updates: Magellan Medicaid Administration The attached update was provided to the panel. The speaker spoke from this handout. Please follow the link for the update.

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 new business as permitted by the Texas Open Meetings Act.
Announcements of drugs recommended for the Medicaid PDL: Magellan Medicaid Administration (vote required)

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