PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Epidiolex (cannabidiol)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— up to 20 mg/kg/day
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Epidiolex (cannabidiol) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

DRAVET SYNDROME

For **initial** authorization:

1. Member is 2 years of age or older; AND
2. Medication must be used for the treatment of seizures associated with Dravet syndrome; AND
3. Member has serum transaminases (ALT and AST) and total bilirubin baseline levels submitted with prior authorization request prior to starting treatment; AND
4. Member has been taking one or more antiepileptic drugs (e.g., clobazam, valproate, stiripentol, levatiracetam, topiramate, etc.) and has chart notes confirming presents of at least 4 convulsive seizures (all countable atonic, tonic, clonic, and tonic-clonic seizures) per month.
5. **Dosage allowed:** The recommended starting dosage is 2.5 mg/kg taken twice daily (5mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day). Based on individual clinical response and tolerability, Epidiolex can be increased up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day). See drug package insert for titration.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes have been provided that show the member has decrease in frequency of seizures; AND
2. Member does not have elevations of transaminase levels greater than 3 times the upper limit of normal and bilirubin levels greater than 2 times the upper limit of normal.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

LENNOX-GASTAUT SYNDROME (LGS)

For **initial** authorization:

1. Member is 2 years of age or older; AND
2. Medication must be used for the treatment of seizures associated with Lennox-Gastaut syndrome; AND
3. Member has serum transaminases (ALT and AST) and total bilirubin baseline levels submitted with prior authorization request prior to starting treatment; AND
4. Member has been taking one or more antiepileptic drugs (e.g., clobazam, valproate, lamotrigine, levatiracetam, rufinamide, etc.) and has chart notes confirming presents of at least of 8 drop seizures per month.
5. **Dosage allowed:** The recommended starting dosage is 2.5 mg/kg taken twice daily (5mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day). Based on individual clinical response and tolerability, Epidiolex can be increased up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day). See drug package insert for titration.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes have been provided that show the member has decrease in frequency of seizures; AND
2. Member does not have elevations of transaminase levels greater than 3 times the upper limit of normal and bilirubin levels greater than 2 times the upper limit of normal.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Epidiolex (cannabidiol) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/31/2018	New policy for Epidiolex created.

References:

1. Epidiolex [package insert]. Carlsbad, CA: Greenwich Biosciences, Inc.; June, 2018.
2. ClinicalTrials.gov Identifier: NCT02091375. Antiepileptic Efficacy Study of GWP42003-P in Children and Young Adults With Dravet Syndrome (GWPCARE1). Available at: https://clinicaltrials.gov/ct2/show/NCT02091375. Accessed on July 26, 2018.
3. ClinicalTrials.gov Identifier: NCT02224560. A Study to Investigate the Efficacy and Safety of Cannabidiol (GWP42003-P; CBD) as Adjunctive Treatment for Seizures Associated With Lennox-Gastaut Syndrome in Children and Adults (GWPCARE3). Available at: https://clinicaltrials.gov/ct2/show/NCT02224560?term=NCT02224560&rank=1. Accessed on July 26, 2018.
4. ClinicalTrials.gov Identifier: NCT02224690. A Study to Investigate the Efficacy and Safety of Cannabidiol (GWP42003-P; CBD) as Adjunctive Treatment for Seizures Associated With Lennox-Gastaut Syndrome in Children and Adults (GWPCARE4). Available at: https://clinicaltrials.gov/ct2/show/NCT02224690?term=GWPCARE4&cond=Lennox+Gastaut+Syndrome&rank=1. Accessed on July 26, 2018.
5. Devinsky O, Patel AD, Cross JH, et al. Effect of Cannabidiol on Drop Seizures in the Lennox–Gastaut Syndrome. *N Engl J Med* 2018;378:1888-97.
6. Thiele EA, Marsh ED, French JA, et al. Cannabidiol in patients with seizures associated with Lennox-Gastaut syndrome (GWPCARE4): a randomised, double-blind, placebo-controlled phase 3 trial. *The Lancet*. Published online January 24, 2018 http://dx.doi.org/10.1016/S0140-6736(18)30136-3.

7. Devinsky O, Cross JH, et al. Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome. N Engl J Med 2017;376:2011-20.

Effective date: 09/14/2018
Revised date: 08/31/2018