Provider Bulletin

News and Information



June 11, 2020

FDA Recall of Certain Manufacturers of Metformin Extended-Release Tablets

On May 28, 2020, the Food and Drug Administration (FDA) announced they requested five drug manufacturers to voluntarily recall their Metformin Extended-Release (ER) products from the marketplace due to higher than acceptable levels of N-Nitrosodimethylamine (NDMA), a potential cancer causing chemical. When people are exposed to higher than acceptable levels of NDMA over extended periods of time, it increases their risk of cancer. Below are the dates of manufacturer recall and the manufacturers impacted. The following company recall notices have been received by the FDA:

- June 1 Amneal and Apotex recalled all lots/batches of their Metformin Extended-Release products
- June 5 Actavis (Teva) and Marksans Pharma Limited (Time Cap Labs) recalled certain impacted lots/batches of their Metformin Extended-Release products

What should patients taking an impacted product do?

Patients should continue taking Metformin ER tablets even after recalls occur, until they consult with their health care professional who can prescribe a replacement. Patients with type 2 diabetes could face health risks if they stop taking their prescribed Metformin.

What should prescribers do?

Prescribers can request that members be switched to a Metformin ER manufacturer that has not recalled their product. In addition, UCare covers the immediate release version of Metformin, which is an alternative. No immediate release Metformin products are impacted by the recall.

Where can I find additional information?

The FDA has information on their website for health care professionals and patients. <u>Click here</u> to see the FDA news release.

Is UCare reaching out to impacted members and their providers?

Yes, UCare's pharmacy department will be sending out letters to impacted members that can be accurately identified and their providers. These letters will include information on alternative drugs on the formulary, and direct members to reach out to their prescriber for alternatives. UCare will mail the letters in mid-June.

Questions?

If you have further questions, please call UCare's Provider Assistance Center at 612-676-3300 or 1-888-531-1493 toll free or visit <u>ucare.org/providers</u>.

