Indian Health Service
National Pharmacy and Therapeutics Committee
Medication Update

March 29, 2023

FDA Approves First OTC Naloxone Nasal Spray

On March 29th 2023, ***the U.S. Food and Drug Administration (FDA) approved Narcan, 4 milligram naloxone hydrochloride nasal spray for over-the-counter (OTC), nonprescription use – the first naloxone product approved for use without a prescription.*** Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose. Today's action paves the way for the life-saving medication to reverse an opioid overdose to be sold directly to consumers in places like drug stores, convenience stores, grocery stores and gas stations, as well as online.

Background

Drug overdose persists as a major public health issue in the United States, with more than 101,000 reported fatal overdoses occurring in the 12-month period ending in October 2022, primarily driven by synthetic opioids, such as illicit fentanyl.

Narcan nasal spray was first approved by the FDA in 2015 as a prescription drug. In accordance with a process to change the status of a drug from prescription to nonprescription, the manufacturer provided data demonstrating that the drug is safe and effective for use as directed in its proposed labeling. The manufacturer also showed that consumers can understand how to use the drug safely and effectively without the supervision of a healthcare professional. The application to approve Narcan nasal spray for OTC use was granted priority review status and was the subject of an advisory committee meeting in February 2023, where committee members voted unanimously to recommend it be approved for marketing without a prescription.

Additional considerations

The use of Narcan nasal spray in individuals who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness and increased blood pressure.

The FDA has taken a series of measures to help facilitate access to naloxone products. In November 2022, the FDA announced its preliminary assessment that certain naloxone products, such as the one ultimately approved today, have the potential to be safe and effective for over-the-counter use and encouraged sponsors to submit applications for approval of OTC naloxone products. The FDA previously announced in 2019 that it had designed, tested, and validated a model naloxone Drug Facts Label (DFL) with easy-to-understand pictograms on how to use the drug to encourage manufacturers to pursue approval of OTC naloxone products. The model DFL was used to support the approved application along with the results of a simulated use Human Factors validation study designed to assess whether all the components of the product with which a user would interact could be used safely and effectively as intended.

Through the FDA Overdose Prevention Framework, the FDA remains focused on responding to all facets of substance use, misuse, substance use disorders, overdose and death in the U.S. The framework's priorities include: supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing; encouraging harm reduction through innovation and education; advancing development of evidence-based treatments for substance use disorders; and protecting the public from unapproved, diverted or counterfeit drugs presenting overdose risks.

Indian Health Service resources

The Indian Health Service (IHS) National Pharmacy and Therapeutics Committee voted to add naloxone to the IHS National Core Formulary for the treatment of opioid overdose in May of 2014, and reviewed it again in August

of 2018. This was done in light of the epidemic of opioid overdose deaths in Indian Country, with rural areas hit hardest. Among American Indian and Alaska Native people in metropolitan and non-metropolitan areas, the rates of drug overdose deaths from 1999 to 2015 rose 261 and 519 percent respectively. This formulary medication addition ensures access to naloxone for patients at IHS federal direct care and participating tribal and Urban Indian Organization sites.

The IHS Heroin Opioids and Pain Efforts (HOPE) Committee has also developed additional technical assistance resources to assist sites with equipping patients and community members with naloxone. A new *Naloxone Keeps the Circle Strong* campaign and customizable resources are available on the HOPE Website.

References:
1. U.S. Food and Drug Administration. FDA Approves First Over-the-Counter Naloxone Nasal Spray. Published online March 29, 2023
2. Indian Health Service National Pharmacy and Therapeutics Committee, Treatment of Opioid Overdose, May 2014
3. Indian Health Service National Pharmacy and Therapeutics Committee, Opioid Use Disorder, August 2018
4. Indian Health Service. HOPE Committee. Opioid Stewardship in the Indian Health Service, Naloxone Training Toolkit