NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

PBM-2017-16 **ADDENDUM** **SEPTEMBER 25, 2017**

ITEM: **Procrit® (epoetin alfa) 1 mL Single-Dose, Preservative-Free Solution: Recall Due to Presence of Glass Particles**

SPECIFIC INCIDENT(S): Janssen Products, L.P., is conducting a voluntary recall for two additional lots of Procrit® (epoetin alfa) 1 mL Single-Dose, Preservative-Free Solution due to the presence of thin glass flakes (lamellae) observed during a routine quality inspection.

GENERAL INFORMATION:

- Procrit® (epoetin alfa) is indicated for the treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis and not on dialysis; anemia due to zidovudine in HIV-infected patients; anemia due to the effects of concomitant myelosuppressive chemotherapy; and reduction of allogeneic red blood cell (RBC) transfusions in patients undergoing elective, noncardiac, nonvascular surgery.
- Intravenous administration of a sterile injectable product with particulates could have potentially serious adverse events, which could include embolic, thrombotic, and other vascular events (e.g., phlebitis). Risks of injecting particulates by the subcutaneous route could include foreign body granuloma, local injection site reactions, and increased immunogenicity.
- Additional affected products started shipping November 30, 2016, and include:

Description	Lot #	Exp Date	NDC	UPC	Econo #
PROCRIT VL 10000U 1ML 6 NR	G290530A	07/31/2018	59676031001	35967631001	1804681
PROCRIT VL 10000U 1ML 25 NR	G290531A	07/31/2018	59676031002	35967631002	3278371

- To date, no adverse events have been reported to the manufacturer.
- This is an extension of the product sequestration actions in **Product Recall Office Log # 12345** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of Procrit® (epoetin alfa) 1 mL Single-Dose, Preservative-Free Solution product(s) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch- online.htm, or by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate

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providers who prescribe this agent (e.g., **nephrologists, primary care providers, hematology/oncology staff, infectious disease staff, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.

- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 10/10/2017):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
  - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
    - Identify the patient(s).
    - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
      - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template. doc .
      - This template can be altered according to site-specific needs.
    - Provide patient(s) in possession of the recalled product with instructions on the following:
      - How to return the product being recalled to the pharmacy.
      - How to obtain a new supply of product.
      - Patients should not continue to take the product until they obtain replacement product.
      - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
  - Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html.

SOURCE: Manufacturer

REFERENCE(S): McKesson Urgent Drug Recall [Data on file, Date 09/14/17]. Manufacturer Recall, written communication, September 14, 2017.

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.