FDA-approved Therapies Derived from CBD

Frequently Asked Questions

What does it mean to be an FDA-approved therapy derived from CBD?

The U.S. Food and Drug Administration (FDA) examines potential therapies for safety and efficacy. It approves a therapy when the benefits outweigh the potential risks for a specific condition(s), also known as indication(s). Products made with cannabidiol (CBD) are considered to be derived from cannabis. Not all products made from CBD go through the FDA-approval process, which includes multiple studies to determine a product's safety and efficacy for treating a particular medical condition. For example, products considered dietary supplements that do not make health claims are not regulated by the FDA.

Are there currently any FDA-approved therapies derived from CBD?

On June 25, 2018, the FDA approved Epidiolex®, an oral solution of CBD, for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in individuals two years of age or older. This is the first FDA-approved medication that contains a purified substance derived from cannabis, and it is the first FDA-approved treatment option for individuals with Dravet syndrome.

Epidiolex® is a purified, 99% oil-based solution of CBD, which is a compound derived from the Cannabis sativa plant. CBD is one of over 100 chemicals found in the cannabis plant. Unlike tetrahydrocannabinol (THC), another chemical found in the plant, CBD does not cause intoxication or euphoria (often referred to as the "high"). While derived from the cannabis plant, CBD does not produce the same effect as the whole plant.

Now that the DEA has announced that Epidiolex® will be Schedule V, how soon can I get it?

Now that Epidiolex® is both FDA-approved and scheduled by the DEA, it should be ready for distribution on the market by the end of 2018. The DEA's determination, however, does not override state-controlled substance laws. If a state considers cannabis Schedule I under its laws, Epidiolex® cannot be prescribed until it is scheduled by the state. The Epilepsy Foundation is actively working with legislators and regulators in these states to secure access to this potential treatment option. For more information on the status of this treatment in your state, please visit: **advocacy.epilepsy.com/statefdapathway**

If you live in a state that has already rescheduled FDA-approved therapies derived from CBD, you and your doctor can begin exploring this potential treatment option if your physician feels the benefits outweigh the risks. If you receive a prescription, please note that it can take up to three weeks from the prescribing date to receive the treatment.

What does Schedule V mean?

Under the Controlled Substances Act, the DEA has the authority to classify drugs, substances, and certain chemicals used to make medications into five distinct categories, or schedules, depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. Medical value and abuse potential determinations are informed by large-scale clinical trials conducted under the guidance of the FDA. The abuse rate is critical in determining the schedule for a drug.

Recently, the DEA placed Epidiolex® in Schedule V. Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of limited quantities of certain narcotics which are known to cause dependency. This is the lowest tier of the drug schedule. Other medicines such as certain cough syrups or antidiarrheals are also Schedule V. Schedule V medications to treat epilepsy include pregabalin (Lyrica®), lacosimide (Vimpat®), and brivaracetam (Briviact®).

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What action(s) does my state need to take for FDA-approved therapies derived from CBD to be available?

Each individual state has its own laws that define the governing body responsible for ensuring a therapy is available to its citizens after FDA approval and DEA scheduling. In many states, it is the state legislature that is responsible for rescheduling a drug. In others, it is a state agency such as the Board of Pharmacy or Department of Health.

Can Epidiolex® be prescribed to individuals without Lennox-Gastaut syndrome or Dravet syndrome?

When a medication is approved by the FDA, it is done so narrowly. For example, Epidiolex® is currently approved for Lennox-Gastaut and Dravet syndromes. This is because those were the specific syndromes tested during the clinical trials and there was enough evidence to indicate the medication was medically appropriate for those syndromes. Once a medication is approved for any syndrome or condition, a physician may prescribe that medication for "off-label" uses if there is a recognized medical basis for those uses. Off-label use is when physicians prescribe a medication for a condition or age group other than those included in the original approval.

Off-label use is legal and routine in medical practice as long as there is a recognized medical basis for these uses, with more than one in five prescriptions written for off-label use. A physician may prescribe off-label medication if they believe their patient may benefit from a medication that was not previously approved for the patient's specific condition or age group. However, some health insurance plans may not cover any or all medications prescribed for off-label use. If a health insurance plan will cover off-label use, individuals may still be subject to a step therapy or "fail first" process in which they will be required to try a number of less expensive medications, and fail to gain or maintain seizure control, before gaining coverage for the off-label medication.

How is Epidiolex® different from commercial grade CBD sold over-the-counter and in dispensaries?

Unlike CBD purchased over-the-counter or through a dispensary, Epidiolex® has been subject to controlled clinical trials to test the safety and efficacy of the medication, along with careful review through the FDA's drug approval process.

Epidiolex® is a pharmaceutical-grade version of the CBD oil sold over-the-counter and in dispensaries, and neither of these products contains THC. However, the FDA has issued warnings in the past that the purported benefits of unapproved, unregulated, commercial CBD products may be overstated.

Because of the adequate and well-controlled clinical studies that supported approval of Epidiolex®, prescribers can have confidence in the treatment's uniform strength and consistent delivery for treating individuals with complex and serious epilepsy syndromes. This uniformity provides reliability and stability of each dose of Epidiolex® that commercial grade CBD lacks. Commercial grade CBD products contain varying and often unverifiable amounts of CBD so there is no way to ensure the same, reliable dosing from vendor to vendor. For CBD oil not purchased in a medical cannabis dispensary, the lack of manufacturing safety oversight means there is no way to ensure that other chemicals (such as pesticides) are not in these products.

Are state laws for legal CBD still necessary given the FDA's approval of a new CBD-derived therapy?

While an FDA-approved therapy derived from CBD is a significant step for the epilepsy community, it has only been approved and indicated for two specific types of epilepsy—Lennox-Gastaut and Dravet syndromes. There are many individuals living with epilepsy who cannot find seizure control even after working through all available prescription treatments with their physicians. For individuals who cannot access FDA-approved treatments derived from cannabis, local access to CBD and cannabis more broadly is important. The Epilepsy Foundation is committed to supporting physician-directed care, and to exploring and advocating for all potential treatment options for epilepsy, including CBD oil and medical cannabis. We support safe, legal access to medical cannabis if an individual and their treating physician feel that the potential benefits of medical cannabis for uncontrolled epilepsy outweigh the risks. While not everyone with

epilepsy should or would consider medical cannabis as a treatment option, some people living with uncontrolled seizures have reported beneficial effects and reduced seizure activity when using medical cannabis, especially strains rich in CBD. Furthermore, additional research is needed on the connection between cannabis and seizures and broader legal access will support increased research efforts.

For additional information and the latest on state rescheduling efforts, visit advocacy.epilepsy.com/statefdapathway