ALS ASSOCIATION
Global Research. Nationwide Advocacy. Local Care.




February 7, 2023

David Cordani
Chairman and Chief Executive Officer
Cigna Corporation
Bloomfield, CT.

Dear Mr. Cordani:

On behalf of the ALS Association and all those living with amyotrophic lateral sclerosis (ALS) and their families, we respectfully request that CIGNA reconsider its policy regarding coverage of RELYVRIO™. **Specifically, we ask that CIGNA reverse its National Formulary Coverage Policy decision of February 1, 2023, which calls for the denial of RELYVRIO™ for people with ALS.** Failure to do so will result in the reduction of quality and quantity of life – an avoidable and unacceptable outcome. We have copied Nicole Jones, General Counsel and Joseph Sobel, Chief Medical Officer of Cigna Corporation on this email.

As you know, 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 more than 30,000 people in the United States.

Benefits of access to RELYVRIO™ include a survival advantage of about six months along with longer functional independence. Because the average life expectancy of someone diagnosed with ALS is about two and a half years, a six-month survival advantage is significant.

For that reason, many insurers and pharmacy benefit management firms have provided coverage for all adults with ALS. CIGNA'S policy is out of step with all major health insurers, including United Healthcare, Anthem Blue Cross Blue Shield, Aetna, Regence, Providence, and Optum as well as Medicare and the Veteran's Administration.

Cigna's National Formulary Coverage Policy decision of February 1, 2023 to deny coverage is wrong and discriminatory for the following reasons:

- First, this policy is in direct conflict to CIGNA'S initial coverage of the drugs for people living with ALS made in October of 2022 that provided ***Recommended Authorization Criteria***. Under the earlier criteria patients were approved for 6 months after which their neurologist can seek reauthorization for a new 12-month period. Under CIGNA's new policy patients must go through the medical exception process which significantly delays and sometimes denies access and places a heavy paperwork burden on already busy ALS physicians.

- Second, this decision **discriminates against people on CIGNA's commercial plans** given that Medicare, the Veteran's Administration, and all major insurers cover RELYVRIO™.
- Third, this decision **conflicts with FDA's approval of RELYVRIO™ for the treatment of amyotrophic lateral sclerosis for adults.**
- Fourth, this decision takes away the opportunity for someone living with ALS for a survival advantage of about six months along with longer functional independence.
- Fifth, regarding CIGNA's statement that " ***Referral to a specialized multidisciplinary clinic should be considered for patients with ALS to optimize health care delivery, prolong survival, and enhance quality of life.,"*** **please see the attached May 24, 2022, letter from 38 clinicians,** who direct care at these clinics, calling on the FDA to approve RELYVRIO™ so that they can prescribe it for their patients.

We strongly encourage CIGNA to take the following actions:

- 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/"fail first/step therapy, or other deliberate and unnecessary barriers to access.

It is important that CIGNA recognizes that modest benefits are critical for ALS patients and their families as well as the urgency of receiving extremely limited treatments for ALS.

RELYVRIO™ has demonstrated clinical benefit. As such, it **should be accessible to all people living with ALS without restriction as specified by the FDA label.**

We ask that you respond to this request in writing as soon as possible and no later than Monday, February 13, 2023.

Additionally, we ask for the opportunity to talk with CIGNA further regarding this and any future decisions that could impact people living with ALS. Melanie Lendnal, Senior Vice President of Advocacy and Policy and Kathleen Sheehan, Vice President of Public Policy, can assist in setting up a meeting.

We look forward to your response and request that you reply all to those listed on this email.

Respectfully,

Neil Thakur, Ph.D.
Chief Mission Officer
The ALS Association