pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
January 21, 2019	January 22, 2019	*See below

SUBJECT

Prior Authorization of Radicava (edaravone) – 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: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers that the Department of Human Services (DHS) will require prior authorization of prescriptions of Radicava (edaravone).

2. Issue handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Radicava (edaravone) 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 under the MA managed care delivery system should address any questions related to Radicava (edaravone) to the appropriate managed care organization.

BACKGROUND:

*01-19-03	09-19-03	27-19-02	33-19-03
02-19-02	11-19-02	30-19-02	
03-19-02	14-19-02	31-19-03	
08-19-04	24-19-02	32-19-02	

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
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

DHS' 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 DHS Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the September 25, 2018, DUR Board meeting, the DUR Board recommended that DHS require prior authorization of Radicava (edaravone) to ensure appropriate patient selection and drug utilization of Radicava (edaravone). The DUR Board recommended guidelines to determine medical necessity of Radicava (edaravone) that were subject to public review and comment and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of Radicava (edaravone), are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS 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 Radicava (edaravone)) 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

SECTION II
Radicava (edaravone)

I. Requirements for Prior Authorization of Radicava (edaravone)

A. Prescriptions That Require Prior Authorization

All prescriptions for Radicava (edaravone) must be prior authorized.

B. Clinical Review Guidelines and Review of Documentation for Medical Necessity

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

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package insert OR a medically-accepted indication.

   AND

2. Is being prescribed Radicava by or in consultation with a neurologist or other appropriate specialist.

   AND

3. Does not have a contraindication to Radicava.

   AND

4. For a diagnosis of amyotrophic lateral sclerosis (ALS):

   a. Has documentation of a baseline evaluation that includes a Revised ALS Functional Rating Scale (ALSFRS-R) score or results of another standardized assessment tool,

      AND

   b. Has a disease duration of less than 2 years,

      AND

   c. Has a forced vital capacity (FVC) ≥ 80%,

      AND

d. Is not dependent on mechanical invasive ventilation by tracheostomy or intubation,

AND

e. Does not receive tube feedings,

AND

f. Will be prescribed Radicava in combination with riluzole,

OR

g. Has a contraindication or intolerance to riluzole,

OR

h. Has baseline elevations of serum transaminases greater than five times the upper limit of normal.

AND

5. If a prescription for Radicava is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   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 PRESCRIPTIONS FOR RADICAVA (edaravone): Requests for prior authorization of renewals of prescriptions for Radicava (edaravone) that were previously approved will take into account whether the beneficiary:

1. Continues to experience clinical benefit from Radicava based on the prescriber's assessment.

AND

2. Is being prescribed Radicava by or in consultation with a neurologist or other appropriate specialist.

AND

3. For a diagnosis of ALS:

   a. Has documentation of a recent evaluation that includes a ALSFRS-R score or results of another standardized assessment tool,

   AND

   b. Will be prescribed Radicava in combination with riluzole,

   OR

   c. Has a contraindication or intolerance to riluzole,

   OR

   d. Has baseline elevations of serum transaminases greater than five times the upper limit of normal.

AND

4. Does not have a contraindication to Radicava.

AND

5. If a prescription for Radicava is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   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 a prescription for Radicava (edaravone). 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. Radicava [package insert]. Jersey City, NJ: MT Pharma America, Inc.; May 2017.
2. Abe K, Itoyama Y, Sobue G, et al. Confirmatory double-blind, parallel-group, placebo-controlled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. Amyotroph Lateral Scler Frontotemporal Degener. 2014;15(7-8):610-617.
3. Abe K, Aoki M, Tsuji S, et al. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. Lancet Neurol. 2017;16:505-512.
4. Choudry RB, Galvez-Jimenez N, Cudkowicz ME. Disease modifying treatment of amyotrophic lateral sclerosis. In: UpToDate [internet database]. Shefner JM, Targoff IN, eds. Waltham, MA: UpToDate. Updated June 1, 2017. Accessed August 14, 2017.
5. Cedarbaum JM, Stambler N, Malta E, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. J Neurol Sci. 1999;169(1-2):13-21.
6. Rilutek [package insert]. Cary, NC: Covis Pharmaceuticals, Inc.; April 2016.