BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/15/18**
SECTION: DRUGS	**LAST REVIEW DATE: 11/15/18**
	LAST CRITERIA REVISION DATE:
	ARCHIVE DATE:

EPIDIOLEX® (cannabidiol) oral solution

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

EPIDIOLEX® (cannabidiol) oral solution (cont.)

Criteria:

- **Criteria for initial therapy:** Epidiolex (cannabidiol) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a Neurologist

  2. Individual is 2 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     - Seizures associated with Lennox-Gastaut syndrome (LGS)
     - Seizures associated with Dravet syndrome (DS)

  4. Individual has failure, contraindication, or intolerance to **TWO** the following preferred step therapy agents:
     - Valproate
     - Clobazam
     - Topiramate
     - Levetiracetam
     - Lamotrigine

  5. **ALL** of the following baseline tests have been completed before initiation of treatment:
     - Serum transaminases (ALT and AST) and total bilirubin

  6. Not using any other cannabinoid, including medical marijuana

  7. There are **NO** contraindications.
     - Contraindications include:
       - Hypersensitivity to cannabidiol or any of the ingredients in Epidiolex

  Initial approval duration: 2 months

- **Criteria for continuation of coverage (renewal request):** Epidiolex (cannabidiol) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by Neurologist

  2. Individual's condition has responded while on therapy
     - Response is defined as:
       - For LGS:
         - Achieved and maintains a reduction in frequency of drop seizures (atonic, tonic, or tonic-clonic seizures)
       - For DS
         - Achieved and maintains a reduction in frequency of convulsive seizures (all countable atonic, tonic, clonic, and tonic-clonic seizures)

EPIDIOLEX® (cannabidiol) oral solution (cont.)

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    - Contraindications as listed in the criteria for initial therapy section
    - Significant adverse effect such as:
        - Hepatocellular injury
        - Suicidal behavior and ideation
        - Hypersensitivity reaction

5. Not using any other cannabinoid, including medical marijuana

6. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Cannabidiol, the active ingredient in Epidiolex, is a cannabinoid that naturally occurs in the *Cannabis sativa* L. plant. The precise mechanisms by which Epidiolex exerts its anticonvulsant effect in humans are unknown. Cannabidiol does not appear to exert its anticonvulsant effects through interaction with cannabinoid receptors.

Lennox–Gastaut Syndrome (LGS), also known as Lennox syndrome, is a severe and difficult-to-treat form of childhood-onset epilepsy that most often appears between the second and sixth year of life. It is characterized by frequent seizures and can include different seizure types, such as, tonic, atonic, atypical absence, and myoclonic seizures. There may be periods of frequent seizures mixed with brief, relatively seizure-free periods. Most children with LGS experience some degree of impaired intellectual functioning or information processing, along with developmental delays and behavioral disturbances. Systematic review of randomized controlled trials conclude that no drug is highly effective, although valproic acid, lamotrigine, topiramate, rufinamide, felbamate, clobazam, and cannabidiol are possibly helpful.

Dravet syndrome (DS), previously known as severe myoclonic epilepsy of infancy, is a rare early-onset epileptic encephalopathy characterized by refractory epilepsy and neurodevelopmental problems beginning in infancy. Patients present in the first year of life with a prolonged, often febrile, clonic seizure in the setting of normal cognitive and motor development prior to seizure onset. In most, febrile and afebrile seizures, including episodes of status epilepticus, recur repeatedly in the weeks to months after the initial event, and psychomotor impairment begins thereafter. Myoclonus, both epileptic and non-epileptic, occurs frequently. The majority of older children and young adults with DS have motor system dysfunction, gait and postural abnormalities, and cognitive and behavioral impairment. DS seizures tend to be refractory to most anti-seizure drugs, and some patients derive benefit from a ketogenic diet and vagus nerve stimulation. The most commonly used anti-seizure drugs include valproate, clobazam, topiramate, levetiracetam, stirpentol, and cannabidiol. Most patients require two or more agents to achieve reasonable seizure control. Valproate is considered a first-line agent for DS with clobazam added as a second agent if valproate does not control seizures despite adequate valproate dosing and serum levels. Topiramate is a broad spectrum antiseizure agent that is also used as added on therapy.

EPIDIOLEX® (cannabidiol) oral solution (cont.)

Resources:

Epidiolex. Package Insert. Revised by manufacturer 9/2018. Accessed 10/31/18.

UpToDate: Epilepsy syndromes in children. Current through Oct 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/epilepsy-syndromes-in-children?search=Lennox-Gastaut%20syndrome&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

UpToDate: Dravet syndrome: Genetics, clinical features, and diagnosis. Current through Oct 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/dravet-syndrome-genetics-clinical-features-and-diagnosis?search=Lennox-Gastaut%20syndrome&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3

UpToDate: Dravet syndrome: Management and prognosis. Current through Oct 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/dravet-syndrome-management-and-prognosis?search=Lennox-Gastaut%20syndrome&source=search_result&selectedTitle=10~150&usage_type=default&display_rank=10

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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