

# HHSC: Drug Utilization Review Board, Part One

**January 21, 2022** 



<u>Drug Utilization Review Board</u> develops and submits recommendations for (<u>Preferred Drugs | Vendor Drug Program (txvendordrug.com)</u> 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. The DUR board is composed of 20 total members: 17 physicians and pharmacists providing services across the entire population of Medicaid and representing different specialties; two representatives from Medicaid managed care organizations as nonvoting members; and a consumer advocate representing people enrolled in the program.

## **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. Tonche-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)
- Natalie N. Vanek, M.D. (Houston) New Member
- Kathryn L. Velasquez, Pharm. D. (Houston) **New Member**
- Carlos Viesca, M.D. (El Paso)

#### **Managed care representatives**

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

#### **Consumer advocate**

• Dennis A. Borel (Austin)



- **1. Call to order**. The meeting was convened by the Chair, Dr. Robert Hogue. A quorum was present.
- **2.** Consideration of November 12, 2021, draft meeting minutes. The minutes were approved as drafted.
- 3. <u>Announcement: Drug Utilization Review Board Conflict of Interest Policy</u>
  Review Please follow the link for detail.
- **4.** HHS Ethics Policy refresher training for the board Please follow the links for detail.

## 5. Public comment on the drug classes to be reviewed for the Medicaid Preferred Drug List (PDL):

Acne Medications. Source Mayo Clinic

**Topical medications** The most common topical prescription medications for acne are:

- **Retinoids and retinoid-like drugs.** Drugs that contain retinoic acids or tretinoin are often useful for moderate acne. These come as creams, gels and lotions. Examples include tretinoin (Avita, Retin-A, others), adapalene (Differin) and tazarotene (Tazorac, Avage, others). You apply this medication in the evening, beginning with three times a week, then daily as your skin becomes used to it. It prevents plugging of hair follicles. Do not apply tretinoin at the same time as benzoyl peroxide.
- Topical retinoids increase your skin's sun sensitivity. They can also cause dry skin and redness, especially in people with skin of color. Adapalene may be tolerated best.
- **Antibiotics.** These work by killing excess skin bacteria and reducing redness and inflammation. For the first few months of treatment, you may use both a retinoid and an antibiotic, with the antibiotic applied in the morning and the retinoid in the evening. The antibiotics are often combined with benzoyl peroxide to reduce the likelihood of developing antibiotic resistance. Examples include clindamycin with benzoyl peroxide (Benzaclin, Duac, others) and erythromycin with benzoyl peroxide (Benzamycin). Topical antibiotics alone aren't recommended.
- **Azelaic acid and salicylic acid.** Azelaic acid is a naturally occurring acid produced by a yeast. It has antibacterial properties. A 20% azelaic acid cream or gel seems to be as effective as many conventional acne treatments when used twice a day. Prescription azelaic acid



(Azelex, Finacea) is an option during pregnancy and while breast-feeding. It can also be used to manage discoloration that occurs with some types of acne. Side effects include skin redness and minor skin irritation.

- Salicylic acid may help prevent plugged hair follicles and is available as both wash-off and leave-on products. Studies showing its effectiveness are limited. Side effects include skin discoloration and minor skin irritation.
- **Dapsone.** Dapsone (Aczone) 5% gel twice daily is recommended for inflammatory acne, especially in women with acne. Side effects include redness and dryness.
- Evidence is not strong in support of using zinc, sulfur, nicotinamide, resorcinol, sulfacetamide sodium or aluminum chloride in topical treatments for acne.

#### **Oral medications**

- **Antibiotics.** For moderate to severe acne, you may need oral antibiotics to reduce bacteria. Usually the first choice for treating acne is a tetracycline (minocycline, doxycycline) or a macrolide (erythromycin, azithromycin). A macrolide might be an option for people who can't take tetracyclines, including pregnant women and children under 8 years old.
  - Oral antibiotics should be used for the shortest time possible to prevent antibiotic resistance. And they should be combined with other drugs, such as benzoyl peroxide, to reduce the risk of developing antibiotic resistance.
  - Severe side effects from the use of antibiotics to treat acne are uncommon. These drugs do increase your skin's sun sensitivity.
- Combined oral contraceptives. Four combined oral contraceptives are approved by the FDA for acne therapy in women who also wish to use them for contraception. They are products that combine progestin and estrogen (Ortho Tri-Cyclen 21, Yaz, others). You may not see the benefit of this treatment for a few months, so using other acne medications with it for the first few weeks may help. Common side effects of combined oral contraceptives are weight gain, breast tenderness and nausea. These drugs are also associated with increased risk of cardiovascular problems, breast cancer and cervical cancer.
- **Anti-androgen agents.** The drug spironolactone (Aldactone) may be considered for women and adolescent girls if oral antibiotics aren't helping. It works by blocking the effect of androgen hormones on the oil-producing glands. Possible side effects include breast tenderness and painful periods.
- **Isotretinoin.** Isotretinoin (Amnesteem, Claravis, others) is a derivative of vitamin A. It may be prescribed for people whose moderate or severe acne hasn't responded to other treatments. Potential side effects of oral isotretinoin include inflammatory bowel disease, depression and severe birth defects. All people receiving isotretinoin must participate in an FDA-approved risk management program. And they'll need to see their doctors regularly to monitor for side effects.



## Acne agents, oral

**No Public Comment** 

## Acne agents, topical.

**No Public Comment** 

**Analgesics.** Analgesics are medicines that are used to relieve pain. They are also known as painkillers or pain relievers. Technically, the term analgesic refers to a medication that provides relief from pain without putting you to sleep or making you lose consciousness.

Many different types of medicines have pain-relieving properties, and experts tend to group together those medicines that work in a similar way. Two of the most common groups of pain killers are nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids (narcotics), but there are many more. Sometimes experts will group analgesics together based on their potency, or how strong they are. An example of this is the World Health Organization's analgesic ladder. This step-wise approach to pain relief recommends non-opioid analgesics such as acetaminophen and NSAIDs for mild-tomoderate pain; weak opioids, such as codeine, dihydrocodeine or tramadol, for moderate-to-severe pain; and stronger opioids, such as oxycodone and morphine, for severe pain. (Source: Drugs.com)

## Analgesics, narcotics long.

**No Public Comment** 

## **Analgesics, narcotics short**.

**No Public Comment** 

**Angiotensin modulators**. Angiotensin II receptor blockers help relax your veins and arteries to lower your blood pressure and make it easier for your heart to pump blood.

Angiotensin is a chemical in your body that narrows your blood vessels. This narrowing can increase your blood pressure and force your heart to work harder.

Angiotensin II receptor blockers block the action of angiotensin II. As a result, the medication allows your veins and arteries to widen (dilate). (Source: Drugs.com)

## **Angiotensin modulator combinations.**

**No Public Comment** 



## **Angiotensin modulators.**

**No Public Comment** 

Antiparkinson's agents Antiparkinson agents aim to replace dopamine either by drugs that release dopamine or those that mimic the action of dopamine. Parkinson's disease is a degenerative disorder of movement that occurs due to dopamine deficiency in the basal ganglia. Antiparkinson agents attempt to replace dopamine and treat or halt the symptoms such as tremor, hypokinesia, and so on. (Source: Drugs.com)

#### **No Public Comment**

**Antimigraine Agents.** Antimigraine agents are used to treat <u>migraine</u> headaches. Migraines are different from other headaches because they occur with symptoms such as <u>nausea</u>, <u>vomiting</u>, or sensitivity to light. Some people who get migraines have warning symptoms, called an aura, before the actual <u>headache</u> begins. Pain relieving drugs can be taken as soon as the pain begins and include agents in the drug classes such as ergots, triptans and NSAID's. (Source: Drugs.com)

## Antimigraine agents, other.

#### **Public Comment**

**David Miley, Teva Pharmaceuticals** spoke in support of (Ajovy) <u>Preventive Treatment of Migraine-AJOVY®</u> (fremanezumab-vfrm) injection speaking from information on the company website. Please follow the link for detailed information.

Jan McLean, Amgen Medical Affairs spoke in support of (Aimovig) Amgen Aimovig (aimovigcopaycard.com) speaking from information on the company website. Please follow the link for detailed information.

**Chelsea LaRue, Biohaven Pharmaceuticals** spoke in support of (Nurtec ODT) <u>Acute Treatment of Migraine and Preventive Treatment of Episodic Migraine | Nurtec® ODT (rimegepant)</u> speaking from information on the company website. Please follow the link for detailed information.

**Christopher** \_\_\_\_\_\_ (inaudible) Abvie, spoke in support of (Ubrelvy) What is UBRELVY® (ubrogepant)? Acute Treatment for Migraine Attacks speaking from information on the company website. Please follow the link for detailed information.



He also spoke in support of (Qulipta) <u>Episodic Migraine Preventive Treatment | QULIPTA™</u> (<u>atogepant) HCP (quliptahcp.com)</u> speaking from information on the company website. Please follow the link for detailed information.

**Michael Shepherd, Eli Lilly** spoke in support of (Emgality) Preventive Migraine Treatment | Emgality® (galcanezumab-gnlm) speaking from information on the company website. Please follow the link for detailed information.

He also spoke in support of (Reyvow) <u>Acute Medication Treatment for Migraine | REYVOW®</u> (<u>lasmiditan</u>) speaking from information on the company website. Please follow the link for more detailed information.

There was also written testimony made available.

## **Antimigraine agents, triptans.**

#### **No Public Comment**

Bladder relaxant preparations Medications for Urinary Frequency
Other names: Detrusor instability; Irritable Bladder; Unstable Bladder
Overactive bladder is a problem with bladder storage function that causes a sudden urge to urinate.
The urge may be difficult to suppress, and overactive bladder can lead to the involuntary loss of urine (incontinence). (Source: Drugs.com)

#### **No Public Comment**

Glucagon agents Glucagon is a hormone that increases blood sugar levels. It also slows involuntary muscle movements of the stomach and intestines that aid in digestion. Glucagon is a prescription medicine used to treat very low blood sugar (hypoglycemia). Glucagon is also used to stop stomach movement during radiologic (x-ray) examinations undertaken to diagnose certain disorders of the stomach or intestines. Glucagon is available as an auto-injector, prefilled syringe, or injection vial. (Source: Drugs.com)



#### **Public Comment**

**Kunahl Rumani, (inaudible)** spoke in support of (Gvoke) <u>Gvoke HypoPen® (glucagon injection): For Very Low Blood Sugar (gvokeglucagon.com)</u> speaking from information on the company website. Please follow the link for more detailed information.

**Jeremy Schmidt, Family nurse practitioner** spoke in support of Gvoke.

**Dana Robar, Diabetes Educator and Family Member** shared a personal success story about Glucagon. Recommended approving all options.

**Emily Smith, Zealand Pharma** spoke in support of (Zegalogue) <u>ZEGALOGUE® | Very Low Blood</u> <u>Sugar Treatment by Injection</u> speaking from information on the company website. Please follow the link for more detailed information.

Written testimony was also provided to the Board.

**H. pylori treatment** *Helicobacter pylori* (*H.pylori*) is a type of bacteria that can infect your stomach and digestive tract. Infection is common, and more than two-thirds of the world's population is infected, although the rate of infection is declining as more people get access to clean water and sanitation.

Most people with *H. pylori* become infected as a child and most don't know they are infected as it can live harmlessly in your body, without causing any symptoms. In other people, *H. pylori* slowly attacks the lining of the stomach and is a common cause of dyspepsia (indigestion).

Continued damage can lead to the development of gastric ulcers, which are sores or erosions in the lining of your stomach. For some people, an infection can lead to stomach cancer. (Source: Drugs.com)

#### **Public Comment**

**Wendy Borgleson, Redhill Biopharma** spoke in support of Talicia <u>RedHill Biopharma - Our</u> <u>Medicines - Talicia®</u> speaking from information on the company website. Please follow the link for more detailed information.



Immunomodulators, atopic dermatitis Other names: Allergic Dermatitis; Contact Dermatitis; Dermatitis, Allergic; Dermatitis, Contact Atopic dermatitis is a skin condition characterized by a recurring rash associated with itch. Most people with atopic dermatitis have at least one of the following other conditions: hay fever, asthma, chronic urticaria, or food allergies. Dermatitis is another name for skin inflammation and the word "eczema" may be used interchangeably with dermatitis; therefore, atopic dermatitis is the same as atopic eczema. Atopic dermatitis is common among certain families and it usually starts in early childhood, although it can occur at any age. It is the most common form of eczema seen in children. The exact cause of atopic dermatitis is not known, but researchers believe it may involve genetics, a defect in the skin's barrier, the environment, and/or the immune system. (Source: Drugs.com)

#### **Public comment**

**Min Nguyen, Pfizer** spoke in support of (Eucrisa) <u>Homepage (pfizerpro.com)</u> speaking from information on the company website. Please follow the link for more detailed information.

**Intranasal rhinitis agents** Treatment of nonallergic rhinitis depends on how much it bothers you. For mild cases, home treatment and avoiding triggers might be enough. For more-bothersome symptoms, certain medications may provide relief, including:

- **Saline nasal sprays.** Use an over-the-counter nasal saline spray or homemade saltwater solution to flush the nose of irritants and help thin the mucus and soothe the membranes in your nose.
- **Corticosteroid nasal sprays.** If your symptoms aren't easily controlled by decongestants or antihistamines, your doctor might suggest a nonprescription corticosteroid nasal spray, such as fluticasone (Flonase Allergy Relief) or triamcinolone (Nasacort Allergy 24 Hour). Prescription nasal sprays also are available.

Corticosteroid medications help prevent and treat inflammation associated with some types of nonallergic rhinitis. Possible side effects include nasal dryness, nosebleeds, headaches and throat dryness.

• **Antihistamine nasal sprays.** Try a prescription antihistamine spray such as azelastine (Astelin, Astepro) or olopatadine hydrochloride (Patanase). While oral antihistamines don't seem to help nonallergic rhinitis, nasal sprays containing an antihistamine might reduce symptoms.



- **Anti-drip anticholinergic nasal sprays.** The prescription drug ipratropium is often used as an asthma inhaler medication. But it's now available as a nasal spray and can be helpful if a runny, drippy nose is your main complaint. Side effects can include nosebleeds and drying of the inside of your nose.
- Decongestants. Available over-the-counter or by prescription, examples include
  pseudoephedrine-containing drugs (Sudafed 12 Hour) and phenylephrine (Neo-Synephrine,
  others). These medications help narrow the blood vessels, reducing congestion in the nose.
  Possible side effects include high blood pressure, heart pounding (palpitations) and
  restlessness.

Over-the-counter oral antihistamines, such as diphenhydramine (Benadryl), cetirizine (Zyrtec Allergy), fexofenadine (Allegra Allergy) and loratadine (Alavert, Claritin), typically don't work nearly as well for nonallergic rhinitis as they do for allergic rhinitis.

In some cases, surgical procedures might be an option to treat complicating problems, such as a deviated nasal septum or persistent nasal polyps (Source: Mayo Clinic)

#### **No Public Comment**

<u>Movement disorders</u> The term movement disorders refers to a group of nervous system (neurological) conditions that cause you to have abnormal voluntary or involuntary movements, or slow, reduced movements. <u>MayoClinic</u>

#### **Symptoms**

Parkinson's disease symptoms include tremors, muscle rigidity, slow movement, and impaired balance and coordination known as postural instability. However, each of these symptoms is shared by other movement disorders. Read more on everydayHEALTH

#### Causes

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. Read more on MedlinePlus

#### **Treatments**

Depending on your specific condition, treatment options may include:

- Medications. Your doctor may prescribe medications to control and relieve symptoms.
- Botox (botulinum toxin) injections.
- Other <u>Read more on MayoClinic</u>

#### **Public Comment**



**David Miley, Teva Pharmaceuticals** spoke in support of (Austedo) <u>Tardive Dyskinesia Treatment, Causes, & Symptoms (austedo.com)</u> speaking from information on the company website. Please follow the link for more detailed information.

**John Dison, Neurocrine Biosciences** spoke in support of (Ingrezza) <u>TD Assessment & Management | INGREZZA® (valbenazine) capsules | For Professionals (ingrezzahcp.com)</u> speaking from information on the company website. Please follow the link for more detailed information.

**Amber Hoberg, representing herself as a nurse practitioner** spoke in support of medications for Tardive Dyskinesia mentioning Austedo.

**Greg Hansch, NAMI Texas** spoke in support of retention of the preferred medications already on the PDL.

**Neuropathic pain** The International Association for the Study of Pain (2011) defines neuropathic pain as 'pain caused by a lesion or disease of the <u>somatosensory</u> nervous system'. It can result from damage anywhere along the neuraxis: peripheral nervous system, spinal or supraspinal nervous system<sup>[1]</sup>.

- 1. Central neuropathic pain is defined as 'pain caused by a lesion or disease of the central somatosensory nervous system'.
- 2. Peripheral neuropathic pain is defined as 'pain caused by a lesion or disease of the peripheral somatosensory nervous system'.

Neuropathic pain is very challenging to manage because of the heterogeneity of its aetiologies, symptoms and underlying mechanisms.

Conditions frequently associated with neuropathic pain can be categorized into two major group, pain due to damage in the central nervous system and pain due to damage to the peripheral nervous system. (Source: physio-pedia)

#### **No Public Comment**

**Oncology** A branch of medicine that specializes in the diagnosis and treatment of cancer. It includes medical oncology (the use of chemotherapy, hormone therapy, and other drugs to treat cancer), radiation oncology (the use of radiation therapy to treat cancer), and surgical oncology (the use of surgery and other procedures to treat cancer).



## Oncology, oral - breast

#### **Public Comment**

**Elise Panchek, Eli Lilly** spoke in support of (Verzenio) <u>HR+ HER2- Early and Metastatic Breast</u> <u>Cancer Treatment | Verzenio® (abemaciclib)</u> speaking from information on the company website. Please follow the link for more detailed information.

Written testimony was also provided.

## Oncology, oral - hematologic

#### **Public Comment**

**Lee Ding, Medical Affairs Ed BeiGene** spoke in support of (Brukinsa) <u>BRUKINSA® (zanubrutinib)</u> <u>BTK Inhibitor official BeiGene website</u> speaking from information on the company website. Please follow the link for more detailed information. He spoke on another product that was inaudible

## Oncology, oral - lung

No Public Comment but written testimony was provided.

Oncology, oral - other

**No Public Comment** 

Oncology, oral - prostate

**No Public Comment** 

Oncology, oral - renal cell

No Public Comment but written testimony was provided



## Oncology, oral - skin

#### No Public Comment but written testimony was provided

Phosphate binders Phosphate binders are used to decrease the absorption of phosphate from food in the digestive tract. They are used when there is an abnormally high blood phosphate level (hyperphosphatemia) which can be caused by impaired renal phosphate excretion or increased extracellular fluid phosphate loads. Phosphate binders react with phosphate to form an insoluble compound, making it unable to be absorbed from the gastrointestinal tract. When taken regularly with meals, phosphate binders lower the concentration of phosphate in serum. (Source: Drugs.com)

#### **No Public Comment**

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 cyclooxygenase, 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. (Source: Drugs. Com)

#### **No Public Comment**

<u>Potassium binders</u> Potassium binders are drugs that bind to extra potassium in your bowels. This excess potassium is then removed from your body through your stool. These medications often come in a powder that you mix with water and drink with a meal. They're sometimes taken rectally with an enema.

There are various types of potassium binders made with different ingredients. It's important to follow your medication's instructions carefully. Always take a potassium binder 6 hours before or after taking any other medications.

Your doctor will likely suggest other measures to help manage your potassium levels. These may include:

• going on a low-potassium diet



- reducing or adjusting the dosage of any medication that causes your body to retain potassium
- prescribing a diuretic to increase your urine output and flush out excess potassium
- dialysis

There are several types of potassium binders your doctor may prescribe:

- sodium polystyrene sulfonate (SPS)
- calcium polystyrene sulfonate (CPS)
- patiromer (Veltassa)
- sodium zirconium cyclosilicate (ZS-9, Lokelma)

Patiromer and ZS-9 are newer types of potassium binders. They're safe to take with medications often prescribed for heart disease that can increase the risk of hyperkalemia. (Source: Healthline.com)

#### **Public Comment**

**Keith Semisky, Astra Zeneca** spoke in support of Lokelma <u>Hyperkalemia Treatment | LOKELMA®</u> (sodium zirconium cyclosilicate) 5g | 10g for oral suspension | For HCPs (lokelma-hcp.com) speaking from information on the company website. Please follow the link for more detailed information

Progestins for cachexia predominantly affects people in the late stages of serious diseases like cancer, HIV or AIDS, and congestive heart failure. The Society on Sarcopenia, Cachexia and Wasting Disorders defines cachexia as "a multifactorial syndrome characterized by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment."

The disease causes involuntary weight loss, muscle wasting, and often a decrease in body fat. The loss of skeletal muscle may lead to physical weakness and impairment. According to estimates, more than 160,000Trusted Source people are hospitalized with a cachexia diagnosis every year in the United States. (Source: Medical News Today)

## **No Public Comment**

<u>Proton pump inhibitors</u> PPIs reduce the production of acid by the stomach. They work by irreversibly blocking an enzyme called H+/K+ ATPase which controls acid production. This enzyme is also known as the proton pump and is found in the parietal cells of the stomach wall. PPIs treat conditions that are caused by either an overproduction of stomach acid or exacerbated by stomach acid. Taking a PPI once a day inhibits around 70% of proton pumps, so a small amount of acid is still available for food digestion.



#### PPIs may be used for the treatment of:

- Acid reflux, also called gastroesophageal reflux disease (GERD)
- Conditions characterized by an overproduction of stomach acid (such as <u>Zollinger-Ellison</u> <u>syndrome</u>)
- <u>Duodenal or stomach ulcers</u> including those caused by <u>NSAIDs</u>
- In combination with certain antibiotics for the eradication of *Helicobacter pylori*, a bacteria associated with duodenal ulcer recurrence
- <u>Erosive esophagitis</u>, and to maintain healing of erosive <u>esophagitis</u>.(Source: Drugs.com)

#### **No Public Comment**

**Smoking cessation** Smoking cessation, usually called quitting smoking or stopping smoking, is the process of discontinuing tobacco smoking. Tobacco smoke contains nicotine, which is addictive and can cause dependence. As a result, nicotine withdrawal often makes the process of quitting difficult.

In the U.S., about 70% of smokers would like to quit smoking, and 50% report having made an attempt to do so in the past year. Smoking is the leading preventable cause of death worldwide. Smoking cessation significantly reduces the risk of dying from smoking-related diseases such as coronary heart disease, chronic obstructive pulmonary disease (COPD), and lung cancer.

Many strategies can be used for smoking cessation, including abruptly quitting without assistance ("cold turkey"), cutting down then quitting, behavioral counseling, and medications such as bupropion, cytisine, nicotine replacement therapy, or varenicline. Most smokers who try to quit do so without assistance. However, only 3–6% of quit attempts without assistance are successful long-term. 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.[8] A meta-analysis from 2018, conducted on 61 randomized controlled trials, showed that among people who quit smoking with a cessation medication (and some behavioral help), approximately 20% were still nonsmokers a year later, as compared to 12% who did not take medication.

In nicotine-dependent smokers, quitting smoking can lead to symptoms of nicotine withdrawal such as nicotine cravings, anxiety, irritability, depression, and weight gain.[10]:2298 Professional smoking cessation support methods generally attempt to address nicotine withdrawal symptoms to help the person break free of nicotine addiction. (Source: Wikipedia)



#### **No Public Comment**

**Stimulants and related agents** CNS stimulants (CNS stands for central nervous system) are medicines that stimulate the brain, speeding up both mental and physical processes. They increase energy, improve attention and alertness, and elevate blood pressure, heart rate and respiratory rate. They decrease the need for sleep, reduce appetite, improve confidence and concentration, and lessen inhibitions. Experts aren't exactly sure how CNS stimulants work, although they suspect they increase levels of one or more neurotransmitters in the brain, such as dopamine, norepinephrine, or serotonin. They may also have other effects, depending on the actual drug. For example, phentermine possibly indirectly increases leptin levels – leptin is a substance that tells us we feel full.

CNS stimulants may be useful for the treatment of certain conditions characterized by symptoms such as prolonged fatigue, inability to concentrate, or excessive sleepiness. CNS stimulants may also be used to help with weight loss in people who are morbidly obese. CNS stimulants have been used for the following conditions:

- Attention deficit disorder
- Chronic <u>lethargy</u>
- Morbid <u>obesity</u> unresponsive to other treatments
- Narcolepsy
- Neonatal apnea
- Postural orthostatic tachycardia syndrome
- Prolonged <u>depression</u> that is unresponsive to traditional antidepressants

Unfortunately, some people misuse CNS stimulants for their ability to increase energy levels. Some CNS stimulants also create a brief feeling of euphoria or temporarily increase self-confidence. (Source: Drugs.com)

#### **Public Comment**

**Daniel Tan, Child Psychiatrist** testified for two reasons: for Foster children who he treats and in support of (Jornay PM) <u>JORNAY PM®</u> (<u>methylphenidate HCI) | Official Site</u>.

Patrick Harvey, Supernus Medical Affairs spoke in support of (Qelbree) What is Qelbree™? | Qelbree™ For ADHD speaking from information on the company website. Please follow the link for more detailed information.



Mathew Bronze, Child Psychiatrist spoke in support of (Azstarys) <u>Treating Your ADHD With</u>
AZSTARYS™

**Lance Lewis, company representative** spoke in support of (Azstarys) <u>Treating Your ADHD With AZSTARYS™</u> speaking from information on the company website. Please follow the link for more detailed information.

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

<u>Bylvay capsule (oral) / Bile salts</u> A company representative commented on <u>Home – Patients |</u>
<u>Bylvay</u>

<u>Bylvay pellet (oral) / Bile salts</u> A company representative commented on <u>Home – Patients |</u>
<u>Bylvay</u>

Invega Hafyera (intramuscular) / Antipsychotics A company representative commented on About INVEGA HAFYERA™ | INVEGA™ (paliperidone palmitate) LAI Portfolio (janssenschizophreniainjections.com)

<u>Livmarli (oral) / Bile salts</u> A company representative commented on <u>LIVMARLI™ (maralixibat)</u> | The First and Only FDA-Approved Treatment for Alagille Syndrome

Loreev XR capsule ER 24H (oral) / Anxiolytics No public comment but company website is NEW | HCP | LOREEV XR™ (lorazepam) extended-release capsules (loreevxrhcp.com)

<u>Lybalvi (oral) / Antipsychotics</u> A company representative commented on <u>LYBALVI®</u> (olanzapine and samidorphan) Is Now Available | Official Website | Alkermes®

<u>Miconatate OTC (topical) / Antifungals, topical</u> No comment but the Web MD website on Miconatate <u>Topical: Uses, Side Effects, Interactions, Pictures, Warnings & Dosing - WebMD</u>

<u>Mucinex instasoothe cough OTC (oral) / Cough and Cold, non-narcotic No comment but the company website is Mucinex InstaSoothe Sore Throat + Cough Relief | Mucinex USA</u>



Rezurock (oral) / Immunosuppressives, oral A company representative commented on REZUROCK™ (belumosudil) | Official Patient Website

- **7.** Therapeutic and clinical drug reviews and updates: Magellan Medicaid Administration. Updates to the classes were presented verbally but now materials were shared with the public.
- **8. 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.

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