pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
December 14, 2020	January 5, 2021	*See below

SUBJECT

Prior Authorization of Evrysdi (risdiplam) – 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:

1. Inform providers that the Department of Human Services (Department) will require prior authorization of prescriptions for Evrysdi (risdiplam).
2. Issue new handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Evrysdi (risdiplam) 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 Evrysdi (risdiplam) to the appropriate managed care organization.

BACKGROUND:

*01-20-56	09-20-55	27-20-51	33-20-52
02-20-49	11-20-49	30-20-48	
03-20-49	14-20-50	31-20-56	
08-20-59	24-20-50	32-20-48	

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 website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

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

DISCUSSION:

Evrysdi (risdiplam) was recently approved by the U.S. Food and Drug Administration for the treatment of spinal muscular atrophy in patients two months of age and older. During the October 21, 2020, meeting, the DUR Board recommended that the Department require prior authorization of Evrysdi (risdiplam) to ensure appropriate patient selection and drug utilization. The DUR Board recommended guidelines to determine medical necessity of prescriptions for Evrysdi (risdiplam) that 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 Evrysdi (risdiplam) 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 Evrysdi (risdiplam)) 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

I. Requirements for Prior Authorization of Evrysdi (risdiplam)

A. Prescriptions That Require Prior Authorization

All prescriptions for Evrysdi (risdiplam) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Evrysdi (risdiplam), 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 survival motor neuron (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 Evrysdi (risdiplam);

    AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed Evrysdi (risdiplam) 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. Will not be using Evrysdi (risdiplam) concomitantly with Spinraza (nusinersen).

    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 AUTHORIZATIONS FOR EVRYSDI (RISDIPLAM): The determination of medical necessity of a request for renewal of a prior authorization for Evrysdi (risdiplam) that was previously approved will take into account whether the beneficiary:

1. Is prescribed Evrysdi (risdiplam) by or in consultation with a neurologist with experience treating SMA; **AND**

2. Is prescribed a dose that is consistent with 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. Based on the prescriber's assessment, continues to benefit from Evrysdi (risdiplam); **AND**

6. Will not be using Evrysdi (risdiplam) concomitantly with Spinraza (nusinersen).

   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 Evrysdi (risdiplam). 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. Evrysdi (risdiplam) prescribing information. Genentech, Inc, August 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.
4. Carvalho J. Infants Receiving Evrysdi Continue to Improve and Achieve Motor Milestones, Phase 2/3 Trial Data Show. SMA News Today. September 29, 2020.