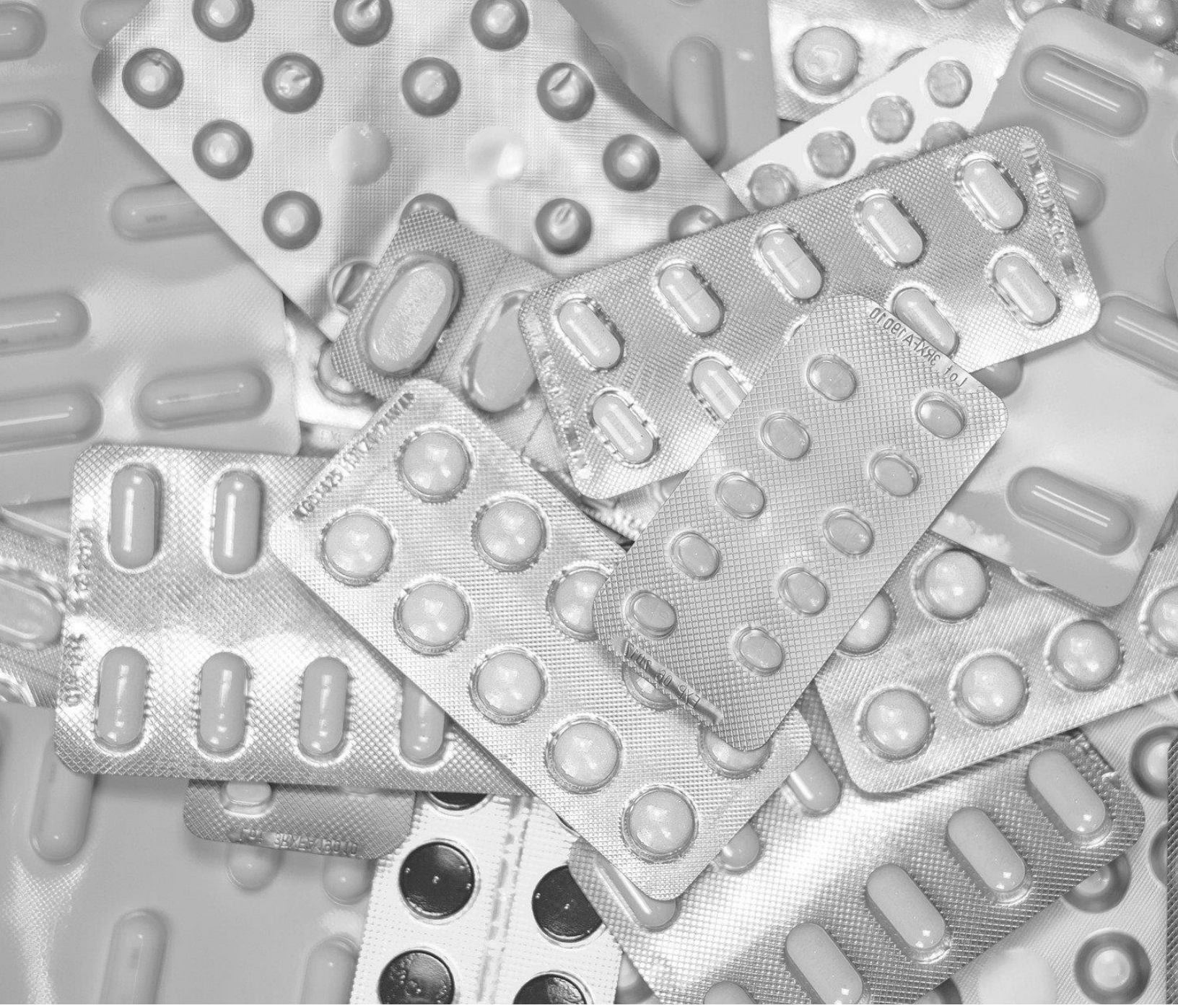

HHSC: Drug Utilization Review Board (Part 1: Drug Class Reviews), January 24, 2020

The Texas Drug Utilization Review Board meets quarterly to develop criteria and standards impacting Texas Medicaid, including:

- Developing and submitting recommendations for the **Texas Medicaid preferred drug list**
- Suggesting clinical prior authorizations on outpatient prescription drugs.
- Recommending educational interventions for Medicaid providers.
- Reviewing drug utilization across the Medicaid program.

The DUR board is composed of 20 total members: 18 physicians and pharmacists who provide services across the entire population of Medicaid recipients and who represent different specialties, two representatives from Medicaid managed care organizations as nonvoting members, and a consumer advocate representing people enrolled in the Medicaid program. Members include:

- Robert L. Hogue, M.D., F.A.A.F.M. (Brownwood) (**Chair**)
- J. Nile Barnes, Pharm. D., BCPS (Dripping Springs)
- Scott Blaszczyk, Pharm.D., BCGP (Dallas)
- Deborah E. Briggs, M.D. (Austin)
- Marlo Brawner, M.D. (Livingston)
- Deeatra S. Craddock, Pharm. D, BCACP (Carrollton)
- Jennifer Fix, Pharm. D (Burleson)
- Connie Gelineau, Pharm.D. (Richardson)
- Heather Holmes, M.D. (Amarillo)
- Summer A. Keener, Pharm. D (San Antonio)
- Alejandro D. Kudisch, M.D., D.F. A.P.A. (McAllen)
- Jill N. Lester, Pharm. D. (Dallas)
- Thanhhao T. Ngo, Pharm. D. (Austin)
- Richarad Noel, M.D. (Spring)
- Kim Pham, D.O. (Dallas)

Managed care positions

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

Consumer advocate position

- Dennis A. Borel (Austin)

1. Call to order. The meeting was called to order by the Chair, Robert Hogue. There are two new board members: Marlo Brawner, M.D. and Connie Gelineau, Pharmacist.

2. Approval of minutes from October 25, 2019. The minutes were approved as written.

3. Texas Insurance Code chapter 1360, subchapter E-1, as adopted by HB 1584, 86th Leg., R.S. (2019) update – coverage of prescription drugs for stage four advanced, metastatic cancer and associated conditions. Ms. Priscilla Barilla made the presentation. She stated that, "The bill prohibits health plans from requiring members to fail first on a drug or to prove history of failure on a drug. For those reasons we will be updating out preferred drug list exception criteria to add this as an allowable exception for the use of the nonpreferred drug. The implementation of this change will occur with the January PDL change. Are there any questions?" (None asked.) "Thank you for the opportunity to update you on the exceptions to the PDL criteria."

HB 1584 amends the Insurance Code relating to health benefit plan coverage of prescription drugs for stage-four advanced, metastatic cancer and applies only to a health benefit plan that is delivered, issued for delivery, or renewed on or after January 1, 2020. The bill took effect on September 1, 2019.

4. New business: Public comment on drug classes to be reviewed for the Medicaid preferred drug list (PDL):

Acne agents, oral. Not all acne clears up with topical medications (the creams, lotions, and gels that you apply to your skin). Oral medications, also called systemic medications, work internally to improve the skin. You take them by mouth. Some medications you'll take just once a day, others you'll take more often, ideally at the same time every day. Persistent or severe cases of acne are difficult to control, and in the majority of cases requires oral medications. Severe acne (sometimes called cystic acne or nodular acne) creates large, deep, inflamed breakouts. Topical medications can't get deep enough to effectively treat these types of blemishes.

Another obstacle: acne often occurs on other areas of the body, like your back or shoulders. It can be tough to reach those areas to effectively apply topical treatments.

Oral acne medications, on the other hand, can work on deeply inflamed blemishes and you don't have to be a contortionist to get the medication where you need it. (Very Well Health)

Public Comment. None offered.

Acne agents, topical. Topical acne agents are creams, gels, lotions, and washes that are used on the skin and contain ingredients that treat acne. They are typically used for mild acne, although some may be used for the treatment of severe acne in conjunction with prescription medicines. Topical acne agents include antiseptic washes that contain ingredients to gently cleanse the skin; and creams, lotions, or gels that exfoliate the skin, inhibit bacterial growth, speed up skin cell renewal or decrease the formation of comedones.

Public Comment. None offered.

Analgesics, narcotics long. Narcotic agents are potent analgesics which are effective for the relief of severe pain. Analgesics are selective central nervous system depressants used to relieve pain. The term analgesic means "without pain". Even in therapeutic doses, narcotic analgesics can cause respiratory depression, nausea, and drowsiness. Nonpharmacological treatment is recommended as the first line of treatment. Acetaminophen is no longer recommended but NSAIDS are recommended for chronic pain. Opioids are only recommended when other treatments fail and only the lowest dose should be used. Long acting opioids should be avoided. The use of codeine and other drugs have been scaled back for use with children.

Public Comment. None offered.

Analgesics, narcotics short. Narcotic agents are potent analgesics which are effective for the relief of severe pain. Analgesics are selective central nervous system depressants used to relieve pain. The term analgesic means "without pain". Even in therapeutic doses, narcotic analgesics can cause respiratory depression, nausea, and drowsiness.

Public Comment.

Glen Wells,[1] **WraSer Pharmaceuticals,** stated that dosing of pharmaceuticals and opioids has come under scrutiny and caution is being exercised. He cited some inconsistencies in items that are on the Preferred Drug List (PDL), and addiction rates of those substance compared to others that are not on the PDL. Dihydrocodeine bitartrate/acetaminophen /caffeine requires a prior authorization while other, more high-risk combinations do not. Drugs falling into this category include Dvorah, Panlor®, and Trezix.

Angiotensin modulator combinations. These agents are a fixed-dose combination of two or three of the following: an angiotensin II receptor blocker (ARB) or an angiotensin-converting enzyme (ACE) inhibitor in combination with a calcium channel blocker (CCB) or a beta blocker, with or without the addition of a thiazide diuretic. ACE inhibitors included in this class of combination products include benazepril, perindopril, and trandolapril, components of Lotrel, Prestalia, and Tarka. ACE inhibitors prevent the conversion of angiotensin I to angiotensin II, a potent vasoconstrictor, by competing with angiotensin I for the active site of ACE. Calcium channel blockers inhibit calcium ions from moving across the cell membrane. The limitation of calcium entering into the cells causes a decrease in mechanical contraction of myocardial and smooth muscle, thereby causing dilation of systemic arteries and a decrease in total peripheral resistance, systemic blood pressure, and the afterload of the heart.

Public Comment.

[1] Spelling uncertain.

Ms. Duong,[2] **Novartis,** spoke on Entresto. She provided information from the website and Black Box warning. The drug received a class one A recommendation in heart failure patients to reduce sudden cardiac death. It is now on two treatment guidelines for professionals to reduce mortality and morbidity. Post-approval has now exceeded four years. There are thus several studies that support the use of Entresto and resulting reduction in pharmacy costs. In October of 2019, it was approved for symptomatic heart failure in pediatric patients one year and older. Another trial demonstrated its in-hospital efficacy compared to Enalapril. The speaker asked that the drug remain on the Texas PDL.

From Company Websites:
Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction. Entresto is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB. Click here for full Prescribing Information, including Boxed WARNING.

Angiotensin modulators. Angiotensin receptor blockers (ARBs) are indicated for the treatment of hypertension either alone or in combination with other antihypertensive medications.

Public Comment. None offered.

Antimigraine agents, other. Antimigraine agents are used to treat migraine headaches. Migraines are different from other headaches because they occur with symptoms such as nausea, vomiting, or sensitivity to light. Some people who get migraines have warning symptoms, called an aura, before the actual headache begins.

Public Comment.

Jennifer Ward, Eli Lilly spoke on Emgality. There was no updated information since last year.

David Miley, Teva Pharmaceuticals, provided information from the website (*he was reading from a document so rapidly it was impossible to follow his presentation*). The product is used to treat migraine patients. He cited data from studies supporting his position. An autoinjector is under development. He requested adding Ajovy to the preferred drug list.

Scott (last name unclear), Amgen Medical Affairs, provided information on Aimovig from the website. The mechanism of action is unique, effecting the receptor. Four-and-a-half-year data has been released. Results of the study in episodic migraine patients showed a 50%

[2] Spelling uncertain.

reduction and many reported being migraine-free. They made an update to the Product Information (provided in the warnings and precautions link below). They asked to ensure that Texas providers have therapeutic options for patients.

Q: What is the average duration of treatment? **A**: The Phase II trial went for 12 weeks, and then they could move on to a five-year extension.

From Company Websites:

Emgality is a once-monthly preventive treatment specifically developed to help give you more migraine-free days. Please see company website by clicking the link for additional information.

Ajovy is a prescription medicine used for the preventive treatment of migraine in adults. Please see Patient Information Leaflet within the full Prescribing Information.

Aimovig is a prescription medicine used for the preventive treatment of migraine in adults. It is not known if the drug is safe and effective in children under 18 years of age. Click here for the full Prescribing Information and Patient Product Information.

Antimigraine agents, triptans. Antimigraine agents are used to treat migraine headaches. Migraines are different from other headaches because they occur with symptoms such as nausea, vomiting, or sensitivity to light. Some people who get migraines have warning symptoms, called an aura, before the actual headache begins.

Triptans are a class of medications that are selective serotonin 5-hydroxytryptamine (5-HT) (1B/1D) receptor agonists. Triptans are primarily used in the acute treatment of moderate to severe migraine. Triptans, which first came to market in the early 1990s, come in different formulations, both brand and generic.[1] These include oral medications such as tablets, capsules and quick dissolving tablets, subcutaneous injections, nasal sprays, and transdermal patch.

Public Comment. None offered.

Bladder relaxant preparations. As many as 46 million Americans 40 years of age or older reported OAB symptoms. Men and women with OAB experience symptoms such as a sudden urgency to urinate that is frequent and cannot be controlled. These uncontrollable urges to urinate can sometimes lead to leakage – accidental wetting.

According to the American Urological Association (AUA), which is a leading advocate for the specialty of urology, the lack of bladder control may affect a person's daily activities.

Many people with OAB just learn to cope with their condition, rather than talk to their HCP about it, because they are embarrassed or think it can't be treated. They plan their daily activities around being close to bathrooms to avoid urine leaks and accidents.

Public Comment. None Offered.

Glucagon agents. In the US, Glucagon (glucagon systemic) is a member of the drug class glucose elevating agents and is used to treat Diagnosis and Investigation and Hypoglycemia.

Public Comment.

Jennifer Ward, Eli Lilly, spoke about nasal glucagon or Baqsimi. Ms. Ward provided information from the company website. There is no need to inhale the product, as it is passively absorbed. The product had a 97 percent success rate. The product is only recommended for extreme hypoglycemia.

Kinnar Amani,[3] **Xeris Pharmaceuticals,** stated they have a product (that the writer heard as) Gvoke. Please see the link to the company for more information. He requested that his company's product be included in the PDL.

From Manufacturers Websites.

Baqsimi is indicated for the treatment of severe hypoglycemia in patients with diabetes ages 4 years and above. Please see Full Prescribing Information including Patient Information provided. Please see Instructions for Use included with the device.

Xeris (Glucagon) is a drug that requires multiple steps in order to prepare and administer successfully. Thus, during emergency situations it is difficult for someone who experiences severe hypoglycemia to receive a full dose of glucagon. Xeris is dedicated to developing tools, for persons with diabetes and their caregivers, that simplify the administration and provide a full dose of glucagon—to immediately and successfully treat severe hypoglycemia.

H. Pylori treatment. Therapy for H. pylori infection consists of 10 days to 2 weeks of one or two effective antibiotics, such as amoxicillin, tetracycline (not to be used for children <12 yrs.), metronidazole, or clarithromycin, plus either ranitidine bismuth citrate, bismuth subsalicylate, or a proton pump inhibitor.

Public Comment. None Offered.

[3] Spelling uncertain.

Immunomodulators, atopic dermatitis are substances that alter the immune response by augmenting or reducing the ability of the immune system to produce antibodies or sensitized cells that recognize and react with the antigen that initiated their production. Immunomodulators include corticosteroids, cytotoxic agents, thymosin, and immunoglobulins. Some immunomodulators are naturally present in the body, and certain of these are available in pharmacological preparations.

Public Comment.

Christine (last name unclear), Pfizer, spoke in support of retaining Eucrisa on the PDL.

Alton Humphrey,[4] Pediatrician, discussed the issues with atopic dermatitis in her patients. She spoke in support of Eucrisa. She stated that it is effective and does not have a Black Box warning.

Q: What is your approach with patients under the age of two? The speaker stated that she has felt comfortable prescribing the drug off-label.

Kevin Dirkoff,[5] (not clearly articulated) spoke in support of Dupixent. There is not significant new information on this drug.

David (last name unclear), Physician Assistant, spoke in support of Eucrisa. He stated that he primarily serves Medicaid patients from the Rio Grande Valley. He stated that they can treat flair-ups. However, Eucrisa, with its safety profile, is good for moderate cases. It is a unique medication.

From Company Websites:

Eucrisa is a prescription ointment used on the skin (topical) to treat mild-to-moderate eczema (atopic dermatitis) in adults and children 2 years of age and older. Do not use Eucrisa if you are allergic to crisaborole or any of the ingredients in Eucrisa. Eucrisa may cause side effects including allergic reactions at or near the application site. These can be serious and may include hives, itching, swelling, and redness. If you have any of these symptoms, stop using Eucrisa and get medical help right away. The most common side effect of Eucrisa is application site pain, such as burning or stinging. Eucrisa is for use on skin (topical use) only. Do not use Eucrisa in your eyes, mouth, or vagina. See Full Prescribing Information.

Dupixent is a prescription medicine used to treat people 12 years of age and older with moderate-to-severe atopic dermatitis (eczema) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. DUPIXENT can be

[4] Spelling uncertain.
[5] Spelling uncertain.

used with or without topical corticosteroids. It is not known if DUPIXENT is safe and effective in children with atopic dermatitis under 12 years of age. It is to be used with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in people aged 12 years and older whose asthma is not controlled with their current asthma medicines. Dupixent helps prevent severe asthma attacks (exacerbations) and can improve your breathing the product may also help reduce the amount of oral corticosteroids you need while preventing severe asthma attacks and improving your breathing. It is not used to treat sudden breathing problems. It is not known if it is safe and effective in children with asthma under 12 years of age.

It is also to be used with other medicines to treat chronic rhinosinusitis with nasal polyposis in adults whose disease is not controlled. It is not known if it is safe and effective in children with chronic rhinosinusitis with nasal polyposis under 18 years of age.

Intranasal rhinitis agents. Common symptoms are a stuffy nose, runny nose, sneezing, and post-nasal drip. In rhinitis, the inflammation of the mucous membrane is caused by viruses, bacteria, irritants or allergens. The most common kind of rhinitis is allergic rhinitis, which is usually triggered by airborne allergens such as pollen and dander.

Public Comment.

Mary Porter,[6] Optinose, spoke in support of Xhance. She read from a paper stating that it is designed to treat adults with CRS. She presented information from the company website. Sleep disorders and quality of life issues are the focus of this product. Nasal polyps are an issue that this drug attempts to address.

Xhance uses an Optinose Exhalation Delivery System (EDS) designed to deliver medication high and deep in the nasal passages to regions where nasal polyps originate and sinuses drain and ventilate. Please see full Prescribing Information, including Instructions for Use.

Movement disorders. If you have a movement disorder, you can experience different kinds of impaired movement. Dyskinesia is abnormal uncontrolled movement and is a common symptom of many movement disorders. Tremors are a type of dyskinesia.

Nerve diseases cause many movement disorders, such as Parkinson's disease. Other causes include injuries, autoimmune diseases, infections and certain medicines. Many movement disorders are inherited, which means they run in families.

[6] Spelling uncertain.

Treatment varies by disorder. Medicine can cure some disorders. Others get better when an underlying disease is treated. Often, however, there is no cure. In that case, the goal of treatment is to improve symptoms and relieve pain.

Public Comment.

Laurie Baily,[7] **NAMI, Texas,** Tardive Dyskinesia (TD) has been under-identified and untreated. This condition often goes unidentified by both the physician and the patient. Symptoms include mild to severe twitching, shaking, or jerking in the hands, feet, face, or torso. Involuntary blinking, tongue movements, and other unintentional, uncontrollable movements can also be signs of TD. This condition can impact employability and cause social isolation. There are now treatments on the market that can change all this. NAMI asks for access to a wide array of treatments presented here today.

Mr. Borel stated that the symptoms are similar to Tourette's Syndrome and asked if there is a connection. Ms. Baily stated that she did not believe that there was a relationship. The symptoms are similar, but they are not tied.

Stephen R. Saklad, Pharm. D., Professor at UT College of Pharmacy and San Antonio State Hospital, stated he has seen the ravages of TD during the years of his practice. He is asking that the two agents presented be approved as preferred agents. There were suits filed in the past regarding the care of patients. As a result, he is asking that deutetrabenazine (Austedo®) and valbenazine (Ingrezza™) be included as preferred agents. Both are modifications of tetrabenezine, addressing short duration of action and lack of specificity. For effective treatment, sometimes both medications are needed. Use of the medications will reduce the cost of care to Texas.

Dr. Craddock inquired how long it takes to see patient response? The speaker stated it can be 3-6 weeks depending on the medication.

Dr. Barnes asked if there are any patent populations that would prefer the three drugs. The speaker stated that the two new drugs are much more precise, and he would never use Tetrabenazine. The drugs are metabolized differently. You can't pick one or the other agents.

Dr. Kudisch asked about the total number of patients he has seen on these drugs and about suicidology. The speaker replied, about ten each. He stated that all the patients are in the state hospitals under court order and by the time they get there, their symptoms can be extreme. The patients are less likely to have depression and suicidal ideation compared to Tetrabenazine.

[7] Spelling uncertain.

A Company Representative speed-read a statement in support of Deutetrabenazine (Austedo). (*It was impossible to fully catch his statement*.) He stated that their product addresses chorea, associated with Huntington's Disease. He provided information from the company website for Austedo. He stated that Austedo is also being investigated related to Tourette's Syndrome.

John Deason, Neurocrine Biosciences, spoke in support of their product Ingrezza. He spoke from the information provided on the company website and stated it has no Black Box warnings. He stated that there are no head-to-head studies, but he presented information from other studies. He asked that Ingrezza be considered for inclusion as preferred.

Information below was provided from company websites where available or other reliable sites.

Xenazine is indicated for the treatment of chorea associated with Huntington's disease. Xenazine can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease. Anyone considering the use of Xenazine must balance the risks of depression and suicidality with the clinical need for control of chorea. Close observation of patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior should accompany therapy. Patients, their caregivers, and families should be informed of the risk of depression and suicidality and should be instructed to report behaviors of concern promptly to the treating physician.

Particular caution should be exercised in treating patients with a history of depression or prior suicide attempts or ideation, which are increased in frequency in Huntington's disease. Xenazine is contraindicated in patients who are actively suicidal, and in patients with untreated or inadequately treated depression [see Contraindications (4), Warnings and Precautions (5.1)

Austedo is a prescription medicine used to treat adults with tardive dyskinesia (TD). In clinical studies, people were able to continue taking mental health medications like antipsychotics or antidepressants while on the drug. Austedo can cause serious side effects in people with Huntington's disease, including: depression, suicidal thoughts, or suicidal actions. Do not start taking Austedo if you are depressed (have untreated depression or depression that is not well controlled by medicine) or have suicidal thoughts. Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts or feelings. This is especially important when Austedo is started and when the dose is changed. Call your healthcare provider right away if you become depressed, have unusual changes in mood or behavior, or have thoughts of suicide. Please read the accompanying Medication Guide.

Ingrezza capsules—a prescription medicine used to treat adults with movements in the face, tongue, or other body parts that cannot be controlled (tardive dyskinesia). It is not known if the drug is safe in children. Ingrezza may cause serious side effects, including:

- Sleepiness (somnolence). Do not drive, operate heavy machinery, or do other dangerous activities until you know how INGREZZA affects you.

- Heart rhythm problems (QT prolongation). INGREZZA may cause a heart problem known as QT prolongation.
- Symptoms of QT prolongation may include: fast, slow, or irregular heartbeat, shortness of breath, dizziness or fainting.
- Parkinson-like symptoms. Symptoms include: shaking, body stiffness, trouble moving or walking, or keeping your balance.

Please see Ingrezza full product Information.

Neuropathic pain. Neuropathic pain is pain caused by damage or disease affecting the somatosensory nervous system. Neuropathic pain may be associated with abnormal sensations called dysesthesia or pain from normally non-painful stimuli (allodynia). It may have continuous and/or episodic (paroxysmal) components. The latter resemble stabbings or electric shocks.

Public Comment. None offered.

Phosphate binders. Phosphate binders are medications used to reduce the absorption of phosphate and taken with meals and snacks. They are typically used in people with chronic kidney failure (CKF) as they often have difficulty getting rid of the phosphates that get into their blood (i.e., the serum phosphate in chronic kidney failure is typically elevated). These agents work by binding to phosphate in the GI tract, thereby making it unavailable to the body for absorption. Hence, these drugs are usually taken with meals to bind any phosphate that may be present in the ingested food. Phosphate binders may be simple molecular entities (such as magnesium, aluminium, calcium, or lanthanum salts) that react with phosphate and form an insoluble compound. Phosphate binders such as sevelamer may also be polymeric structures which bind to phosphate and are then excreted.

Public Comment. None offered.

Platelet aggregation inhibitors. Platelet aggregation inhibitors work in different places of the clotting cascade and prevent platelet adhesion, therefore no clot formation.

Aspirin, the most commonly used antiplatelet drug changes the balance between prostacyclin (which inhibits platelet aggregation) and thromboxane (that promotes aggregation). It irreversibly inhibits the enzyme cyclo-oxygenase, which leads to reduction in thromboxane synthesis in platelets and prostacyclin in vascular endothelial cells. The vascular endothelium recovers and can synthesize more prostacyclin, but thromboxane synthesis only recovers after new platelets are formed.

Platelet aggregation inhibitors are used acutely in myocardial infarction, atrial fibrillation, following coronary bypass, angioplasty and stenting. It is also used as prophylaxis to prevent myocardial infarction and stroke.

Public Comment.

Kirstin Marr,[8] Astra Zeneca, spoke in support of Brilinta. She updated the committee on two outcome trials. She discussed a 19,000-patient study comparing patients who take Brilinta to those who have been taking aspirin alone. They evaluated stable patients who have not had a stroke. The twilight study looked at dual platelet therapy compared to Brilinta alone. They found reduction in bleeding rates.

Brilinta is indicated to reduce the rate of cardiovascular death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS) or a history of myocardial infarction. For at least the first 12 months following ACS, it is superior to clopidogrel. Brilinta also reduces the rate of stent thrombosis in patients who have been stented for treatment of ACS. Please read full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

Progestins for cachexia. Progestins are synthetic steroid hormones that activate the progesterone receptor in a similar way to progesterone, but each individual progestin has its own distinctive effect. The progestins are used to treat amenorrhea, premenstrual tension and abnormal uterine bleeding. As they prevent ovulation, progestins are a major constituent of oral contraceptives and other forms of contraception. Progestins can also act to decrease levels of some hormones so can be used to treat hormonally sensitive cancers, for transgender hormone suppression and for precocious puberty.

Public Comment. None offered.

Proton pump inhibitors. The proton pump inhibitors are a group of drugs that reduce the secretion of gastric (stomach) acid. They act by binding with the enzyme H+, K(+)-ATPase, hydrogen/potassium adenosine triphosphatase, which is sometimes referred to as the proton pump.

Public Comment. None offered.

Smoking cessation. Smoking cessation (also known as quitting smoking) is the process of discontinuing tobacco smoking. Tobacco smoke contains nicotine, which is addictive. Nicotine withdrawal makes the process of quitting often very prolonged and difficult.

[8] Spelling uncertain.

Seventy percent of smokers would like to quit smoking, and 50 percent report attempting to quit within the past year. Smoking is the leading preventable cause of death worldwide. Tobacco cessation significantly reduces the risk of dying from tobacco-related diseases such as coronary heart disease, chronic obstructive pulmonary disease (COPD), and lung cancer. Due to its link to many chronic diseases, cigarette smoking has been restricted in many public areas. Many different strategies can be used for smoking cessation, including quitting without assistance ("cold turkey" or cut down then quit), behavioral counseling, and medications such as bupropion, cytisine, nicotine replacement therapy, or varenicline. Most smokers who try to quit do so without assistance, though only 3% to 6% of quit attempts without assistance are successful. Behavioral counseling and Medications each increase the rate of successfully quitting smoking, and a combination of behavioral counseling with a medication such as bupropion is more effective than either intervention alone. Since nicotine is addictive, quitting smoking leads to symptoms of nicotine withdrawal such as nicotine cravings, anxiety, irritability, depression, and weight gain. Professional smoking cessation support methods generally attempt to address nicotine withdrawal symptoms to help the client break free of nicotine addiction.

Public Comment.

Vigia Henry,[9] Pfizer, stated that they did not have any updated information related to their product, Chantix, and she requested the product remain on the preferred drug list.

The Chair asked if this has been used in e-cigarette cessation. The speaker answered in the negative.

The Chantix website was not responding at the time this report was drafted. Drugs.com provided the following information.

Chantix (varenicline) is a smoking cessation medicine that is used together with behavior modification and counseling support to help you stop smoking. See also: Chantix dosage information.

Stimulants and related agents. Stimulants, also called Psychostimulants can be defined as psychoactive drugs that induce temporary improvements in either mental or physical function or both. From CMS.gov:

- Adult Stimulants Dosing Chart (PDF) (updated November 2015)
- Adult Stimulants Fact Sheet (PDF) (updated November 2015)
- Pediatric Stimulants Dosing Chart (PDF) (updated November 2015)
- Pediatric Stimulants Fact Sheet (PDF) (updated November 2015)

[9] Spelling uncertain.

Public Comment.

Rita Maubahil,[10] **Adlon Therapeutics,** stated their support for Adhansia XR, speaking from information found on the company website. There are six capsule strengths. She focused on the formulation of the product, stating that it is a single daily dose with 20% of the dose being available for immediate release and 80% for extended release. She stated that some people are taking multiple stimulant medications daily and this could replace that. She requested their expert review.

Deb Profant, Jazz Pharmaceuticals, spoke in support of solriamfetol (Sunosi™). The drug is a once-a-day product to improve wakefulness. She presented information found on the company website. The speaker requested that Sunosi be added to the PDL for Texas.

Dev Inkland, [11] **Ironshore Pharmaceuticals,** spoke in support of their product, methylphenidate ER (Jornay PM™). He stated that this is the only ADHD medicine given at night and lasting throughout the day. He described their development process and provided information from the company website. He stated that the drug provides a smooth profile. They conducted two studies to determine the effect in the morning and the evening, and the data gathered included parental rating.

The Chair asked about trouble with diarrhea and constipation. The speaker stated that they did not study this in their two studies, but they did not see any particular problem.

Dr. Kudisch inquired about the duration of action. The speaker stated that this was hard to determine because they looked at performance before and after the classroom. They also looked at behaviors in the evening. The effect continues through the waking day. Dr. Kudisch inquired about the optimum dosing time. The speaker stated that they recommend about 8:00pm.

Ann Whitney Cates,[12] **Pediatrician,** spoke in support of Jornay PM, stating that her practice treats a lot of ADHD patents and the majority are Medicaid patients. She described some patients' experience with the medication. One parent reported that her child appeared normal 24 hours a day for the first time ever. No other stimulant on the market has the delayed release mechanism that Jornay PM has.

Dr. Gelineau asked about the improvements in testing experienced by the patient she described. The speaker stated that they do not have any scales to report but the parent's description was significant improvement and the patients seem to eat better.

[10] Spelling uncertain.
[11] Spelling uncertain.
[12] Spelling uncertain.

Dr. Kudisch asked about activity at the end of the day when the medication is wearing off. The speaker stated that there is some rebound, but this can be addressed through adjusting the dosing time. Some patients have a booster in the afternoon but the majority use this as a monotherapy.

The Chair asked about the other medications that she may prescribe for her patients. The speaker stated that she uses a broad spectrum of extended release medications, and it depends on the child.

Daniel Than,[13] Child Psychiatrist, spoke in support of Jornay PM. He stated that he is glad that Texas Medicaid will look at the needs of the patients first. He has treated 50 patients with Jornay PM with very few treatment failures. The drug lasts all day until bedtime. This functions as a nonstimulant. It works not only at wake-up time but through the day until bedtime. Jornay PM is emerging as a quality product compared to the other drugs in this class. He recommended the continuation of Jornay PM on the PDL.

Mr. Borel inquired about the percentage of patients getting ADHD medication. The speaker stated that it is large because of the population he serves (foster children and crack babies).

Adhansia is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older. CNS stimulants, including Adhansia XR, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy. Please read Full Prescribing Information, including Boxed Warning.

Sunosi is a prescription medicine used to improve wakefulness in adults with excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea (OSA).

Sunosi does not treat the underlying cause of obstructive sleep apnea and does not take the place of any device prescribed for obstructive sleep apnea, such as a continuous positive airway pressure (CPAP) machine. It is important that you continue to use these treatments as prescribed by your healthcare provider. Please see full Prescribing Information and Medication Guide.

Jornay PM is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older. It is a federally controlled substance (CII) because it contains methylphenidate, which can be a target for people who abuse prescription medicines or street drugs. Keep Jornay PM in a safe place to prevent misuse and abuse. Selling or giving away Jornay PM may harm others and is against the law. Tell your healthcare provider if you or your child has ever abused or been dependent on alcohol, prescription medicines, or street drugs.

[13] Spelling uncertain.

5. Public comment and therapeutic and clinical drug reviews on new drugs to be reviewed for the Medicaid PDL: (Company websites or other reliable information was used to research/report on the drugs listed below. In some cases, limited information was available.)

Nourianz (oral)/Antiparkinson's agents. From the company website: Nourianz is a prescription medicine used with levodopa and carbidopa to treat adults with Parkinson's disease (PD) who are having "off" episodes.

Public Comment. None offered.

Proair Digihaler (inhalation)/Bronchodilators, beta agonist. ProAir® DigihalerTM inhalation powder is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease. For treatment of acute episodes of bronchospasm or prevention of symptoms associated with bronchospasm, the recommended dosage for adults and children 4 years of age or older is 2 inhalations repeated every 4 to 6 hours. More frequent administration or a larger number of inhalations is not recommended. In some patients, 1 inhalation every 4 hours may be sufficient.

ProAir Digihaler is indicated for the prevention of exercise-induced bronchospasm in patients four years of age and older. For prevention of exercise-induced bronchospasm, the recommended dosage for adults and children four years of age or older is two inhalations 15 to 30 minutes before exercise.

Public Comment.

A representative from the company made himself available to answer questions. The anticipated launch date will be sometime this year.

Duaklir Pressair (inhalation)/chronic obstructive pulmonary disease agents— Duaklir Pressair (aclidinium bromide and formoterol fumarate) is a combination of an anticholinergic and a long-acting beta2-adrenergic agonist (LABA) indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Common side effects of Duaklir Pressair include:

- upper respiratory tract infection,
- headache,
- back pain,
- cough,
- sinusitis,
- influenza,
- tooth abscess,

- insomnia,
- dizziness,
- dry mouth,
- sore throat,
- muscle spasms,
- musculoskeletal pain,
- joint pain,
- pain in extremities,
- urinary tract infection (UTI), and
- increased blood creatine phosphokinase

The dose of Duaklir Pressair is 400 mcg/12 mcg, twice daily (once in the morning and once in the evening). Duaklir Pressair may interact with other adrenergic drugs, xanthine derivatives, steroids, diuretics or non-potassium sparing diuretics, monoamine oxidase inhibitors (MAOIs), tricyclic antidepressants, beta-blockers, QTc prolonging drugs, or anticholinergics. Tell your doctor all medications and supplements you use. Tell your doctor if you are pregnant or plan to become pregnant before using Duaklir Pressair; it is unknown how it would affect a fetus. It is unknown if Duaklir Pressair passes into breast milk. Consult your doctor before breastfeeding.

Public Comment. None offered.

Rybelsus (oral)/Hypoglycemics, incretin mimetics/enhancers – Rybelsus is a prescription medicine that may help improve blood sugar. If you have Type 2 diabetes, controlling your blood sugar is important. Healthy eating, staying active, and taking the diabetes medicine(s) prescribed by your healthcare provider all work together to help you reach your blood sugar goals.

Public Comment.

A representative from the company stated that the drug was approved in 2019 by the FDA. She read from the company website. Click the link above for more information on the drug, including Black Box warnings and side effects. The company requested the drug be included in the PDL.

Fiasp Penfill (subcutaneous) / Hypoglycemics, insulin and related agents—Fiasp (The insulin aspart, or "Fiasp®", in Fiasp® Penfill®) is a fast-acting insulin used to treat diabetes mellitus in adults. Diabetes mellitus is a condition where your pancreas does not produce enough insulin to control your blood sugar (glucose) level. Extra insulin is therefore needed.

There are two types of diabetes mellitus:

- type 1 diabetes
- type 2 diabetes

Patients with type 1 diabetes always require insulin to control their blood sugar levels.

Some patients with type 2 diabetes may also require insulin after initial treatment with diet, exercise and tablets.

Fiasp® lowers your blood sugar level after injection. When injected under your skin, Fiasp® has a faster onset of action than NovoRapid®. Fiasp® can be injected at the start of a meal, with an option to inject up to 20 minutes after starting a meal. A maximum effect occurs between 1 and 3 hours after the injection and the effect lasts for 3-5 hours.

A company representative stated this drug has been reviewed in the past. They stated that a pediatric indication has been approved. It is now available for adults and children. For more information, follow the item link above. They requested to be added to the PDL.

Xembify (subcutaneous)/immune globulins–Xembify (immune globulin subcutaneous, human- klhw) is a 20% immune globulin solution for subcutaneous injection indicated for treatment of Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older. XEMBIFY (immune globulin subcutaneous, human- klhw) is a 20% immune globulin solution for subcutaneous injection indicated for treatment of Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older. XEMBIFY (immune globulin subcutaneous, human- klhw) is a 20% immune globulin solution for subcutaneous injection indicated for treatment of Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older.

Public Comment. None offered.

Relafen DS (oral)/nonsteroidal anti-inflammatory drugs— Clinical Pharmacology Nabumetone is a non-steroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic properties in pharmacologic studies.

Public Comment. None offered.

6. Therapeutic and clinical drug reviews and updates: Matt Lennertz, Pharm. D., Magellan Medicaid Administration.

Acne Agents Topical: Duac has been discontinued and a generic is available; Aklief, a retinoid acne agent has been approved for ages nine and above.

Angiotensin modulator: Tekturna is now available as a generic.

Antimigraine Other: There have been guideline changes:

- American Headache Society published a position statement in integrating migraine treatment into clinical practice stressing evidence-based therapy and laying out participation criteria.
- American Academy of Neurology and American Headache society offered new guidelines for pharmaceutical pediatric treatment for migraine.

Antimigraine Agents, Triptans: There is a new product, Tosymra, for treatment in adults. It is a 10-milligram spray.

Immunomodulators, atopic dermatitis: Dupixent is now approved for mild to moderate dermatitis in patients 12 years of age or older.

Neuropathic pain:

- Lyrica is now approved for adjunctive therapy for partial onset seizures from one month to under four years of age. Lyrica is also available as a generic.
- Drizalma Sprinkle has been approved for major depressive disorder in adults, general anxiety disorder, diabetic neuropathy, skeletal muscular pain.
- Cautions were released for breathing problems for patients using gabapentin, pregabalin with risk factors for a number of patients.

Platelet aggregation inhibitors: Yosprala has been relaunched by Genus Lifesciences.

Proton pump inhibitors: There has been an update to the International Consensus for the management of patients with nonvariceal upper GI bleeding pharmacological management.

Smoking cessation: Zyban has been discontinued.

The Speaker then described the individual drugs presented above that did not have a speaker. *Texas Insight has already summarized this information for our readers. See above.*

7. 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 Drug Utilization Review (DUR) Board may meet in executive session on one or more items listed under new business as permitted by the Texas Open Meetings Act.

8. Announcements of drugs recommended for the Medicaid PDL: Matt Lennertz, Pharm. D., Magellan Medicaid Administration. ***Only changes have been noted below.***

a. Acne agents, oral—No recommended changes.

b. Acne agents, topical—

- Aklief recommended as non-preferred.
- Duac recommended as preferred.
- Clindagel recommended as preferred.
- Tretinoin gel (Generic) recommended as preferred.

c. Analgesics, narcotics long—

- Xtampza ER recommended as preferred.

d. Analgesics, narcotics short—No recommended changes.

e. Angiotensin modulator combinations—No changes.

f. Angiotensin modulators—No Changes.

g. Antimigraine agents, other—Aimovig recommended as preferred.

h. Antimigraine agents, triptans—Tosymra recommended as non-preferred.

i. Bladder relaxant preparations—No recommended changes.

j. Glucagon agents—

- GlucaGen recommended as preferred.
- Glucagon emergency recommended as preferred.
- Proglycem Suspension recommended as preferred.

k. H. Pylori treatment—No changes.

l. Immunomodulators, atopic dermatitis—No changes.

m. Intranasal rhinitis agents—No changes.

n. Movement disorders—

- Ingrezza recommended as preferred.
- Ingrezza Initiation Pack recommended as preferred.

o. Neuropathic pain—

- Drizalma Sprinkle recommended as non-preferred.
- Lyrica Capsule recommended as nonpreferred.
- Pregabilin Capsule (AG) recommended as preferred.
- Pregabilin Capsule recommended as preferred.

p. Phosphate binders—No changes.

q. Platelet aggregation inhibitors—No recommended changes.

r. Progestins for cachexia—No recommended changes.

s. Proton pump inhibitors—No recommended changes.

t. Smoking cessation—Nicorette Gum and Lozenge recommended as non-preferred.

u. Stimulants and related agents—

- Adderrall XR recommended as non-preferred.
- Amphetamine Salt Combo (AG) recommended as preferred.
- Amphetamine Salt Combo recommended as preferred.
- Jornay recommended for non-preferred.

All the single products reviewed were recommended for nonpreferred.

MOTION: *Accept the recommendations as presented – prevailed*.

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