Humana

Pharmacy Solutions.

Drug withdrawal notice for Relyvrio

To assist you in the care of your patients, we would like to alert you to the market withdrawal of Relyvrio on April 4, 2024.[1] We recommend you contact all patients for whom you have prescribed this medication to warn them about the market withdrawal.

Amylyx Pharmaceuticals announced the market withdrawal of Relyvrio because of results from the Phase 3 PHOENIX trial. In the trial, Relyvrio did not outperform a placebo in improving participants' amyotrophic lateral sclerosis (ALS) functional scale, a measure of their ability to breathe, swallow and speak after 48 weeks. It also did not significantly improve patient-reported quality of life, overall survival and respiratory function. Relyvrio, which was initially approved for the treatment of ALS in adults in 2022, will no longer be available for new patients. Amylyx Pharmaceuticals initiated a process with the U.S. Food and Drug Administration (FDA) to voluntarily discontinue the marketing authorizations for Relyvrio.

Medications included in this withdrawal

You can access the Amylyx Pharmaceuticals notice for more details on the market withdrawal of Relyvrio.

Information for providers:[1]

- We have sent a letter to your Humana-covered patients who have had a claim for Relyvrio and asked them to contact their healthcare providers if they have experienced problems that could be related to using these drug products. Healthcare professionals should re-evaluate and discuss the treatment plan with their patients.
- Patients currently on therapy in the United States who, in consultation with their physician, wish to stay on treatment can be transitioned to a free drug program.
- Patients can report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting Program online, by regular mail or by fax.
    - **Online:** Complete and submit the report.
        - Select "Consumer/Patient (FDA Form 3500B)."
    - **Regular mail or fax:** Download the form (http://www.fda.gov/media/85598/download).
        - Complete and submit "Consumer Voluntary Reporting (Form FDA 3500B)" by mail to the address on the form or by fax to 800-FDA-0178 (332-0178).

Reference

1. "Amylyx Pharmaceuticals announces formal intention to remove Relyvrio®/Albrioza™ from the market; provides updates on access to therapy, pipeline, corporate restructuring, and strategy," Amylyx Pharmaceuticals, last accessed April 11, 2024, https://investors.amylyx.com/news-releases/news-release-details/amylyx-pharmaceuticals-announces-formal-intention-remove#:~:text=CAMBRIDGE%2C%20Mass.%20--%20%28BUSINESS%20WIRE%29--Apr.%204%2C%202024--%20Amylyx,topline%20results%20from%20the%20Phase%203%20PHOENIX%20trial%20trial.