

**NC Medicaid  
Outpatient Pharmacy  
Prior Approval Criteria  
Emlaza**

**Medicaid and Health Choice  
Effective Date: 04/03/2018  
Amended Date: December 6, 2019**

**Therapeutic Class Code:** P5A  
**Therapeutic Class Description:** Glucocorticoids

<b>Medication</b>
Emlaza™

**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 (NCHC) 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 NCHC 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

- a. that is unsafe, ineffective, or experimental/investigational.
- b. 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 Initial Coverage:**

- The beneficiary is 2 years of age or older.
- Documentation is submitted that the beneficiary has a diagnosis of Duchenne Muscular Dystrophy confirmed by genetic testing.
- Documentation is submitted that the beneficiary has tried prednisone and has had inadequate treatment response or has experienced unmanageable and clinically significant side effects such as significant weight gain/obesity, persistent psychiatric/behavioral issues, diabetes, hypertension, or Cushingoid appearance.
- A baseline motor milestone assessment (such as 6-minute walk test (6MWT), North Star Ambulatory Assessment (NSAA), Motor Function Measure (MFM), or Hammersmith Functional Motor Scale (HFMS)) has been done and documentation submitted.
- Medication is prescribed by or in consultation with a neurologist
- Emflaza™ is not given concurrently with live vaccinations.
- Emflaza™ dosing for Duchenne Muscular Dystrophy is in accordance with the USFDA approved labeling.
- Maximum length of initial approval: 6 months

**Criteria for Renewal Coverage:**

- Documentation must be submitted that shows the beneficiary is receiving clinical benefit from Emflaza™ therapy, such as stabilization, maintenance or improvement of muscle strength or pulmonary function, or improvement in motor milestone assessment scores from baseline testing, or motor function must be superior relative to that projected for the natural course of Duchenne Muscular Dystrophy (slowing of decline or slowing of progression).
- Maximum length of renewal approval: 12 months

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**References**

1. Prescriber Information Emflaza™ (deflazacort) Marathon Pharmaceuticals, LLC Northbrook IL, 60062. February 2017. Update June 2019.

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**Criteria Change Log**

04/03/2018	Criteria effective date
12/06/2019	Age change to 2 and up