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GAVIN NEWSOM  
GOVERNOR

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Index: Benefits

**TO:** All County California Children's Services Program and Genetically Handicapped Persons Program Staff, Medical Consultants, Statewide Consultants, and Integrated Systems of Care Division Staff

**SUBJECT:** Epidiolex (Cannabidiol) – Authorization Criteria (Revised 2/10/2020)

## I. PURPOSE

The purpose of this Numbered Letter (N.L.) is to establish California Children's Services (CCS) Program and Genetically Handicapped Persons Program (GHPP) policy on the authorization of Epidiolex, a purified formulation of cannabidiol, to treat seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome.

## II. BACKGROUND

LGS and Dravet syndrome are treatment-resistant epilepsy syndromes that begin in early childhood, and persist into adulthood. LGS features typically include recurrent seizures of multiple types which may include tonic and atonic atypical absence, myoclonic and generalized tonic-clonic seizures, cognitive impairment, behavioral issues, and a distinct pattern of brain activity found on an electroencephalogram (EEG). The syndrome first appears between one and 11 years, and usually before five years of age.<sup>1,2</sup> Partial relief from seizures may be provided with anti-epileptic drugs, rescue treatment, vagal nerve stimulation, and the ketogenic diet.

Dravet syndrome is a childhood epilepsy syndrome that is caused by a gene defect in over 70% of cases, and with initial seizures before 15 months of age.<sup>3</sup> The seizures are numerous, intractable, prolonged, and generally resistant to available anti-epileptic drugs. Prognosis for patients with Dravet syndrome is poor. Most patients require constant care, and the condition can severely impact the patient's and family's quality of life. The primary cause of Dravet syndrome is a mutation in

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<sup>1</sup> <https://rarediseases.org/rare-diseases/lennox-gastaut-syndrome/>

<sup>2</sup> <https://www.childneurologyfoundation.org/disorder/lennox-gastaut-syndrome>

<sup>3</sup> <https://www.ninds.nih.gov/Disorders/All-Disorders/Dravet-Syndrome-Information-Page>

the SCN1A gene that encodes a sodium channel, a part of the cell membrane that is essential to nervous system function.

Epidiolex was approved by the Food and Drug Administration on June 25, 2018, as a first in class cannabidiol therapy to treat LGS and Dravet syndrome. Epidiolex is purified cannabidiol, which does not have the psychoactive properties associated with tetrahydrocannabinol, the other principal component of marijuana. Epidiolex is an oral solution.

### III. POLICY

Effective the date of this letter, the CCS and GHPP programs will authorize Epidiolex when the following criteria are met:

- A. The client is under the care of an epileptologist at a CCS/GHPP approved Epilepsy Special Care Center (SCC) or a CCS-paneled neurologist with expertise in the treatment of epilepsy.
- B. The client has a documented diagnosis of:
  1. LGS, diagnosed by a CCS-paneled neurologist with expertise in epilepsy; or
  2. Dravet syndrome, previously known as severe myoclonic epilepsy of infancy, diagnosed by a CCS-paneled neurologist with expertise in epilepsy. The affected individual has at least three of the following characteristics:
    - a. Normal development before the initial seizure and in the first years of life.
    - b. Typically, the first seizure is tonic-clonic, prolonged, and provoked by fever/illness or temperature change.
    - c. Multiple seizure types, including convulsive seizures which can be generalized tonic-clonic, generalized clonic, or alternating hemi-clonic, often myoclonus or myoclonic seizures and/or absence seizures.
    - d. Seizures that do not respond to anti-epileptic drugs.
    - e. A genetic mutation in the voltage-gated sodium channel (over 70% have the SCN1A gene).<sup>4,5</sup>

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<sup>4</sup> <https://www.ncbi.nlm.nih.gov/pubmed/19203856>

<sup>5</sup> <https://www.uptodate.com/contents/dravet-syndrome-genetics-clinical-features-and-diagnosis>

3. Other intractable epilepsy syndrome if Epidiolex has been prescribed by an epileptologist or a CCS paneled neurologist with extensive expertise in epilepsy, and either criteria a or b below:
    - a. The client has intractable epilepsy that has not responded to two or more anti-epileptic drugs.
    - b. The client has had a reduction in frequency or duration of seizure activity following Epidiolex or CBD oil that was previously prescribed.
  4. Other intractable epilepsy syndrome when prescribed by epileptologist at epilepsy SCC.
- C. The client is age 2 years or older.
- D. For initial authorizations, the SCC or CCS-paneled neurologist has confirmed the diagnosis and appropriateness of the drug by providing the following additional documentation:
1. Medical report describing the epilepsy semiology and inadequate response to other anti-epileptic drugs.
  2. Medical report describing response to Epidiolex if the client does not have Dravet syndrome or LGS.
  3. Genetic test information for Dravet syndrome, if available.
  4. Prescription for Epidiolex.
  5. Baseline lab results for bilirubin and serum transaminases, Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST).
  6. Authorization shall be for up to 12 months.
- E. For reauthorization, the Epilepsy SCC or CCS-paneled neurologist must provide:
1. Evidence of treatment efficacy, such as a reduction in the frequency or duration of seizure activity.
  2. Status of bilirubin and serum transaminases (ALT and AST) lab results, for initial reauthorization only.

- F. Epidiolex requests meeting the criteria above shall be authorized for 12 months or until program end-date.
- G. If the request is for a medical condition not described above, and the requesting provider has clinical documentation and/or scientific evidence that may be relevant to the request, the provider may submit this additional documentation to the Integrated Systems of Care Division (ISCD) Medical Director or designee for consideration during the eligibility determination.

#### **IV. POLICY IMPLEMENTATION**

- A. Epidiolex is not covered by a Service Code Grouping authorization and a separate authorization is needed.
- B. The requesting pharmacy must submit a Service Authorization Request (SAR), clinical documentation listed in section III.A.4, and a copy of the physician signed prescription to its county CCS Program Office or to the Special Populations Authorization Unit at the Department of Health Care Services following applicable CCS Policy:
  - 1. For clients residing in an independent county, all requests shall be submitted to the CCS County Office for processing.
  - 2. For clients residing in a dependent county, all requests shall be submitted to the Special Populations Unit by email at [CCS\\_Operations@dhcs.ca.gov](mailto:CCS_Operations@dhcs.ca.gov) or via secure RightFax number, (916) 440-5768.
  - 3. For clients residing in a county covered by the Whole Child Model, all requests shall be submitted to, and processed by, the managed care plan.

If you have any questions regarding this Numbered Letter, please contact the ISCD Medical Director at [ISCD-MedicalPolicy@dhcs.ca.gov](mailto:ISCD-MedicalPolicy@dhcs.ca.gov).

Sincerely,

#### **ORIGINAL SIGNED BY**

Roy Schutzengel  
Medical Director  
Integrated Systems of Care Division