TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Nusinersen (Spinraza®)	**CRITERIA ID:** TX.CC.PHAR.01
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 2/7/18	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 2/12/19, 10/1/19, 01/08/2020, 1/28/2020, 01/08/21, 11/22/21, 8/1/22, 7/12/23, 4/3/2024, 6/21/2024, 5/14/2025	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for nusinersen (Spinraza®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
NRB = non-risk based

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of nusinersen (Spinraza®); procedure code: J2326.

Description/Mechanism of Action:
Nusinersen (Spinraza®) is an antisense oligonucleotide designed to treat SMA caused by mutations in chromosome 5q that lead to SMN protein deficiency. Using in vitro assays and studies in transgenic animal models of SMA, Spinraza was shown to increase exon 7 inclusion in SMN2 messenger ribonucleic acid transcripts and production of full-length SMN protein.

FDA Approved Indications:
Nusinersen (Spinraza®) is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

Formulations:
Nusinersen (Spinraza®) is available as an intrathecal injectable formulation. Sterile, clear, and colorless solution supplied as a 12 mg/5 mL (2.4 mg/mL) solution in a single-dose, glass vial, free of preservatives.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Spinal Muscular Atrophy

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client has a diagnosis of spinal muscular atrophy (SMA).
3. Documentation of genetic testing must confirm biallelic pathogenic variants in the client's survival motor neuron 1 (SMN1) gene.
4. Documentation of the client's baseline physical function. Testing tools used to measure the physical function must be age-appropriate for the child who is tested, for example, the Hammersmith Infant Neurological Examination (HINE) or Hammersmith functional motor scale expanded (HFMSE). Other examples might include the Upper Limb Module (UML), Baseline 6MWT, or Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND).
5. Documentation of the client's baseline pulmonary status, including any requirements for invasive or non-invasive ventilation.
6. Documentation of the requested dosage and administration schedule, including the number of injections to be administered during the prior authorization period, the requested units per injection, and the dosage calculation.
7. Total number of doses does not exceed 5 doses of 12 mg, prescribed for intrathecal use.

Approval duration: 6 months

II. Continued Therapy

A. Spinal Muscular Atrophy

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. Currently receiving medication via the company benefit or member has previously met initial approval criteria or had received the drug from a previous Medicaid MCO (continuity of coverage).
3. Request for continuation must be received no earlier than 30 days before the current authorization period expires. Requests for recertification/extension of prior authorization received after the current prior authorization expires will be denied for dates of service that occurred before the date the request is received.
4. Documentation of the client's pulmonary status, including any requirements for invasive or non-invasive ventilation. Any changes in pulmonary status that have occurred since the previous prior authorization request must be addressed.
   Note: Spinraza is not a continuing benefit for clients with decreasing pulmonary function while on the medication.
5. The Medical Director will check for improvement in or maintenance of baseline physical function. Providers must use the same testing instrument as used in the initial evaluation. If re-use of the initial testing instrument is not appropriate, for example, due to change in client status or restricted age range of the testing tool, the provider must explain the reason for the change.
   Note: Spinraza should not be continued on clients who experience decreasing physical function while on the medication.
6. Prescriber attestation that the client has been compliant with treatment.
7. Documentation of the requested dosage and administration schedule, including the number of injections to be administered during the PA period, the requested units per injection and the dosage calculation.
8. Dosing does not exceed 12mg every 4 months prescribed for intrathecal use.

Approval duration: 12 months

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc Review	Changed "Justin M. Weiss, Sr. V.P., Pharmacy Operations" to "Karen Tadlock, V.P., Pharmacy Operations" Formatting	2/12/2019

	Under Procedure I.A.: line 8 was added "Documentation of baseline pulmonary status, including...non-invasive ventilation". Line 9 was added "Documentation of the requested dosage...and the dosage calculation" and the original line 8 was made into line 10 and changed 4 doses to 5 doses. Under Procedure II.A: Line 2 was added "Request for continuation must be received...after the date of service requested." Line 5 was added "Neurologist's consultation must be dated...recommending ongoing treatment with nusinersen (Spinraza)." Line 6 was added "Documentation of client's pulmonary status...prior authorization request must be addressed." Line 7 had removed "improvement in the physical exam after starting nusinersen (Spinraza) and" and added "the dosage and administration schedule...from the prescribing clinician that" and "child" changed to "client". Line 8 had removed "in" and replaced with "in or maintenance of baseline", and removed "Examples of the drug showing a positive...scores prior to initiation of therapy." and added "Providers must use the same testing instrument...decreasing physical function while on the medication."	
Ad Hoc Review	Added information and criteria step regarding Centene's Precision Drug Action Committee (PDAC) Added "Nusinersen (Spinraza) is not a continuing benefit for clients with decreasing pulmonary function while on the medication." In II.A.7. Removed age requirement in continuation criteria	10/1/2019
Ad Hoc Review	Removed step 3 from initial approval criteria "Initial request must include documentation supporting medical necessity, including a signed and dated prior authorization request form by the Provider."	01/08/2020
Ad Hoc Review	Age restriction removed from policy per VDP guidance	01/28/2020
Ad Hoc Review	Annual review Remove PDAC designation effective 12/1/21 Reworded criteria #2 under Continued Therapy section to match TMPPM Manual Added TMPPM Manual as a reference	11/22/2021
Ad Hoc Review	Removed specialist requirement Changed to new P&P template Removed step that states Medical Director may approve up to 6 months. Duplication of information since approval duration is only 6 months	8/1/2022

Annual Review	Removed “There must be a statement from the prescribing clinician that the client has taken the drug as prescribed.” From step 5 under continued criteria as this is listed as a separate criteria point under step 7. Formatting changes	7/12/2023
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement	4/3/2024
Ad Hoc Review	Updated continuation criteria approval duration to 12 months	6/21/2024
Annual review	Formatting change for 508 remediation	5/14/2025