

November 29, 2023

Dr. Michelle Gourdine
Chief Medical Officer
CVS Caremark
1 CVS Drive
Woonsocket, Rhode Island 02895

Dear Dr., Gourdine:

On behalf of the ALS Association and all those living with amyotrophic lateral sclerosis (ALS) and their families, we respectfully request that CVS Caremark reconsider its policy regarding coverage of Relyvrio. This policy applies an inappropriate clinical standard for reauthorization of Relyvrio by requiring “documentation of clinical benefit,” interpreting this to mean evidence of stasis or improvement. This is impossible for people living with ALS. As such, **we request that CVS Caremark revise its current policy and provide immediate coverage for Relyvrio that is consistent with the FDA (Food and Drug Administration) approved indication and labeling without any prior authorization requirements.**

As you know, ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord. Over the course of the disease, people lose the ability to move, to speak, and eventually, to breathe. On average, it takes about a year before a final ALS diagnosis is made. The disease is always fatal, usually within five years of diagnosis. There is no cure.

Relyvrio is a combination of two drugs, sodium phenylbutyrate and taurursodiol, which act to prevent nerve cell death by blocking stress signals in cells. The FDA approved Relyvrio for use to treat ALS in 2022. It is designed to slow disease progression by slowing or preventing motor neuron cell death. Motor neurons are the cells that die in ALS. The drug targets both the endoplasmic reticulum (ER) and mitochondria in ALS in motor neurons. This is important because the ER and mitochondria are connected (via mitochondrial membranes) and both play critical roles in maintaining neuron health and survival. Trial data has concluded that Relyvrio can extend life by 10 months and reduce the risk of death, tracheostomy, or permanent assisted ventilation, and first hospitalization.

CVS Caremark’s policy creates a nonsensical and unnecessary barrier to access to Relyvrio for people living with ALS. Even if an initial denial results in a successful appeal it is unconscionable to delay receipt of Relyvrio for people living with ALS who urgently need the demonstrated survival advantage with longer functional independence.

The medical exception process, in and of itself, places an unnecessary and heavy burden on already busy ALS physicians and multi-disciplinary clinics causing significant delays to access for people with ALS who need this drug. These delays include requirements such as prior authorization as well as multiple appeals and external reviews before a person with ALS gains access. Some physicians have reported spending up to 30% of their time advocating for access to



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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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Relyvrio. This is a gross misuse of already stretched resources that has an impact on people's lives.

We strongly believe that ALS physicians and members of the multidisciplinary team treating a person living with ALS are best equipped to make the determination of whether someone would benefit from Relyvrio. Only ALS experts, who are responsible for the care of a person living with ALS, can judge and measure whether a particular person might benefit.

We again, strongly encourage CVS Caremark to take the following actions:

- **Provide immediate coverage for Relyvrio that is consistent with the FDA approved indication and labeling, including in combination with other FDA-approved treatments where appropriate.**
- **Avoid unnecessary delays in access to Relyvrio caused by prior authorization, tiered/fail first/step therapy, or other unconscionable, deliberate, and unnecessary barriers to access.**

We respectfully request a written response by December 11, 2023, and would welcome any discussion about this and any future decisions that could impact people living with ALS.

Respectfully,



Melanie Lendnal, Esq.
Senior Vice President, Policy & Advocacy
The ALS Association