Market withdrawal of all ranitidine products

To assist you in the care of your patients, we want to alert you to the market withdrawal of all ranitidine products on April 1, 2020.[1] We recommend you review your medical records and contact all patients for whom you have prescribed ranitidine to warn them of the recall. You also may have patients who have taken over-the-counter (OTC) ranitidine medications; please advise those patients of the recall. We have listed alternative options below.

The U.S. Food and Drug Administration (FDA) announced that it is requesting manufacturers to withdraw all prescription and OTC ranitidine drugs from the market immediately. This is the latest step in an ongoing investigation of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications (commonly known by the brand name Zantac®).

NDMA is a probable human carcinogen. Low levels of NDMA are commonly ingested in the diet. These low levels would not be expected to lead to an increase in the risk of cancer. However, sustained higher levels of exposure may increase the risk of cancer in humans.

NDMA levels increase in ranitidine even under normal storage conditions, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling. Also, the older a ranitidine product is, or the longer the length of time since it was manufactured, the greater the level of NDMA. The FDA determined that some ranitidine products may result in consumer exposure to unacceptable levels of this impurity.

Monitor the FDA's website for the most up-to-date ranitidine recall information: **www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine**.

Recommendations:

Preferred formulary alternatives:

Recalled medication	Preferred alternative
ranitidine capsules/tablets	famotidine tablets
ranitidine capsules/tablets	omeprazole capsules
ranitidine capsules/tablets	pantoprazole tablets
ranitidine syrup	cimetidine oral solution
ranitidine syrup	famotidine oral suspension
ranitidine injection	famotidine injection

This means that ranitidine will no longer be available effective April 2, 2020. To access CarePlus' formulary drug lists, go to:
www.CarePlusHealthPlans.com/medicare-plans/2020-prescription-drug-guides

Information for providers:[1,2]

- We have sent a letter to your patients who have had a claim for ranitidine and asked them to contact their physicians or healthcare providers about other treatment options before stopping the medicine, as multiple drugs are approved for the same or similar uses as ranitidine and do not carry the same risks from NDMA.

- Healthcare providers should: 1) stop prescribing and dispensing ranitidine to their patients; 2) contact patients currently taking ranitidine, inform them of the market withdrawal and ask them to stop taking the medicine; and 3) discuss alternative treatment options. See the above formulary alternative list.

- In light of the current COVID-19 pandemic, the FDA recommends patients and consumers not take their medicines to a drug take-back location. Per the FDA, ranitidine disposal is recommended in household trash. Patients should:

    1. Remove the pills or liquid from their original container and mix them with an unappealing substance such as dirt, cat litter or used coffee grounds; do not crush pills.
    2. Place the mixture in a container such as a sealed plastic bag.
    3. Throw away the container in their trash at home.
    4. Remove or delete all personal information on the prescription label of empty medicine bottles or packaging, then throw away or recycle them.

- Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

    - **Online:** Complete and submit the report at **www.accessdata.FDA.gov/scripts/medwatch**.
        - Select "Consumer/Patient (FDA Form 3500B)."

    - **Regular mail or fax:** Download form at **www.FDA.gov/node/360547**.
        - 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. U.S. Food and Drug Administration. "FDA Requests Removal of All Ranitidine Products (Zantac) from the Market." www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market. Accessed April 1, 2020.

2. U.S. Food and Drug Administration. FDA Updates and Press Announcements on NMDA in Zantac (ranitidine). www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine. Accessed April 1, 2020.