

Policy: MBP 151.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Spinraza (nusinersen)

I. Policy:

Spinraza (nusinersen)

II. Purpose/Objective:

To provide a policy of coverage regarding Spinraza (nusinersen)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Spinraza (nusinersen) treats spinal muscular atrophy caused by mutations in chromosome 5q that lead to survival motor neuron (SMN) protein deficiency by binding to a specific sequence in the intron downstream of exon 7 of the SMN2 messenger ribonucleic acid (mRNA) transcript and increase production of full-length SMN protein.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Spinraza (nusinersen) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Prescription is being prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
 - Homozygous exon 7 gene deletion OR
 - Homozygous exon 7 conversion mutation OR
 - Compound heterozygous exon 7 mutation

OR

- Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies.

AND

- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)*

*Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

AUTHORIZATION DURATION: If determined to be medically necessary, Spinraza should be approved for an initial authorization duration of 12 months. Subsequent authorizations of Spinraza will be determined medically necessary and should be approved for an authorization duration of 12 months when the following criteria are met:

- Medical record documentation that member is compliant with prescribed nusinersen regimen **AND**
- Medical record documentation that the patient has not received prior treatment with gene therapy (Zolgensma)*

*Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

QUANTITY LIMIT: *Initial approval:* One (1) injection (5ml) per fill with an RX count of 6 for a 12-month authorization duration.

Subsequent approvals: One (1) injection (5ml) per fill with an RX count of 3 for a 12-month authorization duration. Max quantity supply: 5; Max Day Supply: 365; Min Day Supply: 120

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 3/21/17

Revised: 5/2/17 (per DHS), 7/16/19 (Zolgensma, QL's), 9/19/19 (per DHS), 5/9/23 (LOB carve out, Medicaid business segment)

Reviewed: 1/31/18, 10/31/18, 7/1/20, 5/27/21, 5/11/22 (Medicaid PARP statement)