NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Evrysdi

Effective Date: April 14, 2021

Amended Date: January 5, 2026

Therapeutic Class Code: Z1T
Therapeutic Class Description: GENETIC D/O TX - SMN PROTEIN DEFICIENCY TREATMENT

Medication
Evrysdi Tablet and Oral Solution

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
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.

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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

Criteria for Initial Coverage of Evrysdi:

- Beneficiary is age 0 or older

  AND

- Beneficiary has a diagnosis of 5q-autosomal recessive spinal muscular atrophy (SMA);

  AND

- Beneficiary must have SMA phenotype 1, 2 or 3;

  AND

- Must not be used concomitantly with nusinersen (Spinraza) or onasemnogene abeparvovec-xioi (Zolgensma);

  AND

- Prescribed by or in consultation with a neurologist

  AND

- Initial approval shall be for up to 12 months.

Criteria for Continuation of Coverage of Evrysdi:

- Beneficiary continues to meet the above initial criteria;

  AND

- Absence of unacceptable toxicity or treatment related adverse event from the drug;

  AND

- Beneficiary has clinically meaningful response to treatment as demonstrated by at least 1 of the following:

  - Stability or improvement in net motor function/milestones, including but not limited to, the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Bayley Scales of Infant and Toddler development Third Ed. (BSID-III), 6-minute walk test (6MWT), Upper Limb Module (ULM), Motor Function Measure-32 (MFM-32), Revised Upper Limb Module (RULM) etc.
  - Stability or improvement in respiratory function tests [e.g., forced vital capacity (FVC), etc.
  - Reduction in exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the preceding year/timeframe

- Stable or increased beneficiary weight (for beneficiaries without a gastrostomy tube)
- Slowed rate of decline in the aforementioned measures

- Continuation approvals shall be for up to 12 months

References

1. Evrysdi [package insert]. San Franciso, CA; Genentech; August 2020. Updated February 2025.

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Criteria Change Log

04/14/2021	Criteria effective date
01/05/2026	Criteria reviewed and age change down to 0