

## ADMINISTRATION OF NALOXONE

Definition of Naloxone

Naloxone hydrochloride (Naloxone) prevents or reverses the effects of opioids including respiratory depression, sedation, and hypotension.

Naloxone is an essentially pure opioid antagonist, i.e., it does not possess the "agonistic" or morphine-like properties characteristic of other opioid antagonists. When administered in usual doses and in the absence of opioids or agonistic effects of other opioid antagonists, it exhibits essentially no pharmacologic activity.

Naloxone has not been shown to produce tolerance or cause physical or psychological dependence. In the presence of physical dependence on opioids, Naloxone will produce withdrawal symptoms. However, in the presence of opioid dependence, opioid withdrawal symptoms may appear within minutes of Naloxone administration and subside in about 2 hours.

Indications for use of Naloxone

Naloxone is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids. It may be delivered intranasally with the use of a mucosal atomizer device (MAD) or intramuscularly with use of a needle or autoinjector.

Naloxone can be dispensed by a pharmacist or a pharmacy intern under the direct supervision of a pharmacist without a prescription in accordance with this protocol to all the following:

- An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;
- A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose; or
- A peace officer as defined in section 2921.51 of the Revised Code.

*Indications for dispensing Naloxone are:*

1. Previous opioid intoxication or overdose
2. History of nonmedical opioid use
3. Initiation or cessation of methadone or buprenorphine for opioid use disorder treatment
4. Higher-dose (>50 mg morphine equivalent/day) opioid prescription
5. Receiving any opioid prescription plus:
  - a. rotated from one opioid to another because of possible incomplete cross-tolerance
  - b. smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection or other respiratory illness
  - c. renal dysfunction, hepatic disease, cardiac illness or HIV/AIDS
  - d. known or suspected concurrent alcohol use
  - e. concurrent benzodiazepine or other sedative prescription
  - f. concurrent antidepressant prescription
6. Patients who may have difficulty accessing emergency medical services (distance, remoteness)
7. Voluntary request from a family member, friend, peace officer, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

## Precautions and Contraindications

### *Precautions*

- Use in Pregnancy
  - Teratogenic Effects: pregnancy category C, no adequate or well-controlled studies in pregnant women
  - Nonteratogenic Effects: Pregnant women known or suspected to have opioid dependence often have associated fetal dependence. Naloxone crosses the placenta and may precipitate fetal withdrawal symptoms.
- Nursing Mothers: Caution should be exercised when administering to nursing women due to transmission in human milk. Risks and benefits must be evaluated.

### *Contraindications*

- Contraindicated in patients known to be hypersensitive to it or to any of the other ingredients in Naloxone hydrochloride

### *Adverse Reactions*

Adverse reactions are related to reversing dependency and precipitating withdrawal and include fever, hypertension, tachycardia, agitation, restlessness, diarrhea, nausea/vomiting, myalgia, diaphoresis, abdominal cramping, yawning, sneezing

- These symptoms may appear within minutes of Naloxone administration and subside in approximately 2 hours.
- The severity and duration of the withdrawal syndrome is related to the dose of Naloxone and the degree of opioid dependence.
- Adverse effects beyond opioid withdrawal are rare.

## Assessment of Client for Qualification for Naloxone Distribution

### *Subjective Findings*

- Individual is at risk of experiencing an opioid-related overdose or is in a position to assist a family member, friend, or other person in the community (including peace officer) at risk of experiencing an opioid-related overdose
- Individual reports no known sensitivity or allergy to Naloxone hydrochloride

### *Objective Findings*

- Individual is oriented to person, place, and time and able to understand and learn the essential components of overdose response and Naloxone administration
- If person appears to be experiencing a current overdose, 911 should be called immediately and as appropriate, CPR and Naloxone administration should occur as staff is able until EMS arrives
- Screen individual for contraindications/precautions. If a contraindication/precaution exists, refer individual to medical provider for further evaluation.
- If applicable, inform individual of the local treatment options available for opioid addiction/dependence and also provide the Ohio Department of Mental Health and Addiction Services treatment information and referral hotline (1-877-275-6364)

## Authorization to Dispense Naloxone

Per the Ohio Revised Code listed above the Medical Director, Gerald Vallee, as a physician in the state of Ohio may authorize a qualified individual to perform education and provision of

Naloxone and an opioid overdose reversal kit. Naloxone may be dispensed under this protocol without a prescription to:

- An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;
- A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose; or
- A peace officer as defined in section 2921.51 of the Revised Code.

#### Use of Intranasal Naloxone

- Naloxone 2 mg/2 ml prefilled syringe, 2 syringes
- NDC No. 76329-3369-01
- SIG: Spray ½ of syringe into each nostril upon signs of opioid overdose. Call 911. May repeat x1.
- Two mucosal atomization devices (MAD300)
- SIG: Use as directed for Naloxone administration

Directions for use:

1. Call 911 as soon as possible for a person suspected of an opioid overdose with respiratory depression or unresponsiveness, and initiate rescue breathing
2. Remove the two colored caps from the delivery syringe and one from the Naloxone vial.
3. Screw the mucosal atomizer device onto the top of the syringe.
4. Screw the Naloxone vial gently into the delivery syringe.
5. Spray ½ (1 ml) of Naloxone in one nostril and the other ½ (1 ml) in the other nostril.
6. Repeat if there is no response after three minutes.
7. Continue rescue breathing and monitor respiration and responsiveness of the Naloxone recipient until emergency help arrives.

#### Required Education and Counselling Per Ohio Revised Code

In accordance with the Ohio Revised Code listed above Latasha Alvaro, BSN, RN, shall provide education on Naloxone with the individual to whom Naloxone is dispensed. This education shall include the requirement to summon emergency services as soon as practicable either before or after administering Naloxone. Additionally, Latasha Alvaro, BSN, RN, shall personally provide the service of verbal counseling and written educational materials to the individual to whom Naloxone is dispensed, appropriate to the dosage form of the Naloxone dispensed, including, but not limited to, all of the following:

1. risk factors of opioid overdose;
2. strategies to prevent opioid overdose;
3. signs of opioid overdose;
4. steps in responding to an overdose;
5. information on Naloxone, including possible adverse reactions;
6. procedures for administering Naloxone; and
7. proper storage and expiration of Naloxone product dispensed

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