

# Cannabidiol

**Goal(s):**

- To ensure appropriate drug use and restrict to indications supported by medical literature.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Cannabidiol

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at [www.orpdl.org](http://www.orpdl.org)
- Searchable site for Oregon FFS Drug Class listed at [www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

| Approval Criteria   |   |   |
|---|---|---|
| 1. What diagnosis is being treated?   | Record ICD10 code.  |   |
| 2. Is the request for renewal of therapy previously approved by the FFS system?   | <b>Yes:</b> Go to <b>Renewal Criteria</b>                           | <b>No:</b> Go to #3                                   |
| 3. Is this an FDA approved indication?  | <b>Yes:</b> Go to #4  | <b>No:</b> Pass to RPh. Deny; medical appropriateness |
| 4. Is the patient uncontrolled on current baseline therapy with at least one other antiepileptic medication AND is cannabidiol intended to be prescribed as adjuvant antiepileptic therapy? | <b>Yes:</b> Go to #5<br><br>Document current seizure frequency_____ | <b>No:</b> Pass to RPh. Deny; medical appropriateness |
| 5. Is the prescribed dose greater than 25 mg/kg/day?  | <b>Yes:</b> Pass to RPh. Deny; medical appropriateness              | <b>No:</b> Go to # 6                                  |

## Approval Criteria

6. Are baseline liver function tests (LFTs) on file (serum transaminases and total bilirubin levels)?  
AND  
If LFTs are not within normal limits has the cannabidiol dose been adjusted per guidance for moderate to severe hepatic impairment in Table 1?

LFTs should be obtained at 1 month, 3 months, and 6 months after starting treatment with cannabidiol and periodically thereafter as clinically indicated, after cannabidiol dose changes, or addition of other medications that are known to impact the liver.

**Yes:** Approve for 12 months

Document results here:

Date of lab work \_\_\_\_\_

AST \_\_\_\_\_

ALT \_\_\_\_\_

Total

Bilirubin \_\_\_\_\_

**No:** Pass to RPh.  
Deny; medical appropriateness

## Renewal Criteria

1. Are recent LFT's documented in patient records?

AND

If LFTs are not within normal limits has the cannabidiol dose been adjusted per guidance for moderate to severe hepatic impairment in Table 1?

**Yes:** Go to # 2

Document results here:

Date of lab work \_\_\_\_\_

AST \_\_\_\_\_

ALT \_\_\_\_\_

Total

Bilirubin \_\_\_\_\_

**No:** Pass to RPh.  
Deny; medical appropriateness

2. Has seizure frequency decreased since beginning therapy?

**Yes:** Go to #3

Document baseline and current seizure frequency \_\_\_\_\_

**No:** Pass to RPh.  
Deny for lack of treatment response.

3. Is the prescribed dose greater than 25mg/kg/day?

**Yes:** Pass to RPh. Deny; medical appropriateness

**No:** Go to # 4

4. Is cannabidiol intended to be prescribed as adjuvant antiepileptic therapy?

**Yes:** Approve for 12 months

**No:** Pass to RPh.  
Deny; medical appropriateness

**Table 1:** Dose Adjustments of Cannabidiol in Patients with Hepatic Impairment<sup>1</sup>

| <b>Hepatic Impairment</b> | <b>Starting Dosage</b>                 | <b>Maintenance Dosage Range in Patients with Lennox-Gastaut Syndrome (LGS) or Dravet Syndrome (DS)</b> | <b>Maintenance Dosage in Patients with Tuberous Sclerosis Complex (TSC)</b> |
|---------------------------|--|--|---|
| <b>Mild</b>               | 2.5 mg/kg twice daily (5 mg/kg/day)    | 5 to 10 mg/kg twice daily (10 to 20 mg/kg/day)   | 12.5 mg/kg twice daily (25 mg/kg/day)                                       |
| <b>Moderate</b>           | 1.25 mg/kg twice daily (2.5 mg/kg/day) | 2.5 to 5 mg/kg twice daily (5 to 10 mg/kg/day)   | 6.25 mg/kg twice daily (12.5 mg/kg/day)                                     |
| <b>Severe</b>             | 0.5 mg/kg twice daily (1 mg/kg/day)    | 1 to 2 mg/kg twice daily (2 to 4 mg/kg/day)  | 2.5 mg/kg twice daily (5 mg/kg/day)   |

1. Epidolex (cannabidiol) Oral Solution Prescribing Information. Carlsbad, CA; Greenwich Biosciences, Inc. July 2020.

*P&T/DUR Review: 10/22 (SF); 10/21 (DM); 10/20; 6/20; 3/19; 1/19  
Implementation: 11/1/20; 5/1/19; 3/1/19*