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March 13, 2023

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

Dear Mr. Cordani:

Thank you for meeting with us to discuss Cigna's coverage criteria for Relyvrio. As you know, ALS is a rare, progressive, terminal, disease that requires prompt intervention to slow progression.

As we discussed, Cigna's unnecessary, illogical, and discriminatory policy is an outlier among US payers. The deliberate and unconscionable barriers that Cigna has established not only weaponizes time against people living with ALS, but also reduces their quantity and quality of life.

We strongly encourage you to urgently adopt more rational utilization criteria that align with the FDA's decision and label for Relyvrio, insurance industry standards, clinical standards, and the fundamental neurology of ALS.

Cigna's April 1, 2023, Policy Represents a Significant Deviation:
Cigna's restrictive policy is a clear outlier with other major national health insurance carriers that cover Relyvrio including, but not limited to: Medicare, Veteran's Administration, Federal Employee Program, United Health Care, Optum, Aetna Medicare Part D. The same is true for regional insurers including: BCBS of NC, Providence Medicare, Providence Commercial, Regence, Pacific Source: Select Health Commercial, Select Health Medicare, BSCA, Centene, Highmark, BCBS of MI, UPMC. Many other national and regional plans are also covering Relyvrio for adults as the FDA label intended and provides.

Cigna's Policy Ignores Evidence that Relyvrio is Safe and Effective:
As stated by one of the leading ALS experts during our March 8, 2023, call, even a 3-month delay in access to Relyvrio means a reduction of 8% of a patient's remaining lifespan and a significant loss of function - such as the loss of the use of a limb or the ability to climb a flight of stairs.

The evidence presented to the FDA is clear. Relyvrio is safe and effective for people living with ALS. Amylyx Pharmaceuticals published a peer-reviewed paper in the New England Journal of Medicine outlining the results of the CENTAUR phase 2 trial and another outlining the trial's overall survival data in the journal Muscle and Nerve.

Overall, the trial enrolled 137 people with ALS in 25 medical centers through the Northeast ALS (NEALS) Consortium from June 2017 to September 2019. It showed that AMX0035 was well-tolerated and there were no major safety concerns. AMX0035 also significantly decreased the rate of decline in the Revised ALS Functional Rating Scale (ALSFRS-R) compared to placebo.

Almost three years after the first participant started in CENTAUR, in July 2020, the difference in survival between the AMX0035 group and the placebo group was evaluated. People with ALS who received AMX0035 at the start of the CENTAUR trial lived an average of 6.5 months longer than the comparison placebo group.

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The CENTAUR trial included an open label extension phase, where all participants who completed the placebo-controlled phase could enroll and receive AMX0035. Analysis of the data from that study showed that AMX0035 extended life by 10 months and reduced the risk of death, tracheostomy, or permanent assisted ventilation, and first hospitalization.

Given the evidence presented, by creating irrational barriers to access the only logical conclusion is that Cigna is deliberately and willfully putting profit over people's lives.

Cigna's Policy is Unconscionable and Contrary to Science:
We were particularly shocked and appalled by your Chief Medical Officer's statement that it is Cigna's position that Relyvrio was approved based on "hope." Not only is this highly offensive to all those involved in the approval of this drug, including the 38 ALS physicians who signed the attached letter, but is a position that is utterly devoid of any scientific or regulatory rationale.

As you know, two Advisory Committee Meetings were held to vote on Relyvrio. The second FDA Advisory Committee's members recommended approval and the FDA agreed. Yet instead of respecting the decision of these experts and the thousands of others who supported this approval, Cigna has chosen to put a policy in place that overtly discriminates against its commercial subscribers, affectively creating two different classes of similarly situated patients. This is unfair and discriminatory.

For all these reasons we strongly encourage you to urgently adopt more rational utilization criteria that aligns with the FDA's decision and label for Relyvrio, insurance industry standards, clinical standards, and the fundamental neurology of ALS.

As requested by Cigna, we will follow up separately to address the issues presented by each of the criteria for coverage created in the April 1 policy. In the interim, we respectfully request a response to this letter in writing by March 21, 2023. Thank you in advance for your prompt response.

Sincerely,

Melanie Lendnal

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Senior Vice President, Policy, and Advocacy
The ALS Association