

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

**Medicaid and Health Choice
Effective Date**

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Therapeutic Class Code: P5A

Therapeutic Class Description: Glucocorticoids

Medication	Generic Code Number(s)	NDC Number(s)
Emflaza™	23761, 43012, 23762, 43015, 43016	

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

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at <http://www.ncdhhs.gov/dma/epsdt/>.

Criteria for Initial Coverage:

- The beneficiary is 5 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 TM (deflazacort) Marathon Pharmaceuticals, LLC Northbrook IL, 60062. February 2017.

Criteria Change Log

11/11/1111	Criteria effective date