Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

Coverage Determination Considerations for RADICAVA ORS®

Help avoid unnecessary delays in patient access to therapy by providing documentation typically required for Prior Authorization.

Following the preliminary benefit investigation, the ***JourneyMate Support Program***™ Insurance & Access Specialist will triage your patient's prescription to an in-network specialty pharmacy for final coverage determination.

The following are typical documentation requirements the specialty pharmacy may need for the Prior Authorization process, in addition to a completed Benefit Investigation and Enrollment Form with prescriber and patient signatures.

Please submit clinical information that may be required by a health plan to the Insurance & Access Specialist via fax at 1-888-782-6157 as soon as possible:

- ☐ Patient demographic information
- ☐ Prior therapies used for ALS treatment
- ☐ Response to prior therapies
- ☐ Clinical notes from the most recent visit
- ☐ Most recent laboratory results
- ☐ Duration of disease[a]
- ☐ ALS classification[b]
- ☐ ALSFRS-R scores
- ☐ %FVC from a pulmonary function test

This may not be all the information a health plan requires. Please contact the health plan directly for more details.

IMPORTANT NOTE: During the Prior Authorization process, a health plan may contact your office directly to request a confirmation or additional information. Your timely response to the health plan's request may help avoid unnecessary delays in patient access to therapy.[c]

INDICATION

RADICAVA (edaravone) and RADICAVA ORS (edaravone) are indicated for the treatment of amyotrophic lateral sclerosis (ALS).

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

RADICAVA and RADICAVA ORS are contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients of this product. Hypersensitivity reactions (redness, wheals, and erythema multiforme) and cases of anaphylaxis (urticaria, decreased blood pressure, and dyspnea) have occurred with RADICAVA.

%FVC, percent forced vital capacity; ALS, amyotrophic lateral sclerosis; ALSFRS-R, ALS Functional Rating Scale-Revised.

[a]Patient's date of diagnosis.

[b]Per the El Escorial and/or the revised Airlie House diagnostic criteria (definite or probable).

[c]The ***JourneyMate Support Program***™ Insurance & Access Specialist does not fill out any information that requires the medical judgment of the prescriber and only the prescriber can determine whether to pursue a Prior Authorization. Determination of Prior Authorization is at the sole discretion of the health plan. The ***JourneyMate Support Program***™ Insurance & Access Specialist and Mitsubishi Tanabe Pharma America, Inc. do not assume responsibility for, nor do they guarantee the approval of a Prior Authorization request.

See IMPORTANT SAFETY INFORMATION on next page and full Prescribing Information.

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Patients should be monitored carefully for hypersensitivity reactions. If hypersensitivity reactions occur, discontinue RADICAVA or RADICAVA ORS, treat per standard of care, and monitor until the condition resolves.

Sulfite Allergic Reactions

RADICAVA and RADICAVA ORS contain sodium bisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown but occurs more frequently in asthmatic people.

Adverse Reactions

The most common adverse reactions (≥10%) reported in RADICAVA-treated patients were contusion (15%), gait disturbance (13%), and headache (10%). In an open label study, fatigue was also observed in 7.6% of patients receiving RADICAVA ORS.

Pregnancy

Based on animal data, RADICAVA and RADICAVA ORS may cause fetal harm.

To report suspected adverse reactions or product complaints, contact Mitsubishi Tanabe Pharma America, Inc., at 1-888-292-0058. You may also report suspected adverse reactions to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Contact a *JourneyMate Support Program*™ Insurance & Access Specialist for patient-focused answers and resources.

JourneyMate SUPPORT PROGRAM™

Dedicated Team. Patient-Focused Approach.

Insurance & Access Specialist
1-844-772-4548
Monday-Friday, 8:00 AM-8:00 PM ET
radicavahcp.com

The JourneyMate Resource Specialist discusses basic information about Mitsubishi Tanabe Pharma America, Inc. products and does not take the place of a patient's doctor.

Please see full Prescribing Information.

Mitsubishi Tanabe Pharma America

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For US healthcare professionals only.
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