



A Public Entity

Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

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New DHCS DUR Board Educational Article

IEHP reviews the DHCS DUR Board Educational Articles regularly for important information we can pass on to our Provider Network. From the DUR Board Website:

The purpose of this educational intervention component of DUR is to improve the quality and cost-effectiveness of prescribing and dispensing practices for Medi-Cal recipients. Educational interventions include ongoing dissemination of information through the Medi-Cal provider bulletin process about clinically important, drug-specific therapy problems.

Disclaimer: These articles are the result of analyses carried out by the Global Medi-Cal DUR Program and are not official policies of the Department of Health Care Services (DHCS).

Please find attached the newest article, entitled [Drug Safety Communication: Voluntary Recall of Varenicline \(Chantix\) Lots Containing Nitrosamine](https://files.medi-cal.ca.gov/pubsdoco/dur/Articles/dured_31302.pdf) was published August 31, 2021. The article may also be found here: https://files.medi-cal.ca.gov/pubsdoco/dur/Articles/dured_31302.pdf

August 31, 2021



Drug Safety Communication: Voluntary Recall of Varenicline (Chantix) Lots Containing Nitrosamine

Varenicline is a prescription medicine that is used to help adults quit smoking. On July 2, 2021, the U.S. Food and Drug Administration (FDA) announced a voluntary recall of certain lots of varenicline due to levels of a nitrosamine impurity, called N-nitroso-varenicline, above the FDA's acceptable intake limit. N-nitroso-varenicline may be associated with a potential increased cancer risk in humans associated with long-term use, but there is no immediate risk to patients taking this medication.

The FDA recommends that patients taking recalled varenicline should continue with their current medication regimen as prescribed, until either their pharmacist provides a replacement, or their doctor prescribes a different medication. The health benefits of stopping smoking outweigh the cancer risk from the nitrosamine impurity in varenicline.

To minimize risk to patients currently taking varenicline, health care professionals should consider the following actions:

- Consider other available treatment options for patients currently taking varenicline.
- Quarantine any varenicline samples and do not provide them to your patients. Contact the manufacturer directly with questions regarding product return or disposal.
- Report side effects involving varenicline or other medications to the FDA MedWatch program.

The FDA is continuing to investigate the presence of N-nitroso-varenicline in varenicline products and will provide more information as it becomes available. To ensure access to the most recent updates and press announcements, including the full list of recalled lots, refer to "[FDA Updates and Press Announcements on Nitrosamine in Varenicline \(Chantix\)](#)" found on the [Drug Safety and Availability](#) page of the FDA's website.

For questions or comments, please call us at (909) 890-2049.

Sincerely,
IEHP Pharmaceutical Services