

07-23-2020: FDA Medwatch Safety Alert

TOPIC: Opioid Pain Relievers or Medicines to Treat Opioid Use Disorder: MedWatch Safety Alert - FDA Recommends Health Care Professionals Discuss Naloxone with All Patients when Prescribing

ISSUE: FDA is requiring drug manufacturers for all opioid pain relievers and medicines to treat opioid use disorder (OUD) to add new recommendations about naloxone to the prescribing information. This will help ensure that health care professionals discuss the availability of naloxone and assess each patient's need for a naloxone prescription when opioid pain relievers or medicines to treat OUD are being prescribed or renewed. The patient Medication Guides will also be updated.

RECOMMENDATION:

Health Care Professionals:

- Discuss the availability of naloxone with all patients when prescribing or renewing an opioid analgesic or medicine to treat Opioid Use Disorder (OUD).
- Consider prescribing naloxone to patients prescribed medicines to treat OUD and patients prescribed opioid analgesics who are at increased risk of opioid overdose.
- Consider prescribing naloxone when a patient has household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose.
- Additionally, even if the patients are not receiving a prescription for an opioid analgesic or medicine to treat OUD, consider prescribing naloxone to them if they are at increased risk of opioid overdose.
- Educate patients and caregivers on how to recognize respiratory depression and how to administer naloxone. Inform them about their options for obtaining naloxone as permitted by their individual state dispensing and prescribing requirements or guidelines for naloxone. In the state of Florida, patients do not need a prescription to obtain Naloxone. Some local pharmacies carry Naloxone. Patients should check with their local pharmacies to confirm if supplies are in stock. Narcan is only available through the pharmacy counter.
- Emphasize the importance of calling 911 or getting emergency medical help right away, even if naloxone is administered.

Useful Patient Education Information:

- Talk to your health care professionals about the benefits of naloxone and how to obtain it.
- Recognize the signs and symptoms of a possible opioid overdose. These include slowed, shallow, or difficult breathing, severe sleepiness, or not being able to respond or wake up. If you know or think someone is overdosing, give the person naloxone if you have access to it, and always call 911 or go to an emergency room right away. Naloxone is a temporary treatment, so repeat doses may be required. Even if you give naloxone, you still need to get emergency medical help right away.
- If you have naloxone, make sure to tell your caregivers, household members, and other close contacts that you have it, where it is stored, and how to properly use it in the event of an overdose. When using opioid medicines away from home, carry naloxone with you and let those you are with know you have it, where it is, and how to use it. Read the Patient Information leaflet or other educational material and Instructions for Use that comes with your naloxone because it explains important information, including how to use the medicine.

Doctors HealthCare Plans covers naloxone on its formulary in various forms and on the following copayment tiers:

NALOXONE 0.4 MG/ML VIAL	Tier 2
NALOXONE 0.4 MG/ML CARPUJECT	Tier 2
NALOXONE 2 MG/2 ML SYRINGE	Tier 2
NARCAN 4 MG NASAL SPRAY	Tier 3
NALOXONE 2 MG AUTO-INJECTOR	Tier 3 (Generic for Evzio- effective Sept. 1 st 2020)

Source:

<https://www.fda.gov/safety/medical-product-safety-information/opioid-pain-relievers-or-medicines-treat-opioid-use-disorder-medwatch-safety-alert-fda-recommends>