Drug recall notice for Chantix (varenicline) tablets

To assist you in the care of your patients, we would like to alert you to the recall of all lots of Chantix® 0.5 mg and 1 mg tablets on Sept. 16, 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.

The drug manufacturer, Pfizer, has voluntarily expanded the recall on these products to the patient (consumer/user) level due to the presence of a nitrosamine, N-nitroso-varenicline, at or above the U.S. Food and Drug Administration (FDA)-acceptable intake limit. This recall is being conducted with the knowledge of the FDA.

Medications included in this recall
Visit the FDA website for specific details about the recalled medication.

Recommendations
To reduce impact to your patients, please consider the listed alternative options below. (Please note that these alternative products are Z-rated. Therefore, these are not FDA-approved drugs and are not listed as therapeutically interchangeable with brand-name Chantix.)

Preferred alternatives
Apo-Varenicline 0.5 mg tablets
Apo-Varenicline 1 mg tablets
Apo-Varenicline 0.5 mg and 1 mg starter blister pack tablets

Information for providers:[1]

- We have sent a letter to your CarePlus-covered patients who have had a claim for Chantix 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 providers with questions can contact:
  - Pfizer Medical Information at 800-438-1985, option 3, Monday – Friday, 9 a.m. – 5 p.m., Eastern time; or refer to www.pfizermedinfo.com for medical questions regarding the product.
  - Pfizer Drug Safety at 800-438-1985, option 1 (24 hours a day, 7 days a week) to report adverse events and product complaints.
- Patients may report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting Program 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. "Pfizer Expands Voluntary Nationwide Recall to include All Lots of CHANTIX® (Varenicline) Tablets Due to N-Nitroso Varenicline Content," U.S. Food and Drug Administration, last accessed Sept. 22, 2021, www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n?utm_medium=email&utm_source=govdelivery.