Drug recall notice for Hizentra 20% (10 g/50 mL)

To assist you in the care of your patients, we would like to alert you to the recall of one lot of Hizentra® 20% (10 g/50 mL) on Dec. 30, 2021.[1] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them of the recall. This product lot withdrawal is being conducted with the knowledge of the U.S. Food and Drug Administration.

The drug manufacturer, CSL Behring Biotherapies for Life, is voluntarily recalling this product due to an increased frequency of reports of injection-site reactions and hypersensitivity-type events after administration. Injection-site reactions and hypersensitivity are a known risk with subcutaneous immune globulin products.

Other lot numbers of Hizentra are unaffected and remain readily available.

Medications included in this recall

Product name	NDC number	Lot number	Expiration date
Hizentra 20% (10 g/50 mL)	44206045510	P100343632	11/24/2023

Information for providers:[1]

- We have sent a letter to your CarePlus-covered patients who have had a claim for Hizentra 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 professionals with questions regarding this recall can contact CSL Medical Information at 800-504-5434, option 1, Monday – Friday, 8 a.m. – 5 p.m., Eastern time.
- Patients may report adverse reactions or quality problems experienced with the use of these products 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 800-FDA-0178 (332-0178).

Reference:

1. CSL Behring Biotherapies for Life, "Urgent: Voluntary Product Lot Withdrawal," Dec. 30, 2021.