

EPIDIOLEX® FACT SHEET

What is Epidiolex®?

Epidiolex® is a pure, plant-based, pharmaceutical grade cannabidiol (CBD) extract that has proven effective in treating seizures among individuals two years and older with **Dravet** and **Lennox-Gastaut** Syndromes. It is the first FDA-approved drug comprised of an active chemical derived from the marijuana plant.

What is the legal status of Epidiolex®?

After the FDA approved Epidiolex®, the Drug Enforcement Administration (DEA) scheduled Epidiolex® as a **schedule V drug**. This means that Epidiolex® is the only legal form of CBD for sale in the state of Idaho. It is also the only federally legal form of CBD oil.



How does Epidiolex® compare to artisanal CBD?

- Only Epidiolex® was studied and **proven safe and effective** for its approved uses in randomized, placebo-controlled trials.
- Only Epidiolex® must, under federal law, be manufactured strictly in accordance with methods and processes that **ensure the product is consistent** batch-to-batch in quality, strength, and purity
- Epidiolex®'s side effects, contraindications, drug-to-drug interactions, and other risks have been defined and are described in an **FDA-approved label** that the manufacturer is required to update as new safety information surfaces.
- Hundreds of dispensaries and internet distributors selling artisanal CBD products are loosely regulated in comparison to Epidiolex®.
 - Over the past few years, the FDA has sent several warning letters to firms that market **unapproved drugs that allegedly contain CBD**. Testing showed many products did not contain the levels of CBD they claimed to contain.¹
 - A 2017 study published in JAMA found **only 31%** of CBD products purchased online contain the amount of CBD advertised on the label.²
 - In 2017, the CDC investigated reports of emergency department visits in Utah associated with reported exposure to a **product mislabeled as CBD**. The product was found to contain a **synthetic cannabinoid**, but no CBD.³

Epidiolex® will be less expensive for LGS and Dravet patients than unapproved online and dispensary products.

Epidiolex® is priced at **\$32,500 annually**. Let's breakdown the pricing and how this compares to artisanal CBD products. The cost of Epidiolex® increases based on the weight of the patient.

¹ United States Food and Drug Administration (2017). Warning Letters and Test Results for Cannabidiol-Related Products. Retrieved from: <https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm>

² Bonn-Miller, M., Loflin, M., Thomas, B., et al (2017) Labeling accuracy of Cannabidiol extracts sold online. JAMA, 318(17). Retrieved from <https://jamanetwork.com/journals/jama/article-abstract/2661569?redirect=true>

³ Horth, R., Crouch, B., Horowitz, Z., et al. (2018). Notes from the Field: Acute Poisonings from a Synthetic Cannabinoid Sold as Cannabidiol – Utah, 2017-2018. *Morbidity and Mortality Weekly Report*, 67(20). Retrieved from <https://www.cdc.gov/mmwr/volumes/67/wr/mm6720a5.htm>

- For a **25-pound child** with Dravet syndrome or LGS dosed at 10 mg/kg /day, the cost will be about **\$5,052** per year before insurance.
- For a **150-lb teen** with Dravet syndrome or LGS, the cost will be about **\$30,312** per year before insurance.

Epidiolex® will cost about **\$0.12/mg before insurance**. According to a survey of dispensary pricing last year by the marijuana website, Leafly:

Brand	Total CBD (mg)	Price	\$ per mg
Green Mountain	600	\$30	\$0.05
CW Simply Hemp	2100	\$120	\$0.06
Infinite CBD	100	\$8	\$0.08
Endoca	300	\$31	\$0.10
Plus CBD Oil	600	\$54	\$0.11
Highland Pharms	450	\$50	\$0.11
Tasty Hemp Oil	450	\$50	\$0.11
Aunt Zelda's	600	\$70	\$0.12
RSHO Gold Label	750	\$119	\$0.16
ETST Earth Science Tech	450	\$85	\$0.19
Dixie Botanicals	750	\$149	\$0.20
Imbue Botanicals	300	\$64	\$0.23
Mary's Nutritionals Elite	150	\$90	\$0.60

The daily dose to treat a 150-pound teen is 680.4 mg CBD. Depending on the brand of artisanal CBD listed above, that same teen would require **between 1/3 of a bottle to 7 bottles per day**.

What about insurance coverage?

- Online or dispensary CBD products are not covered by insurance because they are not medications.
- Epidiolex® **will be covered** under most Medicaid and insurance plans.
- For commercially insured patients, Greenwich's copay support program means that most patients will **pay no more than \$25 per month** for Epidiolex®. Idaho commercial insurers are reviewing Epidiolex® in their Pharmacy and Therapeutics committees.
- Through Greenwich's Patient Assistance Program, Greenwich **will provide Epidiolex® free of charge to financially eligible patients** who cannot afford their medication or don't have sufficient prescription drug coverage.

What about other health conditions?

Epidiolex® is only approved for LGS and Dravet Syndrome at this time. However, Epidiolex® **may be prescribed off-label** by a physician who believes that the drug can be therapeutic for other conditions. Insurance coverage may be subject to pre-authorization.