

Provider Bulletin



News and Information

Oct. 14, 2021

FDA Announces Chantix Recall

On Sept. 16, 2021, Pfizer announced a voluntary recall of all lots of Chantix 0.5 mg and 1 mg tablets to the patient (consumer/user) level due to the presence of a nitrosamine, N-nitroso-varenicline, at or above the FDA interim acceptable intake limit. Long-term ingestion of N-nitroso-varenicline may be associated with a theoretical potential increased cancer risk in humans, but there is no immediate risk to patients taking this medication. The health benefits of stopping smoking outweigh the theoretical potential cancer risk from the nitrosamine impurity in varenicline. Following is a timeline of events:

- July 2 – Pfizer voluntarily recalled nine lots of Chantix at the warehouse level.
- July 19 – Pfizer expanded its voluntary recall of specific lots to the consumer level.
- Aug. 18 – Pfizer expanded its voluntary recall to additional lots.
- Sept. 17 – FDA announced Pfizer’s voluntary recall to include all lots of Chantix.

What should patients who take the impacted product do?

Patients should continue taking Chantix, even after recalls occur, until they consult with their health care professional who can prescribe a replacement.

What should prescribers do?

Prescribers can request that their patient(s) be switched to Bupropion XL or use nicotine replacement therapy that is on the formulary. An FDA approved generic has recently been added to all UCare formularies and should be available in pharmacies soon. The FDA allows imports of the Apo-Varenicline tablets from Canada. However, those products are not currently covered on UCare formularies for Medicaid members due to regulatory requirements.

Where can I find additional information?

The FDA provides information on their website for healthcare professionals and patients.

[FDA Updates and Press Announcements on Nitrosamine in Varenicline \(Chantix\) | FDA](#)

Is UCare reaching out to impacted members and their providers?

Yes, UCare’s pharmacy department will send letters to impacted members. These letters will include information on alternative drugs within the formulary, as well as direct members to reach out to their prescriber for alternatives. Letters will be mailed around Oct. 14.

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 ucare.org/providers.