



# Example Treatment Initiation Checklist

This example checklist is for reference purposes only. It is not intended to provide treatment initiation guidance or advice for prescribing practices. Treatment initiation guidance is provided solely at the discretion of a healthcare provider. Healthcare providers should always contact the patient's health plan to find out the specific requirements for prescribing RADICAVA ORS®.

## 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.

See **IMPORTANT SAFETY INFORMATION**  
on page 6 and full [\*\*Prescribing Information\*\*](#).

## Prescriber Checklist Example

### Considerations for a patient diagnosed with amyotrophic lateral sclerosis (ALS)<sup>a</sup>

- ☐ **Clinical notes that may be required by a health plan**
  - Existing RADICAVA<sup>®</sup> IV patient continuation criteria
  - Duration of disease (ie, date when the patient was diagnosed)
  - ALS classification per the El Escorial and/or the revised Airlie House diagnostic criteria (definite or probable)
  - ALS Functional Rating Scale-Revised (ALSFRS-R) score
    - Information about the ALSFRS-R score is available at [radicavahcp.com](http://radicavahcp.com)
  - Percent forced vital capacity (%FVC) from a pulmonary function test (PFT)

### The Benefit Investigation and Enrollment Form is the first step to providing access to treatment

- ☐ **Complete, sign, and submit the Benefit Investigation and Enrollment Form to enroll your patient in the JourneyMate Support Program<sup>™</sup>**
  - Be sure to fill out Section 3, Prescription Information. For details, see accompanying RADICAVA ORS<sup>®</sup> Prescription Information
  - Be sure to obtain a copy of the patient's prescription health insurance card
- ☐ **You may need to include Prior Authorization requirements or submit an exception request (based on the patient's health plan)<sup>b</sup>**
  - The JourneyMate Support Program<sup>™</sup> Insurance & Access Specialist can provide available resources and limited Prior Authorization assistance,<sup>c</sup> which may help avoid unnecessary delays in patient access to therapy
    - To learn more, call 1-844-772-4548
  - Include additional information to the payer, if required<sup>d</sup>
    - A Sample Letter of Medical Necessity, Sample Exceptions Letter, and Sample Appeal Letter are available at [radicavahcp.com](http://radicavahcp.com)
  - Request an exception, or appeal a denial of coverage, as appropriate
  - Confirm coverage with the health plan

<sup>a</sup>All health plans vary. Healthcare providers should always check with a patient's health plan to learn more about each plan's coverage requirements.

<sup>b</sup>Individual patient cases may differ based upon insurance provider.

<sup>c</sup>The JourneyMate Support Program<sup>™</sup> 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<sup>™</sup> 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.

Verification of insurance coverage is ultimately the responsibility of the healthcare provider. Since reimbursement by payers is subject to many factors, Mitsubishi Tanabe Pharma America and our service providers do not represent or guarantee that payer reimbursement or any other payment or reimbursement of any kind will be made. Mitsubishi Tanabe Pharma America and our service providers do not reimburse for claims denied by payers. Information provided as a result of the benefit investigation is provided for general reference and informational purposes only. Our service providers make every effort to be accurate in the information provided; however, no representations or warranties are expressed or implied by service providers and Mitsubishi Tanabe Pharma America regarding the accuracy or reliability of the information. Our service providers or Mitsubishi Tanabe Pharma America, or its agents or employees shall not be liable legally, financially, or otherwise, for damages of any kind as a result of or related to these services. Our service providers and other users of this information resulting from benefit investigation services accept full responsibility for use of the service.

<sup>d</sup>Use of this resource does not guarantee health plan reimbursement and is not intended to be a substitute for, or to influence, the independent medical judgment of the physician.

## Prescription Fulfillment Through Specialty Pharmacy

An Insurance & Access Specialist will triage the prescription to an in-network specialty pharmacy.  
The specialty pharmacy will:

- Process the patient's RADICAVA ORS<sup>®</sup> prescription
- Contact the patient to arrange for payment of out-of-pocket costs, including applying any financial cost support that may be available to them, if eligible
- Contact the patient or their caregiver to review their prescription details and shipment information
- Ship the medication to the mailing address the patient has provided

### In-Network Specialty Pharmacies for RADICAVA ORS<sup>®</sup>

Accredo<sup>®</sup>  
Phone 844-412-4764  
Fax 888-302-1028

CVS Specialty<sup>®</sup>  
Phone 800-378-0695  
Fax 800-378-0696

OptumRX<sup>®</sup>  
Phone 855-312-9074  
Fax 877-342-4596

Soleo Health<sup>®</sup>  
Phone 866-288-8210  
Fax 866-288-8119

**For more information, contact your Mitsubishi Tanabe Pharma America representative.**

See **IMPORTANT SAFETY INFORMATION**  
on page 6 and full [\*\*Prescribing Information\*\*](#).



## Prescription Information

This prescription information is for reference purposes only. It is not intended to provide guidance or advice for prescribing practices. Prescription guidance and decisions are solely determined by the healthcare provider. Healthcare providers should always contact the patient's health plan to find out the specific requirements for prescribing RADICAVA ORS<sup>®</sup> (edaravone).

### RADICAVA ORS<sup>®</sup> 105 mg (5 mL) Oral Suspension

**DIAGNOSIS<sup>1</sup>:** G12.21 Amyotrophic lateral sclerosis (progressive spinal muscle atrophy)

**DOSAGE<sup>2</sup>:** **STARTER DOSE:**  
105 mg (5 mL) taken orally or via feeding tube (Nasogastric [NG] tube or Percutaneous Endoscopic Gastrostomy [PEG] tube) once daily for 14 consecutive days, followed by a 14-day drug-free period.

**SUBSEQUENT DOSE:**  
105 mg (5 mL) taken orally or via feeding tube (Nasogastric [NG] tube or Percutaneous Endoscopic Gastrostomy [PEG] tube) once daily for 10 days out of 14 days, followed by 14-day drug-free periods.

**REFILLS:** 11 for a full year

**References:** 1. ICD-10-CM Expert for Physicians. Optum360, LLC; 2023. 2. RADICAVA and RADICAVA ORS. Prescribing Information. Mitsubishi Tanabe Pharma America, Inc.; 2022.

RADICAVA ORS<sup>®</sup> should be taken in the morning on an empty stomach after overnight fasting. Food should not be consumed for 1 hour after administration except water. See Prescribing Information for specific fasting conditions.<sup>2</sup>

**For more information about RADICAVA ORS<sup>®</sup>, contact your Mitsubishi Tanabe Pharma America representative.**

See **IMPORTANT SAFETY INFORMATION** on page 6 and full [Prescribing Information](#).



# Benefit Investigation and Enrollment Form for RADICAVA ORS<sup>®</sup>

## In Section 3:

**SPECIAL NOTE:** Physician must comply with state-specific prescription requirements, such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements could result in follow-up and delayed processing.

- **For patients new to RADICAVA ORS<sup>®</sup>,** check both Starter Dose and Subsequent Dose, as well as Refills quantity. Starter Dose is recommended as the initial treatment cycle. See [Prescribing Information](#).
- **For patients switching from RADICAVA<sup>®</sup> IV to RADICAVA ORS<sup>®</sup>,** check Subsequent Dose and Refills quantity. Upon switching to the oral formulation, patients should follow the same dosing frequency but must follow the fasting requirements with regard to food consumption.

## Two Ways to Submit<sup>a</sup>:



### Online via eSign

1. Access the online Benefit Investigation and Enrollment Form at [www.RadicavaOnlineEnrollmentForm.com](http://www.RadicavaOnlineEnrollmentForm.com)
2. Follow instructions for completing, signing, and submitting the online form to the **JourneyMate Support Program<sup>™</sup>** Insurance & Access Specialist



### By Mail, Fax, or Electronic Fax

1. Download and save the fillable form
2. Print, sign, scan, or photograph, and submit the completed form using:
  - **Mail:** **JourneyMate Support Program<sup>™</sup>** Insurance & Access Specialist  
680 Century Point, Lake Mary, FL 32746
  - **Fax or Electronic Fax:** 1-888-782-6157

A signed [Benefit Investigation and Enrollment Form](#) connects you and your patient with an Insurance & Access Specialist.<sup>b</sup>

**NOTE:** All covered entities are obligated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to have a business associate agreement (BAA) in place with any service provider that handles protected health information (PHI) on their behalf. This includes, among others, electronic data transmission services such as eSign and electronic fax services. Please refer to each service provider's website for more information regarding BAAs and PHI.

<sup>a</sup>Mitsubishi Tanabe Pharma America, Inc. ("MTPA") is not affiliated with any electronic fax service providers (collectively, "service providers"). No fees or remuneration of any kind have been or will be exchanged with any healthcare provider for use of these service providers. Mention of these service providers does not constitute a referral, recommendation, or endorsement of a particular service provider, and similarly, the absence of a service provider's name should not be construed as a negative comment from MTPA about that service provider. MTPA, as well as its employees or agents, shall not be held liable for any damages or harm resulting from any use or reliance on these service providers, and MTPA may modify its policy regarding these service providers at any time without notice.

<sup>b</sup>A patient cannot be enrolled in the **JourneyMate Support Program<sup>™</sup>** without patient authorization, which can be found on the Benefit Investigation and Enrollment Form, or a separate signed Patient Authorization Form for RADICAVA ORS<sup>®</sup> on file. In addition, a Benefit Investigation and Enrollment Form must be submitted for each patient for whom treatment with RADICAVA ORS<sup>®</sup> is requested. Patient insurance benefit investigation is provided as a service by service providers under contract for Mitsubishi Tanabe Pharma America, Inc. Our service providers assist in determining whether treatment can be covered by the payer based on the payer's health plan guidelines and the patient information you provided as authorized by the patient on the Benefit Investigation and Enrollment Form, following your determination of medical necessity.

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## IMPORTANT SAFETY INFORMATION

### Hypersensitivity Reactions

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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 ( $\geq 10\%$ ) 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](http://www.fda.gov/medwatch).

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



Dedicated Team. Patient-Focused Approach.

**Insurance & Access Specialist**

**1-844-772-4548**

Monday-Friday, 8:00 AM-8:00 PM ET

[radicavahcp.com](http://radicavahcp.com)

Please see full **Prescribing Information**.



Mitsubishi Tanabe Pharma America

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