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| **Clinical Policy Title:** | cannabidiol |
| **Policy Number:** | RxA.370 |
| **Drug(s) Applied:** | Epidiolex® |
| **Original Policy Date:** | 03/06/2020 |
| **Last Review Date:** | 10/19/2023 |
| **Line of Business Policy Applies to:** | All line of business (except Medicare) |

## Criteria

**I. Initial Approval Criteria**

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

1. Diagnosis of DS or LGS;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 1 years;
4. Obtain baseline complete blood count (CBC), serum transaminase and total bilirubin prior to initiating therapy;
5. For LGS, failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Banzel® (rufinamide), clobazam, clonazepam, felbamate, lamotrigine, topiramate, valproic acid;
6. Maximum dose does not exceed 20 mg/kg/day.

**Approval Duration**
**Commercial:** 12 months
**Medicaid:** 12 months

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

1. Diagnosis of TSC;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 1 years;
4. Obtain baseline complete blood count (CBC), serum transaminase and total bilirubin prior to initiating therapy;
5. For TSC, failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: carbamazepine, oxcarbazepine, and vigabatrin.;
6. Maximum dose does not exceed 25 mg/kg/day.

**Approval duration**
**Commercial:** 12 months
**Medicaid:** 12 months

**II. Continued Therapy Approval**

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy, or documentation supports that member is currently receiving Epidiolex® for a covered indication and has received this medication for at least 30 days;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. 10 mg/kg orally twice daily (20 mg/kg/day) for DS and LGS;
   b. 12.5 mg/kg twice daily (25 mg/kg/day) for TSC.

**Approval duration**
**Commercial:** 12 months
**Medicaid:** 12 months

**References**


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| Review/Revision History | Review/Revision Date | P&T Approval Date |
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| Policy established. | 01/2020 | 03/06/2020 |

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| Policy was reviewed:<br>1) Policy description table was updated.<br>2) Continuation therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance".<br>3) Approval duration updated for both indications and both initial & continued therapies.<br>4) References were updated. | 07/28/2020 | 09/14/2020 |
| Policy was reviewed:<br>1) Initial Approval Criteria I.A.3 age criteria was updated from "Age ≥ 2 years" to "Age ≥ 1 years".<br>2) Initial Approval Criteria I.A.4 was updated to include "Obtain baseline complete blood count (CBC), serum transaminase and total bilirubin prior to initiating therapy".<br>3) Initial Approval Criteria I.A.4 was updated to remove "Will be used as adjunctive therapy with at least one other antiepileptic drug".<br>4) Initial Approval Criteria I.A.5 was updated to include generic drug names rufinamide and valproic acid.<br>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…".<br>6) Initial Approval Criteria I.B was updated to include indication "Tuberous sclerosis complex". | 05/31/2021 | 09/14/2021 |

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| 7) Continued Therapy Approval Criteria II.A was updated from “Dravet Syndrome or Lennox-Gastaut Syndrome” to “All indications in section I”.<br>8) Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".<br>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…”.<br>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 LGS” and “12.5 mg/kg twice daily (25 mg/kg/day) for TSC”; respectively.<br>11) References were reviewed and updated. | | |
| Policy was reviewed. | 03/23/2022 | 07/18/2022 |
| Policy was reviewed:<br>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.<br>2. References were reviewed and updated. | 11/17/2022 | 11/21/2022 |
| Policy was reviewed: | 04/19/2023 | 07/13/2023 |

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| 1. References were updated. | | |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |