NC Medicaid
Outpatient Pharmacy Prior Approval Criteria
Duvyzat

Effective Date: xx/xx/xxxx

DRAFT

Therapeutic Class Code: Z16
Therapeutic Class Description: Duchenne Muscular Dystrophy Treatments

Medication
Duvyzat (givinostat)

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.

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.

EPSDT and Prior Approval Requirements

1. 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.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide,* 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

Clinical Coverage

- The beneficiary has a diagnosis of Duchenne Muscular Dystrophy confirmed by genetic analysis (i.e., dystrophin deletion or duplication mutation) (genetic test required) **AND**
- The beneficiary is age 6 or older **AND**
- The beneficiary has tried and had an inadequate response after a 6-month duration of therapy with a glucocorticosteroid used to treat DMD **AND**
- The beneficiary will continue to be on a glucocorticosteroid while taking the requested agent **OR**
- The beneficiary has an intolerance or hypersensitivity to a glucocorticosteroid used to treat DMD **OR**
- The beneficiary has an FDA-labeled contraindication to all glucocorticosteroids used to treat DMD **AND**
- The beneficiary's baseline platelet level has been obtained prior to treatment **AND**
- The beneficiary's baseline triglyceride levels have been evaluated **AND**
- If the beneficiary has underlying cardiac disease or is taking concomitant medications that cause QT prolongation, ECGs have been obtained **AND**
- The beneficiary's platelet level is greater than or equal to 150 x 10^9/L and levels will continue to be monitored during treatment with the requested agent **AND**
- The prescriber is a specialist in the area of the beneficiary's diagnosis (e.g., pediatric neurologist), or the prescriber has consulted with a specialist in the area of the beneficiary's diagnosis **AND**
- The beneficiary does NOT have any FDA-labeled contraindications to the requested agent

Renewal Criteria

- The beneficiary has had improvements or stabilization with the requested agent (e.g., slowed disease progression, improved strength, timed motor function, pulmonary function; reduced need for scoliosis surgery) **AND**
- The beneficiary's platelet level will continue to be monitored during treatment **AND**
- The beneficiary's triglyceride levels will continue to be monitored during treatment **AND**
- If the beneficiary has underlying cardiac disease or is taking concomitant medications that cause QT prolongation, ECGs will continue to be monitored as clinically indicated **AND**
- The prescriber is a specialist in the area of the beneficiary's diagnosis (e.g., pediatric neurologist), or the prescriber has consulted with a specialist in the area of the beneficiary's diagnosis **AND**
- The beneficiary does NOT have any FDA labeled contraindications to the requested agent

Duration of Approval

- 12 months

References

1 Duvyzat [package insert]. Concord, MA; ITF Therapeutics, LLC; March 2024.

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Criteria Change Log

xx/xx/xxxx	Criteria effective date