Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors	**DOCUMENT NAME:** Nusinersen (Spinraza®) Criteria
PAGE: 1 of 6	**REPLACES DOCUMENT:** N/A
APPROVED DATE: 2/7/18	**RETIRED:** N/A
EFFECTIVE DATE: 02/07/18	**REVIEWED/REVISED:** 2/12/19, 10/1/19; 01/08/2020, 1/28/2020, 01/08/21
PRODUCT TYPE: STAR, STAR Health, STAR Kids, STAR+PLUS, CHIP, CHIP Prenate	**REFERENCE NUMBER:** TX.PHAR.44

SCOPE:

Superior HealthPlan Pharmacy Department, Medical Directors

PURPOSE:

It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of nusinersen (Spinraza). This medication is a pass through 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 Superior 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.
Additionally, this medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage Precision Drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All Precision Drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All Precision Drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

BACKGROUND:

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.

Formulations:
Nusinersen (Spinraza): 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.

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

PROCEDURE:

I. Initial Approval Criteria

A. Spinal Muscular Atrophy

1. All prior authorization approvals or denials will be determined by a Superior HealthPlan Medical Director.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The SHP pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the SHP Medical Director but will not make the ultimate determination on any case.
3. Diagnosis of spinal muscular atrophy (SMA).
4. Documentation of genetic testing must confirm biallelic pathogenic variants in the client's survival motor neuron 1 (SMN1) gene.
5. Prescribed by or in consultation with a neurologist. The neurologist's consultation should be dated no more than six month prior to the initially requested authorization date. The consultation must include the neurologist's name, credentials, contact information, and must state specifically that the recommendation is for treatment with nusinersen (Spinraza).
6. Documentation of 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).

7. Documentation of baseline pulmonary status, including any requirements for invasive or non-invasive ventilation.
8. 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.
9. Total number of doses does not exceed 5 doses of 12 mg, prescribed for intrathecal use. A maximum of 6 months may be approved by the Medical director.

II. Continued Therapy

A. Spinal Muscular Atrophy

1. 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).
2. Request for continuation must be received no earlier than 30 days before the current authorization period expires. The PA will be denied if received after the date of service requested.
3. All approvals or denials for continued therapy will be reviewed by a Superior Medical Director to continue coverage.
4. Medical necessity determinations will be supported by PDAC UM recommendation. The SHP pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the SHP Medical Director but will not make the ultimate determination on any case.
5. Neurologist's consultation must be dated no more than one rolling year of the recertification/extension date that includes the name, credentials, and contact information for the consulting neurologist recommending ongoing treatment with nusinersen (Spinraza).
6. Documentation of 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. Nusinersen (Spinraza) is not a continuing benefit for clients with decreasing pulmonary function while on the medication.

7. The Provider documents the 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. There must be a statement from the prescribing clinician that the client has taken the drug as prescribed.
8. 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. Nusinersen (Spinraza) should not be continued on clients who experience decreasing physical function while on the medication.
9. The prescribing clinician provides a statement that the client has been compliant with treatment.
10. Dosing does not exceed 12mg every 4 months prescribed for intrathecal use. Approval will not exceed 6 months per Superior Medical Director.

REFERENCES: N/A

ATTACHMENTS: N/A

DEFINITIONS/ABBREVIATIONS: N/A

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REVISION LOG

REVISION	DATE
• Changed "Justin M. Weiss, Sr. V.P., Pharmacy Operations" to "Karen Tadlock, V.P., Pharmacy Operations" • Formatting • 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."	2/12/2019
• 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
• Removed step 3 from initial approval criteria "Initial request must include documentation supporting medical necessity,	01/08/2020

including a signed and dated prior authorization request form by the Provider."	
• Age restriction removed from policy per VDP guidance	01/28/2020
• Annual review • Added required statement of treatment compliance per VDP guidance	01/08/2021

POLICY AND PROCEDURE APPROVAL

Karen Tadlock, V.P., Pharmacy Operations — Approval on file

Dr. David Harmon, Sr. V.P., Chief Medical Officer — Approval on file

Pharmacy & Therapeutics Committee: — Approval on file

NOTE: The electronic approval retained in RSA Archer, Centene's P&P management software, is considered equivalent to a physical signature.