

CANNABIDIOL (CBD) OIL AND EPILEPSY



Our team of Board-Certified Pediatric Neurologists understand firsthand the medical complexity of the care and treatment of epilepsy. Many families face difficult decisions understanding the latest research and recommendations for epilepsy. Recently, cannabidiol (CBD) oil has received much attention as an option for reducing seizures. Here are some of the most commonly asked questions about CBD oil for epilepsy.

What is cannabidiol (CBD)?

Marijuana contains many different chemicals called cannabinoids. Each one can have different effects on the body. These chemicals can be extracted from the marijuana plant and used to make medicines. Two of the main chemicals include:

- Tetrahydrocannabinol (THC) which causes the “high” known with recreational marijuana
- Cannabidiol (CBD) which does not cause a “high”.

CBD extracted from marijuana and then dissolved in oil (such as coconut or sesame oil) is called CBD oil. CBD oil is being evaluated for the treatment of epilepsy as well as many other conditions. So far Texas has legalized CBD-related medications. CBD oil sold in Texas is required to have high levels of CBD and low levels of THC (<0.5%).

How effective is CBD?

Early research has reported improved seizure control in patients when prescribed CBD. The largest, published study is from GW Pharmaceuticals testing a CBD product called Epidiolex, pending FDA approval. The results are promising for patients with a genetic form of epilepsy called Dravet syndrome.¹ Another large study in Israel showed similar results.² Results from the two studies indicated:

- Complete seizure control is rare. 5% in the Dravet study and only 1 patient in the Israeli study stopped having seizures.

- Seizures decreased in HALF in about HALF of the patients in both studies.
- Response rates are similar to many other FDA-approved seizure medications.

These studies and other research have shown promising results for improving seizure control with CBD treatment. However, CBD has limits. It's not a miracle cure and does not work for everyone. As is true for any treatment or procedure, a decision must involve a discussion with a pediatric neurologist on the benefits and risks of CBD.

What about side effects?

- In both studies mentioned above, some patients (4-7%) dropped out due to side effects.
- Some patients experienced mild side effects including sleepiness, nausea, vomiting, diarrhea, appetite changes and increased seizures.
- CBD can interact with other medications, changing the side effect profile. These interactions are important to discuss with your physician.
- Denver Children's hospital reported cases where CBD had no or minimal effect. In some instances, CBD treatment was associated with increased seizures or other serious side effects leading to children being hospitalized.

There are still many unanswered questions regarding CBD treatment, including how to dose products from different manufacturers and long-term effects on health, development, learning, memory and pregnancy. It is important to talk to your physician about the potential side effects.

Is CBD legal in Texas?

In 2015, Governor Greg Abbott signed the Compassionate Use Act. The law allows neurologists and epileptologists to prescribe CBD (with low THC) to people with epilepsy when other treatments have not



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controlled their seizures. The medicine must be grown and produced in Texas and follow strict regulations.

Since September 1, 2017, the Texas Department of Public Safety licensed two companies to grow marijuana in Texas and to produce CBD medication. A third company is pending final licensure. One of the companies is Compassionate Cultivation. Dr. Karen Keough, Epileptologist with Child Neurology Consultants of Austin, serves as the company's Chief Medical Officer.

While more than thirty states have legalized the medical use of marijuana in many different forms, marijuana possession and use (even for medical purposes) are illegal under Federal U.S. Law. These Federal laws also limit access to marijuana for research purposes. However, other federal policies allow states to create regulated systems to utilize marijuana for medical purposes under the state's laws. If considering medical CBD for your child's medical issue, it is important to understand Texas state law.

What determines eligibility in Texas?

A patient may be prescribed CBD if:

- The patient is a permanent resident of Texas.
- The patient is diagnosed with intractable epilepsy.
- The patient and treating physician are both registered in the Compassionate Use Program (CUP) state registry.
- The child's physician determines the risk of the medical use of low-THC cannabis by a patient is reasonable in light of the potential benefit for the patient; and
- A second CUP-registered physician agrees with the recommendation in the CUP registry prior to the first prescription.

Child Neurology Consultants of Austin's three Epileptologists, Dr. Karen Keough, Dr. Jeffrey Kane and Dr. Aaron Cardon are registered in the state compassionate use registry. Visit www.dps.texas.gov/rsd/CUP/ to learn more about the Texas Compassionate Use Program.

Does health insurance cover CBD oil as a treatment for children with epilepsy?

Not at this time. Families will have to pay out-of-pocket for treatment. Cost and dosing is still being evaluated. Based on programs in other states, we estimate the monthly cost will be about \$200 - 500. Additional costs for delivery may be relevant for patients who live far away from the licensed dispensaries, all of which are currently located near Austin.

Where can I find more information about this treatment option?

Visit the Epilepsy Foundation's website (www.epilepsy.com) for more information about CBD for epilepsy. You can also book an appointment with a Child Neurology Consultants of Austin Epileptologist by calling (512) 494-4000.

¹Devinsky, Orrin. *New England Journal of Medicine*. Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome. May 25, 2017.

²M. Tzadok et al. *Seizure*. CBD-Enriched Medical Cannabis for Intractable Pediatric Epilepsy: The Current Israeli Experience. (2016) p 41-44

