

Policy Name:	Epidiolex (cannabidiol)	Policy #:	2694P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Epidiolex.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Epidiolex when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS), seizures associated with Dravet syndrome (DS), or seizures associated with Tuberous Sclerosis Complex (TSC)
- 1.2 Age 1 year of age or older
- 1.3 Prescribed by or in consultation with a neurologist (nervous system doctor)
- 1.4 Documentation of baseline liver function tests (ALT, AST, and total bilirubin levels)
- 1.5 Documented inadequate treatment response, intolerance, or contraindication to at least two of the following medications:
 - Clobazam
 - Valproate/valproic acid
 - Lamotrigine
 - Levetiracetam
 - Topiramate
 - Felbamate
- 1.6 Treatment plan includes the use of at least one other antiepileptic drug (such as above drugs)
- 1.7 Calculated dose does not exceed 20mg/kg/day based on the patient's most recent weight

2. Exclusion Criteria

- 2.1 Due to a lack of data showing that Epidiolex is both safe and effective, and the lack of U.S. Food and Drug Administration (FDA) approval, Epidiolex is considered experimental when used for the following indications:
 - Treatment of autoimmune hepatitis
 - Prevention of ischemia/reperfusion injury resulting from solid organ transplant
 - Any indication other than those listed as covered in the policy

3. Approval Period

- 3.1 Initial Approval: 12 months
- 3.2 Reapproval: 12 months with documented beneficial response

CPT Codes

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HCPCS Codes

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References

1. Epidiolex (cannabidiol) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals Inc; January 2023.
2. Wirrell E, Laux L, Donner E, et al. *Pediatric Neurology* 68 (2017) 18-34. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations From a North American Consensus Panel.
3. Patel AD, Mazurkiewicz-Beldzińska M, Chin RF, et al. Long-term safety and efficacy of add-on cannabidiol in patients with Lennox-Gastaut syndrome: Results of a long-term open-label extension trial. *Epilepsia* 2021; 62:2228.
4. Wijnen B, Armstrong N, Ramaekers B, et al. Cannabidiol for Adjuvant Treatment of Seizures Associated with Lennox-Gastaut Syndrome and Dravet Syndrome: An Evidence Review Group Perspective of a NICE Single Technology Appraisal. *Pharmacoeconomics*. 2020 Oct;38(10):1043-1053.
5. Nabavi Nouri M, Zak M, Jain P, Whitney R. Epilepsy Management in Tuberous Sclerosis Complex: Existing and Evolving Therapies and Future Considerations. *Pediatr Neurol* 2022; 126:11.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.