Humana Healthy Horizons® in South Carolina | Healthy Connections

Drug withdrawal notice for Oxbryta

To assist you in the care of your patients, Humana Healthy Horizons® in South Carolina is alerting you to the market withdrawal of Oxbryta (voxelotor) on Sept. 26, 2024.[1] We recommend you contact all patients for whom you have prescribed this medication to warn them about the market withdrawal.

Pfizer Inc., the manufacturer of Oxbryta, announced the market withdrawal of Oxbryta and said it is ceasing distribution along with discontinuing all active clinical trials and any expanded access programs for Oxbryta. Recent data obtained by Pfizer shows the benefits of Oxbryta do not outweigh the risks for the sickle cell patient population.

The U.S. Food and Drug Administration previously approved Oxbryta under its accelerated approval pathway in 2019. The drug is used for the treatment of sickle cell disease in those 12 years old and older.

Pfizer's data indicated a higher rate of vaso-occlusive crisis (acute painful crisis) and deaths in patients with sickle cell disease that received the drug, which requires further assessment.

"FDA has been conducting a safety review of the postmarketing clinical trial data for Oxbryta, the real-world registry studies, as well as postmarketing data from the FDA Adverse Event Reporting System (FAERS)," the FDA said in the withdrawal notice. "At the conclusion of this safety review, FDA will communicate any additional findings, if necessary."

Medications included in this withdrawal
Visit the FDA website for more details on the market withdrawal of Oxbryta.

Information for providers:[1]

- We have sent a letter to your Humana Healthy Horizons-covered patients who have had a claim for Oxbryta and asked them to contact their providers if they have experienced problems that may be related to using these drug products. Providers should stop prescribing Oxbryta and discuss alternative treatment options with their patients.
- 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 phone or by fax.
    - Online: Submit the report.
        - Select "Form FDA 3500 - Voluntary Reporting."
    - Phone or fax: Download the form.
        - Complete and submit "Form FDA 3500 - Voluntary Reporting" by phone at 800-FDA-1088 (332-1088) or by fax to 800-FDA-0178 (332-0178).

Reference

1. "FDA is alerting patients and health care professionals about the voluntary withdrawal of Oxbryta from the market due to safety concerns," U.S. Food and Drug Administration, last accessed Oct. 2, 2024, https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerting-patients-and-health-care-professionals-about-voluntary-withdrawal-oxbryta-market-due?utm_medium=email&utm_source=govdelivery.