

ALASKA MEDICAID  
Prior Authorization Criteria

**Epidiolex® (Cannabidiol)**

**FDA INDICATIONS AND USAGE**<sup>1</sup>

Epidiolex is indicated, in patients 2 years of age and older, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome.

**APPROVAL CRITERIA**<sup>1,2</sup>

1. Patient is 2 years of age or older **AND**;
2. Patient has the diagnosis of Lennox-Gastaut or Dravet syndrome **AND**;
3. Prescribed by or in consultation of a neurologist **AND**;
4. Patients seizures have not been controlled by at least a trial of 2 antiepileptic drugs **AND**;
5. Patient will use as an adjunctive therapy with at least one other antiepileptic drug **AND**;
6. Serum transaminases and bilirubin levels are obtained prior to starting treatment.

**DENIAL CRITERIA**<sup>1,2</sup>

1. Patient is less than 2 years of age **OR**;
2. Patient does not the diagnosis of Lennox-Gastaut or Dravet syndrome **OR**;
3. Not being prescribed by or in consultation of a neurologist **OR**;
4. Patients seizures have been controlled by other antiepileptic drugs **OR**;
5. Patient is not using as an adjunctive therapy with at least one other antiepileptic drug **OR**;
6. Serum transaminases and bilirubin levels have not been obtained prior to starting treatment.

**CAUTIONS**<sup>1</sup>

- Can cause elevated transaminase levels especially when used with valproate. Monitoring should occur prior to start, 1 month, 3 months, 6 months and as clinically indicated.
- Caution should be used when driving or operating machinery due to somnolence and sedative effects.
- Patients should be monitored for suicidal thoughts or behaviors.

**DURATION OF APPROVAL**

- Initial Approval: up to 4 months
- Reauthorization Approval: up to 12 months if the patient is responding positively and doses have not exceeded 20mg/kg/day

**QUANTITY LIMITS**

Epidiolex® Criteria  
Version: 1  
Original: 10/10/2018  
Approval: 11/16/2018  
Effective: 1/15/2019

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- 5 – 100ml bottles (100mg/ml)
- Doses do not exceed 20mg/kg/day

**REFERENCES / FOOTNOTES:**

1. Epidiolex Prescribing Information. Carlsbad, CA: Greenwich Biosciences, Inc.; June 2018. Available at:  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/2103651bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/2103651bl.pdf). Accessed October 10, 2018.
2. American Academy of Neurology and the American Epilepsy Society. Treatments for Refractory Epilepsy; Guideline Summary for Clinicians. Available at:  
[http://tools.aan.com/professionals/practice/pdfs/clinician\\_ep\\_treatment\\_e.pdf](http://tools.aan.com/professionals/practice/pdfs/clinician_ep_treatment_e.pdf). Accessed October 10, 2018.