NC Medicaid
Prior Approval Criteria
Itvisma

Effective Date: xx/xx/xxxx

DRAFT

Therapeutic Class Code: Z0K
Therapeutic Class Description: Gene Therapy Agents – SMN Protein Deficiency

Medication
Itvisma

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

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 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

Initial Approval Criteria:

- Beneficiary must be ≥2 years of age; **AND**
- Beneficiary has a diagnosis of spinal muscular atrophy (SMA); **AND**
- Beneficiary has a diagnosis of 5q spinal muscular atrophy (SMA) confirmed by either bi-allelic deletion or dysfunctional point mutation of the survival motor neuron 1 (SMN1) gene; **AND**
    - Beneficiary is treatment-naïve for any SMN-targeting agents for SMA (e.g. nusinersen (Spinraza), risdiplam (Evrysdi)) AND is able to sit independently but has never had the ability to walk independently; **OR**
    - Beneficiary has received prior SMN-targeting agents for SMA (e.g. nusinersen (Spinraza), risdiplam (Evrysdi)) AND has one or more of the following:
        - Able to sit independently, but has never had the ability to walk independently; **OR**
        - Has 3 or fewer copies of SMN2 gene; **OR**
        - Achieve and subsequently lost the ability to walk independently; **AND**
- Is administered intrathecally using a lumbar puncture by healthcare professionals (e.g. interventional radiologist or neurologist) experience in performing lumbar punctures; **AND**
- Beneficiary is clinically stable in their overall baseline health status (e.g. hydration and nutritional status, respiratory status) prior to administration; **AND**
- Beneficiary does not have an active, clinically significant infection, that would contraindicate intrathecal administration, as determined by the treating clinician; **AND**
- Beneficiary must have a baseline anti-adeno-associated virus serotype 9 (anti-AAV9) antibody titer of ≤ 1:50 measured by ELISA; **AND**
- Baseline liver function will be assessed prior to initiating therapy and will continue to be monitored for at least 3 months after therapy and as clinically indicated; **AND**
- Baseline platelet counts will be assessed prior to initiating therapy and will continue to be monitored on a regular basis (e.g., at least weekly for the first month and as clinically indicated until platelet counts return to baseline); **AND**

- Baseline creatinine and hemoglobin will be assessed prior to initiating therapy and will continue to be monitored on a regular basis as clinically indicated; **AND**
- Beneficiary is up to date with all vaccinations in accordance with current vaccination guidelines, with consideration of seasonal RSV and Flu prophylaxis as clinically appropriate, prior to initiating therapy; **AND**
- Is administered with systemic corticosteroids in accordance with FDA labeling; **AND**
- Beneficiary must NOT have previously received treatment with SMA gene therapy (e.g., onasemnogene abeparvovec-xioi [Zolgensma]); **AND**
- Will NOT be used concurrently with other SMN-targeting agents for SMA (e.g., Spinraza, Evrysdi, Zolgensma).

Duration: One treatment course
Renewal: N/A

References

1. Novartis Gene Therapies, Inc. Itvisma Package Insert. Bannockburn, IL. November 2025.

Criteria Change Log

xx/xx/xxxx	Criteria effective date