NC Division of Medical Assistance
Outpatient Pharmacy
Prior Approval Criteria
Spinraza

Medicaid and Health Choice
Effective Date: May 26, 2017
Amended Date: October 4, 2017

DRAFT

Therapeutic Class Code: Z1T
Therapeutic Class Description: GENETIC D/O TX EXON INCLUSION ANTISENSE OLIGONUCLEOTIDE

Medication	Generic Code Number(s)	NDC Number(s)
Spinraza	42836	

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:~~

~~**All** criteria A through D below shall be met.~~

~~**A.** A diagnosis of Spinal Muscular Atrophy (SMA) (5q SMA) is established by, or in consultation with a neurologist with expertise in the treatment of SMA~~

~~**AND**~~

~~**B.** Genetic confirmation of a diagnosis of SMA, with documentation of a loss of, or defect in, the survival motor neuron (SMN) 1 gene.~~

~~**AND**~~

~~**C.** Prior to starting nusinersen (Spinraza) therapy, documentation of baseline motor function, with objective function-based testing (such as with a HINE or CHOP-Intend score, Hammersmith functional motor scale, or Upper Limb Module).~~

~~**AND**~~

~~**D.** Documentation of comprehensive SMA care, including physical therapy, respiratory care, and nutrition support as part of the patient's care plan.~~

~~**Initial authorization shall be for 4 loading doses at a maximum dosing of 12mg for each loading dose.**~~

~~Criteria for Renewal Coverage:~~

~~A. Initial therapy met the criteria above~~
~~**AND**~~
~~B. Documentation shall be submitted that indicates the medication is effective, including documentation of clinically significant improvement of motor function or stabilization of motor function loss, which **must** include clinical documentation of a physical assessment, motor function function-based testing, and need for medical intervention related to SMA symptoms, relative to baseline (and/or previous authorization period). Overall motor function must be improved/superior relative to that projected for the natural course of SMA.~~

~~**Renewal authorizations shall be for a maximum of two doses (12 mg per dose) administered in 4 month intervals.**~~

~~References~~

1. ~~Spinraza™ (nusinersen) injection for intrathecal use [package insert]. Cambridge, MA: Biogen, Inc; December 2016~~

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~~Criteria Change Log~~

~~05/26/2017 (v1)~~	~~Criteria effective date~~
~~10/04/2017 (v2)~~	~~Criteria amended to include all types SMA~~