Radicava® (edaravone) IV infusion 30mg/100mL

Example Treatment Initiation Checklists

Example checklists are for reference purposes only. These example checklists are 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®.

Prescriber Checklist Example

Considerations for a patient diagnosed with amyotrophic lateral sclerosis (ALS)*

- ☐ **Clinical notes that may be required by a health plan**
  - 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
  - Percent forced vital capacity (%FVC)

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*™**
- ☐ **Include a prescription for RADICAVA®. For details, see accompanying RADICAVA® Prescription Information**
- ☐ **Select appropriate site(s) of care in consultation with patient and insurance plan**
  - Home infusion | Doctor's office | Infusion center | Hospital

- ☐ **Send referral to treating site(s) of care**
  - Fax orders, the ***JourneyMate Support Program***™ Patient ID, required clinical notes as described above, and administrative information (eg, IV/access line)
    - RADICAVA® may be administered via a central or peripheral IV device
  - Request follow-up treatment notes that may, in your judgment, be appropriate

Infusion Provider Checklist Example

With the above completed, the infusion provider may proceed with the patient access process†

- ☐ **Prior authorization requirements (based on patient's health plan)**
  - The ***JourneyMate Support Program***™ Insurance & Access Specialist can provide limited prior authorization assistance‡
    - To learn more, call 1-844-772-4548
  - Include a Sample Letter of Medical Necessity to payer, if required§
    - A Sample Letter of Medical Necessity is available at radicavahcp.com
  - Request an exception, or appeal a denial of coverage, as appropriate
  - Confirm coverage with health plan
- ☐ **Ordering RADICAVA®**
  - The Order Form for Buy & Bill is available at radicavahcp.com
    - Include the Patient ID assigned by the ***JourneyMate Support Program***™ Insurance & Access Specialist

*All health plans vary. Healthcare Providers should always check with a patient's health plan to learn more about each plan's coverage requirements.

†Individual patient cases may differ based upon insurance provider.

‡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.

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.

§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.

Please see full Indication and Important Safety Information on page 3, and Prescribing Information for RADICAVA® available at radicavahcp.com.

RADICAVA® 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®.

Prescription Information

RADICAVA® 30 mg/100 mL injection for infusion	
DIAGNOSIS[1]	G12.21 Amyotrophic lateral sclerosis (progressive spinal muscle atrophy)
DOSAGE AND ADMINISTRATION[2]	Starter dose: Once daily 60 mg/200 mL, 60-minute IV infusion for 14 consecutive days, followed by cessation for 14 days Maintenance: Once daily 60 mg/200 mL, 60-minute IV infusion for any 10 of 14 days, followed by cessation for 14 days
REFILLS	QUANTITY: (Maximum Quantity: 14-Day Supply)

Please see Prescribing Information for RADICAVA® available at radicavahcp.com.

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

2 ways to submit a prescription with a Benefit Investigation and Enrollment Form*

Online via eSign

You may complete, sign, and submit the enrollment form online to the ***JourneyMate Support Program***™ Insurance & Access Specialist.

1. Access the online Benefit Investigation and Enrollment Form at www.RadicavaOnlineEnrollmentForm.com
2. Follow instructions for completing, signing, and submitting the online form

By Mail, Fax, or Electronic Fax

If you have access to a printer, you may submit a completed and signed Benefit Investigation and Enrollment Form to the ***JourneyMate Support Program***™ Insurance & Access Specialist via 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***™
     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 your office and your patient with support from the *JourneyMate Support Program*™ Insurance & Access Specialist.†

NOTE: All covered entities are obligated under the Health Insurance Portabilty 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.

References: 1. *ICD-10-CM 2022.* United States; Optum360; 2021. **2.** RADICAVA® Prescribing Information. Mitsubishi Tanabe Pharma America, Inc. 2021.

*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, 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.

†A patient cannot be enrolled in the ***JourneyMate Support Program***™ without patient authorization, which can be found on the Benefit Investigation and Enrollment Form, or a separate signed Patient Authorization Form for RADICAVA® on file. In addition, a Benefit Investigation and Enrollment Form must be submitted for each patient for whom treatment with RADICAVA® 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.

Please see full Indication and Important Safety Information on the next page, and Prescribing Information for RADICAVA® available at radicavahcp.com.

INDICATION

Radicava® (edaravone) is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions
Radicava® is contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients in Radicava®. Hypersensitivity reactions (redness, wheals, and erythema multiforme) and cases of anaphylaxis (urticaria, decreased blood pressure, and dyspnea) have been reported. Patients should be monitored carefully for hypersensitivity reactions, and if they occur, discontinue Radicava®, treat per standard of care, and monitor until the condition resolves.

Sulfite Allergic Reactions
Radicava® contains sodium bisulfite, and 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.

Most Common Adverse Reactions
Most common adverse reactions (at least 10% and greater than placebo) are contusion, gait disturbance, and headache.

Pregnancy
Based on animal data, Radicava® may cause fetal harm.

Geriatric Use
No overall differences in safety or effectiveness were observed between patients 65 years of age and older and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

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.

Questions? Contact the *JourneyMate Support Program*™ Insurance & Access Specialist or your Mitsubishi Tanabe Pharma America, Inc. representative.

JourneyMate SUPPORT PROGRAM™
Dedicated Team. Patient-Focused Approach.

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

Please see Prescribing Information for RADICAVA®, also available at radicavahcp.com.

Mitsubishi Tanabe Pharma America

Radicava® (edaravone) IV infusion 30mg/100mL

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