Pharmacy Drug Policy & Procedure

Policy Name:	Epidiolex (cannabidiol)	Policy #:	2694P

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 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

HCPCS Codes

References

1. Epidiolex (cannabidiol) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals Inc; March 2024.
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-Bełdzińska 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.

Created Date: 08/07/19
Effective Date: 08/07/19
Posted to Website: 01/01/22
Revision Date: 08/07/24