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PHARMACY / MEDICAL POLICY – 5.01.578

Amyotrophic Lateral Sclerosis (ALS) Medications

Effective Date:	June 1, 2023	RELATED MEDICAL POLICIES:
Last Revised:	May 9, 2023	None
Replaces:	N/A	

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Introduction

Amyotrophic lateral sclerosis (ALS)—often called Lou Gehrig disease—is a rare condition. It affects nerve cells that control movements like walking, chewing, and breathing. Because the nerve cells can no longer stimulate muscles, they get weak and paralysis sets in. ALS usually affects people between 40 and 70 years old, although some people develop the condition in their twenties and thirties. Symptoms can start in the arms or legs or in the muscles that control swallowing and speech. Regardless of where the symptoms start, the symptoms advance to other areas of the body. ALS usually is a progressive condition. This means it gets worse over time. The rate of progression—how fast it gets worse—varies from person to person. This policy discusses when Radicava®, Radicava ORS®, and Relyvrio™ may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Radicava® (edaravone) IV, Radicava ORS® (edaravone) Oral suspension	**Radicava® (edaravone) and Radicava ORS® (edaravone) may be considered medically necessary when the individual meets the following criteria:** • Individual has been diagnosed with amyotrophic lateral sclerosis (ALS) based on: ○ The **presence** of: ▪ Evidence of lower motor neuron (LMN) degeneration by clinical, electrophysiological or neuropathologic examination **AND/OR** ▪ Evidence of upper motor neuron (UMN) degeneration by clinical examination **AND** ▪ Progressive spread of symptoms or signs within a region or to other regions, as determined by history or examination **AND** ○ The **absence** of: ▪ Electrophysiological or pathological evidence of other disease processes that might explain the signs of LMN and/or UMN degeneration **AND** ▪ Neuroimaging evidence of other disease processes that might explain the observed clinical and electrophysical signs **AND** • Normal respiratory function retained (FVC ≥70% of predicted) **AND** • Disease duration of 2 years or less **AND** • Prescribed by or in consultation with a neurologist or ALS specialist
Relyvrio™ (sodium phenylbutyrate and	**Relyvrio™ (sodium phenylbutyrate and taurursodiol) may be considered medically necessary when the individual meets the following criteria:**

Drug	Medical Necessity
taurursodiol) Oral suspension	• Individual has been diagnosed with amyotrophic lateral sclerosis (ALS) based on: ○ The **presence** of: ▪ Evidence of lower motor neuron (LMN) degeneration by clinical, electrophysiological or neuropathologic examination **AND/OR** ▪ Evidence of upper motor neuron (UMN) degeneration by clinical examination **AND** ▪ Progressive spread of symptoms or signs within a region or to other regions, as determined by history or examination **AND** ○ The **absence** of: ▪ Electrophysiological or pathological evidence of other disease processes that might explain the signs of LMN and/or UMN degeneration **AND** ▪ Neuroimaging evidence of other disease processes that might explain the observed clinical and electrophysical signs **AND** • Individual is ≥ 18 years of age **AND** • Disease duration of 18 months or less **AND** • Slow vital capacity (SVC) of 60% or greater **AND** • Individual does not have a tracheostomy or require permanent assisted ventilation (PAV) **AND** • Prescribed by or in consultation with a neurologist or ALS specialist
Qalsody™ (tofersen) Intrathecal	**Qalsody™ (tofersen) may be considered medically necessary when the individual meets the following criteria:**

Drug	Medical Necessity

	• Individual has been diagnosed with amyotrophic lateral sclerosis (ALS) based on:
	  ○ The **presence** of:
	  ▪ Evidence of lower motor neuron (LMN) degeneration by clinical, electrophysiological or neuropathologic examination
	  AND/OR
	  ▪ Evidence of upper motor neuron (UMN) degeneration by clinical examination
	  AND
	  ▪ Progressive spread of symptoms or signs within a region or to other regions, as determined by history or examination
	  AND
	  ○ The **absence** of:
	  ▪ Electrophysiological or pathological evidence of other disease processes that might explain the signs of LMN and/or UMN degeneration
	  AND
	  ▪ Neuroimaging evidence of other disease processes that might explain the observed clinical and electrophysical signs
	AND
	• Individual has a confirmed mutation in the superoxide dismutase 1 (*SOD1*) gene
	AND
	• Functionality retained for most activities of daily living, defined as a score of 37 or more points on ALS Functional Rating Scale-Revised (ALSFRS-R)
	AND
	• Slow vital capacity (SVC) of 65% or greater
	AND
	• Disease duration of 2 years or less
	AND
	• Prescribed by or in consultation with a neurologist or ALS specialist

Drug	Investigational
As listed	**All other uses of the medications listed in this policy are considered investigational.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Radicava® (edaravone),Radicava ORS® (edaravone) and Qalsody™ (tofersen) may be approved up to 6 months.** **Relyvrio™ (sodium phenylbutyrate and taurursodiol) may be approved up to 12 months.**
Re-authorization criteria	**Future re-authorization of Radicava® (edaravone), Radicava ORS® (edaravone), Relyvrio™ (sodium phenylbutyrate and taurursodiol) and Qalsody™ (tofersen) may be approved up to 12 months when the chart notes demonstrate that the individual continues to show a positive clinical response as documented by the ability to perform most activities of daily living.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation, medication history, respiratory function tests, and other relevant information that could support medical necessity consideration

Coding

Code	Description
HCPCS	
J1301	Injection, edaravone (Radicava®), 1 mg
J3490	Unclassified drugs (use to report Qalsody™)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Benefit Application

Radicava® (edaravone) is managed through the medical benefit. Radicava ORS® (edaravone) and Relyvrio™ (sodium phenylbutyrate and taurursodiol) is managed through the pharmacy benefit. Qalsody™ (tofersen) is managed through the medical benefit.

Evidence Review

Radicava® (edaravone)

Clinical Trials

The efficacy of Radicava for the treatment of ALS was established in a 6-month, randomized, placebo controlled, double-blind study conducted in Japanese individuals with ALS who were living independently and met the following criteria at screening:

1. Functionality retained most activities of daily living (defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale – Revised [ALSFRS-R; described below])
2. Normal respiratory function (defined as percent-predicted forced vital capacity values of [%FVC] ≥80%)
3. Definite or Probable ALS based on El Escorial revised criteria
4. Disease duration of 2 years or less

The study enrolled 69 individuals in the Radicava arm and 68 in the placebo arm. Baseline characteristics were similar between these groups, with over 90% of individuals in each group being treated with riluzole.

Radicava was administered as an intravenous infusion of 60 mg given over a 60-minute period according to the following schedule:

- An initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug-free period (Cycle 1)
- Subsequent treatment cycles with daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods (Cycles 2-6)

The primary efficacy endpoint was a comparison of the change between treatment arms in the ALSFRS-R total scores from baseline to Week 24. The ALSFRS-R scale consists of 12 questions that evaluate the fine motor, gross motor, bulbar, and respiratory function of individuals with ALS (speech, salivation, swallowing, handwriting, cutting food, dressing/hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, and respiratory insufficiency). Each item is scored from 0-4, with higher scores representing greater functional ability. The decline in ALSFRS-R scores from baseline was significantly less in the RADICAVA-treated individuals as compared to placebo.

Safety

In randomized, placebo-controlled trials, 184 ALS individuals were administered Radicava 60 mg in treatment cycles for 6 months. The population consisted of Japanese individuals who had a median age of 60 years (range 29- 75) and were 59% male. Most (93%) of these individuals were living independently at the time of screening.

Table 1 below lists the adverse reactions that occurred in ≥ 2% of individuals in the Radicava-treated group and that occurred at least 2% more frequently than in the placebo-treated group in randomized placebo-controlled ALS trials. The most common adverse reactions that occurred in ≥10% of Radicava-treated individuals were contusion, gait disturbance, and headache.

Table 1. Adverse Reactions in Radicava® and Placebo-Treated Groups

Adverse Reaction	Radicava (N=184)	Placebo (N=184)
Contusion	15	9
Gait disturbance	13	9
Headache	10	6
Dermatitis	8	5

Adverse Reaction	Radicava (N=184)	Placebo (N=184)
Eczema	7	4
Respiratory failure, respiratory disorder, hypoxia	6	4
Glycosuria	4	2
Tinea infection	4	2

Relyvrio™ (sodium phenylbutyrate and taurursodiol)

Clinical Trials

The CENTAUR-OLE trial was a single-arm, open-label extension study in which participants completing the 6-month randomized phase (the CENTAUR trial) were eligible to receive Relyvrio™ for up to 30 months (132 weeks). Overall, 66% of participants originally randomized in the CENTAUR trial enrolled in the OLE, which included 56 participants (64%) from the Relyvrio™ arm and 34 participants (71%) from the placebo arm. The post-hoc, long-term, intention-to-treat (ITT) survival analysis showed a difference in median survival of 4.8 months in the group originally randomized to Relyvrio™ compared to those originally randomized to placebo (23.5 months and 18.7 months, respectively; HR, 0.64; 95% CI, 0.42–0.995, P = 0.0475). The ongoing Phase 3 PHOENIX trial (NCT05021536) is a 48-week, randomized, placebo-controlled trial that will evaluate the Amyotrophic Lateral Sclerosis Functional Rating Scale–Revised (ALSFRS-R) as a primary outcome measure along with survival. The PHOENIX trial has an estimated enrollment of 600 individuals with definite or clinically probable ALS within 24 months of symptom onset, which is a less stringent inclusion criteria set compared with the CENTAUR trial. The estimated primary completion date for the PHOENIX trial is in November 2023.

Safety

In the CENTAUR trial, adverse events (AEs) occurring in ≥2% of individuals in the Relyvrio™ arm were primarily gastrointestinal (diarrhea, nausea, salivary hypersecretion, and abdominal discomfort). Gastrointestinal AEs were reported more frequently in the Relyvrio™ arm than in the placebo arm during the first 3 weeks, and then were reported less frequently for the remainder of the trial. A total of 19% of the participants in the Relyvrio™ arm prematurely discontinued the trial due to AEs, compared to 8% in the placebo arm. The most common AEs leading to discontinuation of the trial regimen were diarrhea (6% in the Relyvrio™ arm versus none in the placebo arm) and respiratory failure (6% in the placebo arm versus none in the Relyvrio™ arm).

Qalsody™ (tofersen)

Clinical Trials

The efficacy of tofersen was studied in a 28-week randomized, double-blind, placebo-controlled trial where 108 individuals with ALS and SOD1 mutation were randomized 2:1 to receive treatment with either tofersen 100mg (n = 72) or placebo (n = 36) for 24 weeks. Participants were allowed to use riluzole and/or edaravone concurrently. These individuals met following inclusion criteria:

1. Slow vital capacity (SVC) $\geq$ 65% of the predicted value.
2. Rapid disease progression, defined based on their ALS Functional Rating Scale-Revised (ALSFRS-R)
3. Disease duration of 2 years or less

The primary efficacy endpoint was a comparison of change in the ALSFRS-R total score between the groups from baseline to Week 28. Although individuals in the tofersen group experienced less decline in the ALSFRS-R score than those in the placebo group, the result was not statistically significant. The secondary efficacy endpoint was a comparison of change in plasma NfL and CSF SOD1 protein between the groups from baseline to week 28. The adjusted geometric mean ratio to baseline for NfL in tofersen group was 0.45, which was significantly lower than the placebo arm's ratio of 1.12 with nominal p-value < 0.0001. Similarly, the adjusted geometric mean ratio to baseline for CSF SOD1 protein in treatment group was 0.65, which was significantly lower than the placebo arm's ratio of 0.98 with nominal p-value < 0.0001.

Safety

The most common adverse effects were pain, fatigue, arthralgia, myalgia, and elevated CSF white blood cell. Some of the individuals also experienced less common serious adverse effects, such as myelitis and radiculitis, papilledema, aseptic meningitis, and elevated intracranial pressure.

2019 Update

Reviewed Radicava® (edaravone) prescribing information and conducted a literature search from June 1, 2018, through July 20, 2019. No new evidence found that would change the policy statement. Added information from the El Escorial revised criteria for the diagnosis of ALS. Added a Length of Approval table and removed the Dosage and Quantity Limits table.

2020 Update

Reviewed Radicava® (edaravone) prescribing information. Updated the re-authorization criteria based on the progressive nature of the disease removing requirement that the respiratory function remains unchanged. The clinical study in the prescribing information documented slowing the loss of respiratory function with Radicava® treatment as supported by the ALSFRS-R score (includes respiratory function as component of score).

2021 Update

Reviewed Radicava® (edaravone) prescribing information and conducted a literature search on the management and treatment of ALS. No new information was identified that would require changes to this policy.

2022 Update

Review prescribing information (PI) and added coverage for Radicava ORS® (edaravone) which is an oral suspension formulation. Per the PI the efficacy of Radicava ORS® is based on a bioavailability study comparing it to Radicava® and Radicava ORS® demonstrated an equivalent area under the concentration-time curve (AUC) and similar pharmacokinetics.

2023 Update

Review prescribing information (PI) and added coverage for Relyvrio™ (sodium phenylbutyrate and taurursodiol). Reviewed coverage criteria of all drugs in this policy. Added coverage criteria for Qalsody™ (tofersen) for the adult individuals with indication of ALS with *SOD1* gene mutation.

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History

Date	Comments
07/01/17	New policy, approved June 13, 2017. Added newly approved agent for ALS.
01/30/18	Minor formatting edits were made to the policy.
07/01/18	Annual Review, approved June 22, 2018. Literature review was conducted from 06/13/2017 to 06/13/2018. Benefit application information was added to reflect medical benefit and no changes to criteria made.
01/01/19	Coding update, added new HCPCS code J1301 (new code effective 1/1/19). Removed HCPCS code J3490.
09/01/19	Annual Review, approved August 13, 2019, effective December 5, 2019. Added information from the El Escorial revised criteria for the diagnosis of ALS.
12/01/20	Annual Review, approved November 19, 2020. Updated re-authorization criteria removing requirement that the respiratory function remains unchanged.
11/01/21	Annual Review, approved October 5, 2021. No changes to policy statements.
08/01/22	Annual Review, approved July 25, 2022. Added Radicava ORS (edaravone) oral suspension to policy with the same coverage criteria as intravenous Radicava.
04/01/23	Interim Review, approved March 14, 2023. Changed title from "Radicava® (edaravone)" to "Amyotrophic Lateral Sclerosis (ALS) Medications". Added coverage for Relyvrio (sodium phenylbutyrate and taurursodiol) for the treatment of ALS is adults. Removed requirements to be diagnosed with definite or probable ALS and to retain functionality for most activities of daily living defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale – Revised [ALSFRS-R] for Radicava (edaravone) and Radicava ORS (edaravone) criteria. Updated requirement to have normal respiratory function retained defined as 70% or greater of predicted FVC from 80% or greater of predicted FVC for Radicava (edaravone) and Radicava ORS (edaravone) criteria. Added prescriber requirement to Radicava (edaravone) and Radicava ORS (edaravone) criteria. Changed the wording from "patient" to "individual" throughout the policy for standardization.

Date	Comments
06/01/23	Annual Review, approved May 9, 2023. Added coverage criteria for Qalsody (tofersen) for adult individuals with indication of ALS with SOD1 gene mutation. Added J3490 to report Qalsody™.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

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XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.