

ALASKA MEDICAID
Prior Authorization Criteria

Epidiolex® (Cannabidiol)

FDA INDICATIONS AND USAGE¹

Epidiolex is indicated, in patients 1 years of age and older, for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, and Tuberous Sclerosis Complex.

APPROVAL CRITERIA^{1,2}

1. Patient is 1 years of age or older **AND;**
2. Patient has the diagnosis of Lennox-Gastaut, Dravet syndrome, or Tuberous Sclerosis Complex **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^{1,2}

1. Patient is less than 1 years of age **OR;**
2. Patient does not the diagnosis of Lennox-Gastaut, Dravet syndrome, or Tuberous Sclerosis Complex **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.

CAUTIONS¹

- 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

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QUANTITY LIMITS

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

REFERENCES / FOOTNOTES:

1. Epidiolex Prescribing Information. Carlsbad, CA: Greenwich Biosciences, Inc.; July 2020. Available at: [https://www.epidiolex.com/sites/default/files/pdfs/VV-MED-03633_EPIDIOLEX_\(Cannabidiol\)_USPI.pdf](https://www.epidiolex.com/sites/default/files/pdfs/VV-MED-03633_EPIDIOLEX_(Cannabidiol)_USPI.pdf). Accessed August 3, 2020.
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. Accessed October 10, 2018.