



Global Research. Nationwide Advocacy. Local Care.



November 9, 2022

The Honorable Denis R. McDonough
Secretary
United States Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

The Honorable Steven L. Lieberman
Deputy to the Deputy Under Secretary for Health
United States Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonough and Dr. Lieberman,

We are writing today to call upon the Veteran’s Administration to make access to RELYVRIO™ immediately available to all persons living with ALS. Benefits of access to RELYVRIO™ include a survival advantage of about six months and an enhance quality of life. Because the average life expectancy of someone diagnosed with ALS is about two and a half years, a six-month survival advantage is significant.

The FDA label states: RELYVRIO is indicated for the treatment of amyotrophic lateral sclerosis for adults.

Given RELYVRIO™ demonstrated clinical benefit, we feel strongly that it should be accessible to all person with ALS without restriction as specified in the FDA label.

ALS is a relentlessly progressive and fatal neurodegenerative disorder caused by motor neuron death in the brain and spinal cord. Motor neuron loss in ALS leads to deteriorating muscle function, the inability to move and speak, respiratory paralysis and eventually, death. More than 90% of people with ALS have sporadic disease, showing no clear family history. ALS affects approximately 29,000 people in the U.S.

Of particular concern to The ALS Association are indications that some payers may choose to restrict access to RELYVRIO™ based on criteria other than the FDA label. We urge you to:

- Provide immediate coverage for RELYVRIO™ that is consistent with the FDA approved indication and labeling, including in combination where appropriate.
- Avoid unnecessary delays in access to RELYVRIO™ caused by prior authorization, tiered/step therapy, or other structural barriers to access.

We further urge payers to reject discriminatory valuation metrics such as quality adjusted life years (QALYs) and equal value of life years gained (evLYG) for ALS drugs. It is important that payers recognize that even modest benefits are critical for ALS patients and their families as well as the urgency of extremely limited treatments for ALS.

We ask that you respond to this request in writing, and we are available to provide further information at any time.

Sincerely,

Melanie Lendnal

Melanie Lendnal



OUR VISION: Create a world without ALS.

OUR MISSION: To discover treatments and a cure for ALS, and to serve, advocate for, and empower people affected by ALS to live their lives to the fullest.

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