

<b>Clinical Policy Title:</b>	cannabidiol
<b>Policy Number:</b>	RxA.370
<b>Drug(s) Applied:</b>	Epidiolex®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All line of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Seizures associated with Dravet Syndrome (DS) or Lennox-Gastaut Syndrome (LGS) (must meet all):

1. Diagnosis of DS or LGS;
2. Baseline complete blood count (CBC), serum transaminase, and total bilirubin were obtained prior to initiating therapy;
3. For LGS, failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Banzel® (rufinamide), clobazam, clonazepam, felbamate, lamotrigine, topiramate, or valproic acid.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

#### B. Seizures associated with Tuberous Sclerosis Complex (TSC) (must meet all):

1. Diagnosis of TSC;
2. Baseline complete blood count (CBC), serum transaminase, and total bilirubin were obtained prior to initiating therapy;
3. Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: carbamazepine, oxcarbazepine, or vigabatrin.

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

### II. Continued Therapy Approval

#### A. All Indications in section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

## References

1. National Institute of Neurological Disorders and Stroke. Dravet Syndrome Information Page. Available at: <https://www.ninds.nih.gov/Disorders/All-Disorders/Dravet-SyndromeInformation-Page>. Accessed August 28, 2024.
2. Wirrell EC. Treatment of Dravet Syndrome. Can J Neurol Sci. 2016 Jun;43 Suppl 3:S13-8. Available at: <https://pubmed.ncbi.nlm.nih.gov/27264138/>. Accessed August 28, 2024.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

3. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment resistant epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. July 10, 2018; 91 (2). Available at: <https://pubmed.ncbi.nlm.nih.gov/30254528/>. Accessed August 28, 2024.
4. National Institute of Neurological Disorders and Stroke. Lennox-Gastaut Syndrome Information Page. Available at: <https://www.ninds.nih.gov/Disorders/All-Disorders/LennoxGastaut-Syndrome-Information-Page>. Accessed August 28, 2024.
5. Panebianco M, Prabhakar H, Marson AG. Rufinamide add-on therapy for refractory epilepsy. Cochrane Database of Systematic Reviews 2018, Issue 4. Art. No.: CD011772. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6494418/>. Accessed August 28, 2024.
6. Hancock EC, Cross JH. Treatment of Lennox-Gastaut syndrome. Cochrane Database of Systematic Reviews 2013, Issue 2. Art. No.: CD003277. Available at: <https://pubmed.ncbi.nlm.nih.gov/23450537/>. Accessed August 28, 2024.
7. Kim HJ, Kim SH, MD, Kang HC, et al. Adjunctive Levetiracetam Treatment in Pediatric Lennox-Gastaut Syndrome. *Pediatr Neurol*. 2014 Oct;51(4):527-31. doi: 10.1016/j.pediatrneurol.2014.06.004. Epub 2014 Jun 25. <https://www.ncbi.nlm.nih.gov/pubmed/25266616>. Accessed August 28, 2024.
8. Grosso S, Franzoni E, Coppola G, et al. Efficacy and safety of levetiracetam: an add-on trial in children with refractory epilepsy. *Seizure*. 2005 Jun;14(4):248-53. <https://www.ncbi.nlm.nih.gov/pubmed/15911359>. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1) Policy description table was updated.</li> <li>2) Continuation therapy criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance”.</li> <li>3) Approval duration updated for both indications and both initial &amp; continued therapies.</li> <li>4) References were updated.</li> </ol>	07/28/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1) Initial Approval Criteria I.A.3 age criteria was updated from “Age ≥ 2 years” to “Age ≥ 1 years”.</li> <li>2) Initial Approval Criteria I.A.4 was updated to include “Obtain baseline complete blood count (CBC), serum transaminase and total</li> </ol>	05/31/2021	09/14/2021

<p>bilirubin prior to initiating therapy”.</p> <p>3) Initial Approval Criteria I.A.4 was updated to remove “Will be used as adjunctive therapy with at least one other antiepileptic drug”.</p> <p>4) Initial Approval Criteria I.A.5 was updated to include generic drug names rufinamide and valproic acid.</p> <p>5) Initial Approval Criteria I.A.6 was updated to include “For DS, failure of at least two of the following, unless contraindicated or clinically significant adverse...”.</p> <p>6) Initial Approval Criteria I.B was updated to include indication “Tuberous sclerosis complex”.</p> <p>7) Continued Therapy Approval Criteria II.A was updated from “Dravet Syndrome or Lennox-Gastaut Syndrome” to “All indications in section I”.</p> <p>8) Continued Therapy Approval Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance...”.</p> <p>9) Continued Therapy Approval Criteria II.A.3 was updated from “If request is for a dose increase, new dose does not exceed 10 mg/kg orally twice daily (20 mg/kg/day)” to “If request is for a dose increase, new dose does not exceed...”.</p> <p>10) Continued Therapy Approval Criteria II.A.3 was updated to include sub-criteria a and b; “10 mg/kg orally twice daily (20 mg/kg/day) for DS and</p>		
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LGS” and “12.5 mg/kg twice daily (25 mg/kg/day) for TSC”; respectively. 11) References were reviewed and updated.		
Policy was reviewed.	03/23/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.6: Updated to remove criteria For DS, failure of at least two of the following, unless contraindicated or clinically significant adverse effects are experienced: clobazam, levetiracetam, topiramate, and valproic acid. 2. References were reviewed and updated.	11/17/2022	11/21/2022
Policy was reviewed: 1. References were updated.	04/19/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024
Policy was reviewed.	12/05/2024	N/A
Policy was reviewed.	12/11/2025	12/11/2025