Drug recall notice for metformin extended-release tablets

To assist you in the care of your patients, we want to alert you to the **drug recall of metformin extended-release (ER) products** effective June 1, 2020.[1] We recommend you review your medical records and contact all patients for whom you have prescribed metformin extended-release tablets. Please inform your patients of the possible problem and consider clinically appropriate changes to preferred formulary alternatives.

The U.S. Food and Drug Administration (FDA) announced that agency laboratory testing showed results of the nitrosamine impurity N-Nitrosodimethylamine (NDMA) above the agency's acceptable level in several lots of the extended-release formulation of metformin. This impurity has been classified as a probable human carcinogen by the International Agency for Research on Cancer (IARC). The agency contacted several companies recommending they voluntarily recall their products. Assessments are underway to determine whether metformin ER recalls will result in shortages, and the agency will work closely with manufacturers to prevent or reduce any impact of shortages.

The FDA continues to evaluate metformin extended-release tablets and will update the inclusion and exclusion list as more information becomes available.

Due to the FDA's ongoing investigation, CarePlus anticipates the recalls to continue. **Monitor the FDA's website for the most up-to-date metformin recall information.**

To search for other medications that your patient's CarePlus plan covers, you can access the plan's drug lists at **www.CarePlusHealthPlans.com/medicare-plans/2021-prescription-drug-guides**.

Information for providers:[1]

- We have sent a letter to your patients who have had a claim for metformin ER 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.
- 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.

Reference:

1. U.S. Food and Drug Administration. "FDA Updates and Press Announcements on NMDA in Metformin." **www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin**. Accessed June 5, 2020.