

El Escorial/Revised Airlie House Diagnostic Criteria for ALS¹



Diagnosis of ALS falls into different categories based on certain criteria.

Definite ALS

Presence of signs of upper motor neuron (UMN) degeneration,^a as well as signs of lower motor neuron (LMN) degeneration^b in the bulbar region and at least 2 of the other spinal regions, or presence of UMN and LMN signs in 3 spinal regions.

Probable ALS

UMN and LMN signs in at least 2 regions. While the regions may be different, some UMN signs must be above the LMN signs. Multiple different combinations of UMN and LMN signs may be present.

Possible ALS

UMN and LMN signs are only in one region or UMN signs alone are present in 2 or more regions, or LMN signs are above UMN signs (the latter distribution of signs needs to be differentiated from multiple non-ALS processes).

Suspected ALS

Only LMN signs in 2 or more regions, although UMN pathology might be demonstrated at autopsy.

^aUMN degeneration includes increased or donic tendon reflexes, spasticity, pseudobulbar features, Hoffmann reflex, and extensor plantar response in 1 or more of the 4 central nervous system regions.¹

^bLMN degeneration includes weakness, wasting, and fasciculation in 1 or more of the 4 central nervous system regions (bulbar, cervical, thoracic, and lumbosacral).¹

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[®] (edaravone) may cause fetal harm.

Please see additional Important Safety Information on back and accompanying full Prescribing Information in pocket.

Patient Documentation Checklist

If you're considering RADICAVA® (edaravone) for a patient with ALS, having certain documents on hand may help streamline the path to approval.

Below is a list of common information used for accessing RADICAVA®.

▼
**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)^a**

^aSee front for more details.

▼
**ALS Functional Rating
Scale–Revised
(ALSFRS-R) score**

▼
**Forced vital
capacity (%FVC)**



Get a Sample Letter of Medical Necessity

If needed, you can download a Sample Letter of Medical Necessity and other resources for you and your staff to access RADICAVA® for your patients at RADICAVA.com/SLMN.



The Searchlight Support® product access program can provide limited prior authorization assistance. **To learn more, call 1-844-SRCHLGT (1-844-772-4548).**

Important Safety Information (*continued*)

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.

Please see accompanying full Prescribing Information in pocket.

Reference: 1. ALS Association. El Escorial World Federation of Neurology criteria for the diagnosis of ALS. www.alsa.org/assets/pdfs/fyi/criteria_for_diagnosis-1.pdf. Accessed June 29, 2018.

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