



HHSC: Drug Utilization Review Board (Day 1) October 22, 2020

Call to order. The meeting was called to order by Dr. Hogue, Chair.

Announcement: October DURB two-day meeting process. This is a two-day meeting. Tomorrow will follow the regular process. Today the Board will be looking at the PDL Classes. There will be no action taken by the DUR Board. All the drugs within the new PDL classes will be preferred and will remain available without a Predispose Authorization (PDA) prior authorization.

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

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

Anticonvulsants keep the nerve cell impulses to a normal level so they don't become excessive and uncontrolled, which is why they are used in seizure disorders and [epilepsy](#). The way anticonvulsants control the nerve impulses is not fully understood but is thought to be by their action on neurotransmitters like GABA, or acting on receptors such as glutamate or by changing the electrical channels in the nerve cell. (Drugs.com)

Public Comment.

Kendra Davies, Greenwich Biosciences, spoke on cannabidiol ([Epidiolex®](#)). The presenter read from the package insert and website information. Please follow the link for detailed information about this product.

Derek Ems, UCB, spoke on midazolam nasal spray ([Nayzilam®](#)). The presenter read from the package insert and website information. Please follow the link for detailed information about this product.

Representative from UCB, spoke on brivaracetam ([Briviact®](#)). The presenter read from the package insert and website information. Please follow the link for detailed information about this product.

Chele Diamond, NAMI Texas, supported open access for all Texans with mental illness including Bipolar disorder. This would provide flexibility for providers to employ the correct and most effective therapeutic program. NAMI Texas believes that the clinical judgement of treatment providers is the only criteria that should be used when treating patients.

Representative from Aquestive Therapeutics, spoke on [sympazan](#). The presenter read from the package insert and website information. Please follow the link for detailed information about this product.

Shannon Mendes, Supernus Pharmaceuticals, spoke on [TrokendiXR](#). The presenter read from the package insert and website information. Please follow the link for detailed information about this product. He also addressed the company information for oxcarbazepine extended release ([Oxtellar XR](#)).

Linzy Hendrickson, Biocodex, spoke on stiripentol ([Diacomit](#)). The presenter read from the package insert and website information. Please follow the link for detailed information about this product.

Ronald Kauffman, Zogenix spoke on [Fintepla](#). The presenter read from the package insert and website information. Please follow the link for detailed information about this product.

Jordan Mathews, Mother, commented on her child who failed on 10 medications. She now takes two medications that have been effective.

Sindi Rosales, Epilepsy Foundation, stated they are pleased with the proposal to put all the medications on the PDL. They are concerned with the management of the class. Epilepsy medications are not interchangeable. They support open access to epilepsy medications. The treating physician is in the best position to choose the appropriate medication for a patient.

Scott Perry, MD Epilepsy Foundation of America (and Texas), stated that they should consider repercussions of changing pharmaceuticals in Texas Medicaid. The medication landscape is under constant change.

Michelle Schoonover, UCB, commented on lacosamide ([Vimpat®](#)). The presenter read from the package insert and website information. Please follow the link for detailed information about this product.

Brian Wensel, Sunovion, spoke on eslicarbazepine ([Aptiom](#)). The presenter read from the package insert and website information. Please follow the link for detailed information about this product.

Yssa Dewoody, Ring 14 USA and Rare Epilepsy Network, described her experience with her daughter and how the seizures have never been under control. The need is to reduce seizures but also to reduce side effects as well. Precision medication requires open access. Epilepsy is not a singular event but impacts all aspects of life. We need access to the emergency intranasal medications.

Lauren Sparks, Parent and the Epilepsy Foundation of Texas, related her personal experience with her daughter. Anticonvulsant medications have changed her life, though not all medications are effective. She said she has concerned that medications will be limited in the future if the medications get on the PDL.

Jeanette Hartshorn, MD, Epilepsy Foundation of America, stated that patients need open access to all medications. Selecting the right medication is as much art as science. The cost for limiting access will be higher than keeping open access.

Charles Begley, Professor UT School of Public Health, stated that the lack of seizure control due to inadequate diagnosis can lead to higher costs. The costs are 2-4 times more costly for patients with seizure control compare wo those with seizure control.

Frank Gilliam, UT Rio Grande Valley and Epilepsy Foundation of South Texas, commented on the need for addressing the adolescent and adult patients. About 50% of people will have their seizures controlled with the first treatment. The 50% of those who are not controlled (3-5 or more seizures per year) have all sorts of socially isolating problems. The goal is to reduce seizure burden. Seizure control has to be balanced against side-effect profiles. Access to drugs or trials should not be a barrier to people and it is a limitation on providing care.

Speaker from the Epilepsy Foundation of Central and South Texas and a Mother of a child with Epilepsy, related the story of her child and the challenges he faced. She stated it was hard work finding the right medication. She asked for open access for all medications in this class.

Hemophilia treatment – (i.e., antihemophilic). Hemophilia is a bleeding disorder caused by a problem in your blood's ability to form a clot. Hemophilia causes you to bleed more and longer than normal. Certain blood cells and substances normally form clots and stop you from bleeding too much. These include platelets, clotting factors, vitamin K, and fibrinogen. Platelets are a type of blood cell that helps form blood clots. Clotting factors are proteins that work with platelets to clot the blood. Hemophilia usually occurs only in men.

The 2 common types of hemophilia are hemophilia A and hemophilia B. Hemophilia A means the level of clotting factor VIII (eight) is lower than normal. Hemophilia B means the level of clotting factor IX (nine) is lower than normal. Hemophilia can be mild, moderate, or severe.

This is based on the amount of clotting factor or the kind of bleeding episodes you have. A bleeding episode is bleeding that lasts longer than several minutes. Bleeding episodes can occur with or without injury.

- **Mild:** You have some clotting factor activity in your blood. You may only have severe bleeding after surgery or a severe injury.
- **Moderate:** You have a low level of clotting factor activity in your blood. You may have bleeding episodes that occur suddenly. You are likely to bleed heavily if you have any type of injury or surgery.
- **Severe:** You have very little clotting factor in your blood. You may have sudden bleeding in your joints, muscles, and other body areas.

You are born with hemophilia. Hemophilia A and B are usually inherited. This means that hemophilia runs in your family. The gene is passed from a parent to the child. A woman may carry and pass the gene that causes hemophilia, but not have hemophilia. In some cases, it is not inherited. (Drugs.com)

Public Comment.

Jaimie Partridge, Bayer Healthcare, spoke on [Jivi](#). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

Eardie Curry, Genentech, spoke on emicizumab-kxwh ([Hemlibra](#)). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

Mr. Curry then went on to address two other medications that were in different classes:

[Ocrevus](#) is used to treat **Multiple Sclerosis**. The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

[Entrectinib \(Rozlytrek\)](#) is used to treat **lung cancer**. The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

Courtney Walker, Novo Nordisk, spoke on their Hemophilia product antihemophilic factor – recombinant, glycopegylated-exei (coagulation factor VIII concentrate) ([Esperoct](#)). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product. Mr. Walker also addressed [NovoVII](#), [Novoeight](#), [Tretten](#), and [Rebinyln](#).

Representative from Sanofi Genzyme, spoke on antihemophilic factor VIII – recombinant, FC fusion protein ([Eloctate](#)). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product. He also spoke on [Alprolix](#).

The representative also spoke on teriflunomide [Aubagio](#), a Multiple Sclerosis Agent. The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

HIV /AIDS (i.e., antiretroviral). Specialists introduced antiretroviral therapy in 1996 in response to the poor success rate among those taking only one [HIV](#) medication at a time. The beginnings of three-drug antiretroviral treatment marked a turning point in the history of HIV treatment. The new treatment design transformed what used to be a diagnosis with a very poor outlook into a manageable condition.

Antiretroviral therapy has a twofold effect on the body. It increases the number of immune cells while also decreasing the number of virus cells present in the body.

Antiretroviral therapy has the following positive effects on HIV:

- stops it from multiplying in the blood
- reduces viral load, which is the number of HIV copies in the blood
- increases the number of CD4 cells, which are immune cells that HIV targets, to improve immune system function
- slows down and prevents the development of stage 3 HIV, or [AIDS](#)
- prevents transmission
- reduces the severity of complications and increases survival rates
- keeps virus counts low in the blood

When prescribing antiretroviral therapy, healthcare providers [typically use](#) a regimen of three or more drugs for the best chances of lowering the amount of HIV in the body.

A person can, however, talk to their healthcare provider about a single pill that contains several medications.

According to the [Centers for Disease Control and Prevention \(CDC\)](#), antiretroviral therapy can reduce viral load to such an extent that it is undetectable. This means that a person can no longer transmit the virus to another person, even via condomless sex.

This concept is called undetectable = untransmittable, or U=U.

The CDC [advises](#) that people with HIV take antiretroviral medication regardless of their health status or how long they have had HIV.

When a person with HIV uses antiretroviral therapy as their healthcare provider instructs, it can help them live a full, healthy life. (MedicalNewsToday.com).

Public Comment.

Amy Metzner, ViiV Healthcare, spoke on fostemsavir ([Rukobia](#)). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

Glen Roth, Merck, spoke on [Doravirine](#) ([Pifeltro](#)). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

Multiple sclerosis agents. Multiple sclerosis (MS) is a condition that affects the nervous system, including the brain, spinal cord, and optic nerves. Symptoms differ among people with the disease but generally include:

- Balance problems
- Concentration and focusing problems
- Fatigue
- Movement difficulties
- Muscle weakness or spasms
- Pain
- Poor bladder or bowel control
- Vision difficulties (blurred or double vision).

Common medications used to treat multiple sclerosis include [Copaxone](#), [Gilenya](#) and [Tecfidera](#).

MS can affect anyone; however, women are up to 3 times more likely to get it than men. The first symptoms generally happen between the ages of 20 and 40. Some people with mild MS may not need treatment whereas others will have trouble getting around and doing daily tasks. Most people with MS have attacks of symptoms followed by a period of recovery when symptoms improve. In others, the condition gradually progresses with time.

MS happens because a person's immune system attacks the covering that wraps around and protects each nerve (this is called the myelin sheath), although experts are still not exactly sure what triggers this. Without this protective covering, nerves become damaged and inflamed and develop scar tissue (this is called sclerosis). This affects how nerve signals are transmitted and interpreted. In severe disease, nerves may not function at all.

Although MS is not considered a hereditary disease, people can inherit genes that give them a higher risk of developing MS (approximately 200 genes have been identified associated with MS). Smokers are also more likely to develop MS than nonsmokers, and research suggests that some incidences of MS may be triggered by a viral infection, such as the Epstein Barr

virus or human herpes virus 6. MS is also more common in countries furthest from the equator. (drugs.com)

Public Comment.

Doug Whiteman, EMD Serono, spoke on cladribine ([Mavenclad](#)). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

Two MS drugs were covered above as part of combined testimony: [Aubagio](#) and [Ocrevus](#).

Oncology: Cancer is the name given to a group of related diseases characterized by the uncontrolled and excessive growth of abnormal cells. More than 200 different types of cancer have been identified.

When these extra cells form a mass or a solid lump of tissue, it is called a tumor. Most cancers form tumors, but not all do. Tumors may be either **benign** or **cancerous**.

Benign tumors do not spread to other parts of the body and are rarely life-threatening. Many breast lumps, for example, are benign. Benign tumors are not cancer.

Malignant tumors crowd out healthy cells, interfere with bodily functions, and draw nutrients from body tissues. Malignant tumors can also spread to other parts of the body via the blood or lymphatic system, forming satellite tumors, called secondary cancers or metastases. Malignant tumors are cancer.

Cancer can occur anywhere in the body and skin cancer is the most commonly reported cancer. Breast cancer is the next most common cancer in women, and in men, it is prostate cancer. Lung cancer and colorectal cancer are also common cancers that occur in both women and men. Cancer can be classified into one of five types:

- Carcinomas – these begin in the skin or tissues that line the internal organs
- Central nervous system cancers – these develop in the brain and spinal cord
- Leukemias – these begin in the blood and bone marrow
- Lymphomas – these start in the immune system
- Sarcomas – these develop in connective tissue such as the bone, cartilage, fat, or muscle.

Cancers are named according to the origin of the cancer (where it first starts) even if it has spread. For example, if prostate cancer has spread to the liver it is still called metastatic prostate cancer.

How does it start?

Cancer starts when a mutation in a normal cell causes irreversible damage to the cell's DNA. If the normal control mechanisms of the body are unable to contain this cell, then it begins to divide at an abnormally fast rate, leading to more mutations and a mass of cells, all of which can proliferate to form more cells.

Are some people more likely to get cancer than others?

Experts have identified several key factors that make some people more likely than others to develop cancer. The most common ones are:

- **High intake of dietary carcinogens:** Certain foods, including those that are processed, salted, pickled, smoked, charred from a grill or barbecue, or treated with nitrites have been associated with a higher risk of cancer. Saturated fats from red meat are also associated with several different types of cancer, including cancer of the colon, rectum, and prostate gland. You can reduce your risk by not eating processed or burnt meats and eating more fiber, fruit, and vegetables.
- **Genetic predisposition:** Certain types of cancer, such as colon and breast cancer, often run in families, and people can inherit this predisposition towards cancer, although other non-genetic (environmental) factors must be present for cancer to develop
- **Estrogen exposure in women:** Women who are exposed to higher levels of estrogen, either via estrogen-containing medication or naturally through going through menstruation early or menopause late, are at increased risk for some cancers, such as those of the breast, ovaries, or uterus. This risk is reduced in women who have had a baby before the age of 35, who exercise regularly, or who consume a low-fat diet
- **Exposure to carcinogens:** People exposed to certain substances have a higher risk of developing certain types of cancer. There are more than two hundred known carcinogens including alcohol, asbestos, coal tar, diesel exhaust, formaldehyde, tobacco, and UV radiation
- **Exposure to some infectious organisms:** Certain viruses (such as hepatitis B, hepatitis C, and human papillomavirus), bacteria (eg, *Helicobacter pylori*) and parasites (eg, *Schistosoma hematobium*) have been associated with a higher risk of cancer
- **Radiation:** Over-exposure to X rays, nuclear radiation, ultraviolet radiation (from sunlight), and even cosmic radiation (aircrew have higher rates of cancer than non-aircrew) can cause DNA injury that may lead to cancer.

Several other factors also increase the risk of cancer such as chronic inflammation, immunosuppression, and obesity.

If you or someone close to you has been diagnosed with cancer, you may be interested to learn more about cancer and/or what treatments to expect. Click here for more information on:

- [Breast Cancer](#)
- [Cervical Cancer](#)

- [Lung Cancer](#)
- [Skin Cancer](#)
- [Prostate Cancer](#)

Treatment Options

There are several treatment options available for cancer. Treatment plans are developed depending on the type of cancer; its location; the extent of cancer and the stage at which it is diagnosed; and the health and well-being of the patient. Treatment may consist of one type of therapy or be a combination of several. The most common types of treatment are listed below.

- **Surgery:** Involves removal of the tumor and sometimes, surrounding tissue and lymph nodes. Surgery can be performed using conventional instruments, cryosurgery (using liquid nitrogen or argon gas), light (photodynamic therapy), high temperatures (hyperthermia), or laser
- **Radiation therapy:** Uses high doses of radiation to kill cancer cells and shrink tumors. The two main types of radiation therapy are external beam and internal radiation
- **Chemotherapy:** Uses specific drugs to kill cancer cells by halting their growth or preventing their multiplication at some point in their life cycle. Drugs may be administered intravenously (into a vein), orally (by mouth), by injection into a muscle, topically (applied to the skin) or in other ways, depending on the drug and the type of cancer. Chemotherapy is often given in cycles of alternating treatment and rest periods
- **Immunotherapy:** A type of biological therapy where drugs are given or procedures are undertaken that help the immune system attack cancer directly or stimulate the immune system in a more general way. Examples of treatments include checkpoint inhibitors, cytokines, treatment vaccines, and adoptive cell transfer
- **Targeted therapy:** These treatments target changes in cancer cells that help them to divide and spread. Monoclonal antibodies are a type of targeted therapy which attach to specific targets on the outer surface of cancer cells
- **Hormone therapy:** Drugs are used to block the body's ability to produce hormones or interfere with how hormones behave in the body
- **Stem cell transplants:** Procedures that restore blood-forming stem cells in people who have had theirs destroyed, either by chemotherapy or high-dose radiation therapy
- **Precision medicine:** Treatment is tailored to each individual, based on a genetic understanding of their cancer. Although not yet routine, doctors hope it will one day be the standard treatment of the future
- **Alternative and complementary therapy:** Includes nonpharmacological treatments such as acupuncture, herbal supplements, and homeopathy. It is important to note; however, that many of these treatments do not have research to support their effectiveness.

Many other drugs may be used during the treatment of cancer, such as [analgesics](#) to relieve pain or antiemetics to prevent or treat [nausea](#) or vomiting.

Some cancer drugs may affect healthy cells in the body, in addition to cancerous cells, and cause side effects such as an increased risk of infection, bruising or bleeding, and extreme tiredness. Some cancer drugs cause hair loss.

Anti-cancer drugs

There are more than 250 different cancer drugs. These can be organized into different categories depending on the way they work, for example:

- **Alkylating agents**: Interfere with DNA linking and include the alkyl sulfonates, ethylenimines, nitrogen mustards, nitrosoureas, and triazines
- **Anthracyclines**: Damage DNA in cancer cells, causing them to die (eg, daunorubicin, doxorubicin, and epirubicin)
- **Antimetabolites**: Affect DNA synthesis (eg, capecitabine, fluorouracil, methotrexate)
- **Aromatase inhibitors**: Block the enzyme aromatase, that converts androgens into estrogen (eg, anastrozole, exemestane, letrozole)
- **CDK 4/6 inhibitors**: Target enzymes, called CDK4 and CDK6 that are important for cell division (eg, abemaciclib, ribociclib, palbociclib)
- **HDAC (histone deacetylase) inhibitors**: Have a number of different actions including inhibiting DNA repair, stopping the proliferation of cancer cells, and stimulating cell death (eg, belinostat, panobinostat, romidepsin, vorinostat)
- **mTOR inhibitors**: blocks an enzyme that regulates growth factors that stimulate cell growth and the formation of new blood vessels (eg, everolimus, temsirolimus)
- **PARP inhibitors**: Used for the treatment of cancers with mutations in their DNA repair genes (eg, olaparib, niraparib, rucaparib)
- **Retinoids**: Inhibit tumor growth, blood vessel formation and tumor spread (eg, alitretinoin, bexarotene)
- **Topoisomerase inhibitors**: Block an enzyme, topoisomerase, that breaks and rejoins DNA strands and is vital for cell division and growth (eg, irinotecan, topotecan)
- **Kinase inhibitors**: Block kinase enzymes that help control important cell functions, such as cell signaling, metabolism, division, and survival (eg, imatinib, nilotinib, sorafenib)
- **Vinca alkaloids**: Extracted from the pink periwinkle plant they inhibit tubulin which is the main constituent of the microtubules of living cells, causing cell death (eg, vinblastine, vinorelbine, vincristine).

See Also

- [Breast Cancer Guide: Causes, Symptoms & Diagnosis](#)
- [Breast Cancer: Treatment and Prevention Options](#)
- [Cervical Cancer](#)
- [Lung Cancer](#)
- [Mesothelioma](#)
- [Prostate Cancer](#)

- [Skin Cancer and Melanoma: Symptoms, Diagnosis and Treatment](#)

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

More News Resources

- [Health Guide](#)
- [Disease Reference](#)
- [Medication List](#)
- [Q & A](#)

Recently Approved

- [Veklury](#)

Veklury (remdesivir) is a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor...

- [Inmaze](#)

Inmaze (atoltivimab, maftivimab, and odesivimab) is a monoclonal antibody...

- [Alkindi Sprinkle](#)

Alkindi Sprinkle (hydrocortisone granules in capsules for opening) is an...

- [Gavreto](#)

Gavreto (pralsetinib) is an oral selective RET kinase inhibitor for the...

(Reference: Drugs.com)

[Oncology, oral – Breast \(i.e., antineoplastic\)](#)

[Oncology, oral – Hematologic \(i.e., antineoplastic\)](#)

[Oncology, oral – Lung \(i.e., antineoplastic\)](#)

[Oncology, oral – Other \(i.e., antineoplastic\)](#)

[Oncology, oral – Prostate \(i.e., antineoplastic\)](#)

[Oncology, oral – Renal cell \(i.e., antineoplastic\)](#)

[Oncology, oral – Skin \(i.e., antineoplastic\)](#)

Public Comment.

Representative from Eli Lilly, spoke on abemaciclib ([Verzenio](#)) (Breast Cancer). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.



The presenter also commented on [Retevmo](#) (for Lung and Thyroid Cancer), citing statistics and reading from the package insert. Please follow the link for more detail.

Mark Bauch, BeiGene, spoke on zanubrutinib ([Brukinsa](#)) (Lymphoma). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

James Beal, Karyopharm, spoke on selinexor ([Xpovio](#)) (Lymphoma). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

Ann Marie Licos, AstraZeneca, spoke on acalabrutinib ([Calquence](#)) (Hematological). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

The presenter commented on osimertinib ([Tagrisso](#)) (Lung) presenting statistics and package insert information. Please follow the link for more detail.

The presenter commented on olaparib ([Lynparza](#)) (Other) presenting statistics and package insert information. Please follow the link for more detail.

The presenter also commented on selumetinib ([Koselugo](#)) (Other) presenting statistics and package insert information. Please follow the link for more detail.

Julie Baker, Deciphera, commented on ripretinib ([Qinlock](#)) (Other). The presenter cited some statistics and read from the package insert and website information. Please follow the link for detailed information about this product.

[Therapeutic and clinical drug reviews and updates: Magellan Medicaid Administration](#)

The information on the new classes was presented by Megellan staff, reading from their presentation materials which can be found by following the link. In addition, each class was summarized by *Texas Insight* above.

Adjourn – Day One. There being no further business, the meeting was adjourned.

This summary contains supplemental information from third-party sources where that information provides clarity to the issues being discussed. Not every comment or statement from the speakers in these summaries is an exact transcription. For the purpose of brevity, their statements are often paraphrased. These documents should not be viewed as a word-for-word account of every meeting or hearing, but a summary. Every effort has been made to ensure the accuracy of these summaries. The information contained in this publication is the property of the organization and is considered confidential and may contain proprietary information. It is meant solely for the intended recipient. Access to this published information by anyone else is unauthorized unless the organization grants permission. If you are not the intended recipient, any disclosure, copying, distribution or any action taken or omitted in reliance on this is prohibited. The views expressed in this publication are, unless otherwise stated, those of the author and not those of the organization or its management.
