RXADVANCE
2 Park Central Drive
Southborough, MA 01772

CLINICAL UPDATE

Brand Name	Narcan; Evzio
Generic Name	naloxone

Clinical Update

FDA recommends health care professionals discuss naloxone with all patients when prescribing opioid pain relievers or medicines to treat opioid use disorder.

FDA Approval Date: July 23, 2020

Safety

The misuse and abuse of illicit and prescription opioids and the risks of addiction, overdose, and death are a public health crisis in the United States. In 2018, an estimated 1.7 million Americans had a substance use disorder involving prescription pain relievers and 0.5 million had a substance use disorder involving heroin. From 1999 to 2018, nearly 450,000 people died from an overdose involving any opioid, including prescription and illicit opioids. Opioids were involved in 46,802 deaths in 2018.Naloxone is an FDA-approved medicine used in emergency treatment for an opioid overdose. An overdose can happen when someone takes too much of an opioid or takes it with certain other medicines or substances, such as alcohol. Opioid overdose is a medical emergency that can result in death. Naloxone works quickly to block the effects of opioids and temporarily reverses the breathing problems caused by the overdose, which can help prevent death. Naloxone is a temporary treatment so repeat doses may be required. Even when naloxone is given to someone. It can be given safely whenever an opioid overdose have occurred. It can be given safely to people of all ages, from infants to elderly adults including a child who has or may have accidentally taken an opioid pain reliever or medicine to treat opioid use disorder OUD. There are three FDA-approved forms of naloxone: a nasal spray, an injectable, and an auto-injector. Naloxone is sold under the brand names Narcan and Evzio, and also as generics. All forms of naloxone can be provided by these programs and used by individuals with or without medical training to reverse the effects of an opioid overdose.In patients who have been using opioids regularly, the use of naloxone may cause symptoms of opioid withdrawal, including feeling nervous, restless, or irritable; body aches; dizziness or weakness; diarrhea, stomach pain, or nausea; fever, chills, or goose bumps; or sneezing or runny nose.

To reduce the risk of death from opioid overdose, the U.S. Food and Drug Administration (FDA) is making the following recommendations about the opioid reversal medicine, naloxone: Patients who are prescribed opioid pain relievers, Health care professionals should discuss the availability of naloxone, and consider prescribing it to patients who are at increased risk of opioid overdose, such as patients who are also using benzodiazepines or other medicines that depress the central nervous system, who have a history of opioid use disorder (OUD), or who have experienced a previous opioid overdose.Patients at increased risk of opioid overdose, health care professionals should consider prescribing naloxone, even if the patient is not receiving a prescription for an opioid pain reliever or medicine to treat opioid use disorder OUD. This may include people with a current or past diagnosis of OUD or who have experienced a previous opioid overdose.Increased access to the opioid reversal medicine, naloxone, may help save lives by preventing opioid overdose deaths. We are requiring the 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.Routinely 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. Patients receiving medicines to treat OUD have a lower risk of opioid overdose than those with OUD who are not being treated; however, they are still

CLINICAL UPDATE

at risk of relapse and opioid overdose. Also, consider prescribing naloxone when a patient has household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose.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. 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.

CLINICAL UPDATE