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| ISSUE DATE December 15, 2020 | EFFECTIVE DATE January 5, 2021 | NUMBER *See below |
| SUBJECT Prior Authorization of Spinraza (nusinersen) – Pharmacy Services | | BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs |

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx>.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Spinraza (nusinersen) submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Spinraza (nusinersen) to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services’ (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists

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| *01-20-53 | 09-20-52 | 27-20-48 | 33-20-49 |
| 02-20-46 | 11-20-46 | 30-20-45 | |
| 03-20-46 | 14-20-47 | 31-20-53 | |
| 08-20-56 | 24-20-47 | 32-20-45 | |

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs Web site at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the October 21, 2020, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of prescriptions for Spinraza (nusinersen) to reflect new efficacy data, Department consultation with specialists in the treatment of spinal muscular atrophy (SMA), and recent U.S. Food and Drug Administration (FDA) approval of Evrysdi (risdiplam) for the treatment of SMA:

- Removal of type I, II, or III from the guideline related to the diagnosis of SMA;
- Addition of a guideline that the dose prescribed is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; and
- Addition of a guideline that the beneficiary will not be using Spinraza (nusinersen) concomitantly with Evrysdi (risdiplam).

The revisions to the guidelines to determine medical necessity of prescriptions for Spinraza (nusinersen), as recommended by the DUR Board, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Spinraza (nusinersen) are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Spinraza (nusinersen)) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Spinraza (nusinersen)

A. Prescriptions That Require Prior Authorization

All prescriptions for Spinraza (nusinersen) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Spinraza (nusinersen), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **One** of the following:

- a. Has a diagnosis of spinal muscular atrophy (SMA) and the corresponding mutation or deletion in the SMN gene found at chromosome 5q13
- b. Has a diagnosis listed in nationally recognized compendia for the determination of medically accepted indications for off-label uses for Spinraza (nusinersen);

AND

2. Is prescribed a dose that is consistent with U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed Spinraza (nusinersen) by or in consultation with a neurologist with experience treating SMA; **AND**
4. Has documentation of a baseline evaluation, including a standardized assessment of motor function, by a neurologist with experience treating SMA; **AND**
5. Is receiving comprehensive treatment based on standards of care for SMA; **AND**
6. Has a documented baseline platelet count that will be repeated prior to each dose; **AND**
7. Will not be using Spinraza (nusinersen) concomitantly with Evrysdi (risdiplam).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR SPINRAZA (NUSINERSEN): The determination of medical necessity of a request for renewal of a prior authorization for

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Spinraza (nusinersen) that were previously approved will take into account whether the beneficiary:

1. Is prescribed Spinraza (nusinersen) by or in consultation with a neurologist with experience treating SMA; **AND**
2. Is prescribed a dose that is consistent with U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Has documentation of an annual evaluation, including a standardized assessment of motor function, by a neurologist with experience treating SMA; **AND**
4. Is receiving comprehensive treatment based on standards of care for SMA; **AND**
5. Has a documented platelet count prior to each dose; **AND**
6. Based on the prescriber's assessment, continues to benefit from Spinraza (nusinersen); **AND**
6. Will not be using Spinraza (nusinersen) concomitantly with Evrysdi (risdiplam).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of the request for a prescription for Spinraza (nusinersen). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. Arnold WD, Kassar D, Kissel JT. Spinal muscular atrophy: diagnosis and management in a new therapeutic era. *Muscle Nerve* 2015; 51:157.
2. Spinraza (nusinersen) prescribing information. Biogen Inc, June 2020.
3. Messina, S, Sframeli, M. New Treatments in Spinal Muscular Atrophy: Positive Results and New Challenges. *Journal of Clinical Medicine*. 2020 July; 9(7): 2222.

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4. Finkel, R, Mercuri, E, Darras, B, et.al. for the ENDEAR Study Group. Nusinersen versus Sham Control in Infantile-Onset Spinal Muscular Atrophy. *New England Journal of Medicine*. 2017; 377:1723-1732.
5. Mercuri, E, Darras, B, Chiriboga, C, et.al. for the CHERISH Study Group. Nusinersen versus Sham Control in Later-Onset Spinal Muscular Atrophy. *New England Journal of Medicine*. 2018; 378:625-635.
6. Vivo, D, Bertini, E, Swoboda, J, et.al. Nusinersen initiated in infants during the presymptomatic stage of spinal muscular atrophy: Interim efficacy and safety results from the Phase 2 NURTURE study. *Neuromuscular Disorders*. 2019; 29: 842–856.