Drug recall notice for Belviq, Belviq XR (lorcaserin)

To assist you in the care of your patients, we would like to alert you to the withdrawal of Belviq and Belviq XR (lorcaserin) on Feb. 13, 2020.[1,2] We recommend you review your medical records and contact all patients for whom you have prescribed these medications to warn them of the recall.

The drug manufacturer, Eisai Inc., has submitted a request to voluntarily withdraw the weight-loss drug from the market. This withdrawal was initiated at the request of the U.S. Food and Drug Administration (FDA), because a clinical trial monitoring the safety of lorcaserin shows an increased occurrence of cancer in patients taking lorcaserin.

Information for providers:[1,2]

- We have sent a letter to your patient(s) who have had a claim for lorcaserin and asked them to contact their physicians or healthcare providers if their medication is included in the recall and if they have experienced problems that may be related to using these drug products.
- Healthcare providers should: 1) stop prescribing and dispensing lorcaserin to their patients; 2) contact patients currently taking lorcaserin and inform them of the increased occurrence of cancer seen in the clinical trial, and ask them to stop taking the medicine; 3) discuss alternative weight-loss medications and/or weight management programs with their patients.
- The FDA is not recommending special screening for patients who have taken lorcaserin. As with any individual patient, regardless of prior lorcaserin treatment, standard screening recommendations for cancer should be implemented.
- Healthcare providers with questions can contact Eisai Medical Information at esi_medinfo@eisai.com or 1-888-274-2378.
- Patients may report adverse reactions or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting program either 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.
        - Select "Form FDA 3500B – Voluntary Reporting for Consumers" and submit by mail to the address on the form or by fax to 1-800-FDA-0178.

References:

1. "FDA requests the withdrawal of the weight-loss drug Belviq, Belviq XR (lorcaserin) from the market." U.S. Food and Drug Administration. Feb. 13, 2020. www.fda.gov/drugs/drug-safety-and-availability/fda-requests-withdrawal-weight-loss-drug-belviq-belviq-xr-lorcaserin-market
2. "Eisai to Voluntarily Withdraw BELVIQ®/BELVIQ XR® in the U.S." Eisai Inc. Feb. 13, 2020. eisai.mediaroom.com/2020-02-13-Eisai-to-Voluntarily-Withdraw-BELVIQ-R-BELVIQ-XR-R-in-the-U-S