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.

Is Epidiolex® on the market and available for prescribing now?

While Epidiolex® is now FDA-approved, it is not ready to be distributed on the market at this time. Because the medication is derived from cannabis, it must go to the Drug Enforcement Administration (DEA) to be placed on the Drug Schedule. Cannabis is a Schedule I substance, meaning it is considered a drug with no currently accepted medical use and high potential for abuse. Schedule I substances cannot be prescribed by physicians or dispensed by pharmacists. The DEA has 90 days from the FDA-approval date to take action on scheduling the substance. An action is expected by September 23, 2018. If the DEA schedules Epidiolex® lower than Schedule I, physicians will be able to prescribe it.

However, scheduling by the DEA does not override state controlled substance laws. If a state considers cannabis a Schedule I substance under its laws, Epidiolex® cannot be prescribed until it is scheduled in that state. The Epilepsy Foundation is actively working with legislators and regulators in the states to secure access to this potential treatment option.

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.

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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