

# **Treatment Initiation: Example Checklists**

The following checklists are for reference purposes only. Healthcare providers should contact the patient's health plan to find out the specific requirements for prescribing RADICAVA® (edaravone).

# PRESCRIBER CHECKLIST EXAMPLE

# Considerations for a patient 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
  - 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 Searchlight Support®
- Include a prescription for RADICAVA®. For details, see pocket insert: Submitting a Prescription for RADICAVA®
- ☐ Select appropriate Site(s) of Care in consultation with patient and insurance plan
  - Home infusion | Doctor's office | Infusion center | Hospital

# ☐ Providing information to treating Site(s) of Care

- IV access/line information
  - RADICAVA® may be administered via a central or peripheral IV device
- Other information may be helpful in consultation with treating Site(s) of Care

# 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)
  - Searchlight Support® can provide limited prior authorization support\*
    - To learn more, call 1-844-SRCHLGT (1-844-772-4548)
  - Include a Letter of Medical Necessity to payer, if required
    - Sample letter 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 Searchlight Support<sup>®</sup>

Verification of insurance coverage is ultimately the responsibility of the provider. Since reimbursement by payers is subject to many factors, RxCrossroads by McKesson and Mitsubishi Tanabe Pharma America do not represent or guarantee that payer reimbursement or any other payment or reimbursement of any kind will be made. RxCrossroads by McKesson and Mitsubishi Tanabe Pharma America 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. RxCrossroads by McKesson makes every effort to be accurate in the information provided; however, no representations or warranties are expressed or implied by RxCrossroads by McKesson and Mitsubishi Tanabe Pharma America regarding the accuracy or reliability of the information. RxCrossroads by McKesson 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. Providers and other users of this information resulting from benefit investigation services accept full responsibility for use of the service.

Mitsubishi Tanabe Pharma America does not assume responsibility for, nor does it guarantee the availability, scope, or quality of the services offered including reimbursement support, prescription fulfillment coordination, and other services under Searchlight Support®. Providers, not Mitsubishi Tanabe Pharma America, are responsible for the services they provide. The Searchlight Support® services have no value apart from the product.

<sup>\*</sup> Patient insurance benefit investigation is provided as a service by RxC Acquisition Company d.b.a. RxCrossroads by McKesson under contract for Mitsubishi Tanabe Pharma America, Inc. ("Mitsubishi Tanabe Pharma America"). RxCrossroads by McKesson provides assistance 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.



### **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.





1-844-SRCHLGT (1-844-772-4548) Monday-Friday, 8 AM-8 PM ET radicavahcp.com

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





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# Submitting a Prescription for RADICAVA®

# PRESCRIPTION INFORMATION (required)

RADICAVA® (edaravone) 30 mg/100 mL injection for infusion	
DIAGNOSIS <sup>1</sup>	G12.21 Amyotrophic lateral sclerosis (progressive spinal muscle atrophy)
DIRECTIONS <sup>2</sup>	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: 7 Days Supply)

Please see accompanying Prescribing Information for RADICAVA®, available in the pocket.

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\*



# DocuSign® PowerForm with electronic signature capability

- Access the DocuSign® PowerForm at radicavahcp.com
- Use the "paper clip" utility in Section 2 of the form to attach a digital file (PDF, JPG, etc.) containing the prescription



### Fax/electronic fax service or mail

Include a copy of complete prescription information as a separate document

**Fax/electronic fax service:** 1-888-782-6157 **Mail:** Searchlight Support®, P.O. Box 2930, Phoenix AZ 85062

A signed *Benefit Investigation and Enrollment Form* connects your office and your patient with personalized support from Searchlight Support<sup>®</sup>.†

**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 DocuSign® and electronic fax services. Please refer to each service provider's website for more information regarding BAAs and PHI.

Please see Indication and Important Safety Information on back and accompanying Prescribing Information for RADICAVA®, also available at radicavahcp.com.

<sup>\*</sup>Mitsubishi Tanabe Pharma America, Inc. ("MTPA") is not affiliated with DocuSign® or 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>†</sup>Searchlight Support® cannot enroll patients in Searchlight Support® services 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 Searchlight Support® 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 RXC Acquisition Company d.b.a. RxCrossroads by McKesson under contract for Mitsubishi Tanabe Pharma America, Inc. ("Mitsubishi Tanabe Pharma America"). RxCrossroads by McKesson provides assistance 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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Questions? Contact Searchlight Support® or your Mitsubishi Tanabe Pharma America, Inc. representative



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

References: 1. American Medical Association. ICD-10-CM 2020: The Complete Official Codebook. United States; American Medical Association, 2019. 2. RADICAVA® Prescribing Information. Jersey City, NJ: Mitsubishi Tanabe Pharma Corporation; August 2018.





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