

**NC Division of Medical Assistance  
Outpatient Pharmacy  
Prior Approval Criteria  
Epidiolex**

**Medicaid and Health Choice  
Effective Date: February 1, 2021  
Amended Date:**

**DRAFT**

**Therapeutic Class Code:** H4E

**Therapeutic Class Description:** Anticonvulsant - Cannabinoid Type

Medication
Epidiolex

**Eligible Beneficiaries**

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NHC beneficiaries.**

**EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age**

**42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- that is unsafe, ineffective, or experimental/investigational.
- that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or

ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

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**EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide:***

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

***EPSDT provider page:***

<https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents>

**Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age**

**EPSDT does not apply to NCHC beneficiaries.** If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

**Criteria for Coverage of Epidiolex**

**Initial Criteria for Coverage**

- Beneficiary must be  $\geq 21$  years of age.

**AND**

- Beneficiary has seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS) or Tuberous Sclerosis Complex

**AND**

- Prescriber to provide attestation that beneficiary's baseline serum transaminases (ALT and AST) and total bilirubin levels have been completed.

**AND**

- Prescriber to provide attestation that beneficiary is not currently using recreational or medicinal cannabis along with this product.

**AND**

- Prescriber to provide attestation that beneficiary has refractory epilepsy (beneficiary has failed to become seizure free with adequate trials of 2 antiepileptic drugs [AED]).

**AND**

- Prescriber to provide attestation that Epidiolex will be used in adjunct to  $\geq 1$  antiepileptic drug. **(not**

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required on reauthorization)

**Continuation of Coverage (renewal request)**

- Beneficiary continues to meet above criteria.

**AND**

- ~~Prescriber to provide attestation to monitoring beneficiary's annual serum transaminases (ALT and AST) and total bilirubin levels.~~

**References**

1. Epidiolex [package insert]. Carlsbad, CA; Greenwich Biosciences; June 2018. Updated July 2020.

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**Criteria Change Log**

02/01/2021	Criteria effective date
10/1/21	<u>Age changed from 2 years of age to 1 year of age and older; Tuberous Sclerosis Complex added to coverage diagnosis</u>
<u>Xx/xx/xxxx</u>	<u>Updated criteria to remove bullets except for diagnosis</u>