August 4, 2020

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Dear provider of pharmaceutical services,

The U.S. Food and Drug Administration (FDA) is recommending healthcare professionals to discuss naloxone with all patients when prescribing opioid analgesics or medicines to treat opioid use disorder (OUD). The FDA is also requiring that labeling for these medicines be updated with recommendations about naloxone for healthcare professionals prescribing these medicines.

NALOXONE HIGHLIGHTS

- Naloxone is an emergency treatment for an opioid overdose, which is a medical emergency that can result in death.
- Naloxone can be a life-saving treatment for individuals that may be at greater risk of an overdose, as it can be administered by individuals with or without medical training to help reduce opioid overdose deaths.
- If administered quickly, naloxone can counter the overdose effects within minutes.
- There are three FDA-approved forms of naloxone: a nasal spray, an injectable, and an auto-injector. All forms of naloxone can be used by individuals with or without medical training to reverse the effects of an opioid overdose.
- Naloxone is available in generic and under the brand names Narcan™ and Evzio™.
- Depending on the state/US territory you live in, naloxone may be available without a prescription

RECOMMENDATIONS FOR HEALTHCARE PROFESSIONALS:

- Routinely discuss the availability of naloxone with all patients and caregivers, both when beginning and renewing treatment with an opioid analgesic or a medicine to treat OUD.
- Consider prescribing naloxone:
    - To patients receiving a prescription for an opioid analgesic or a medicine to treat OUD who are at increased risk of opioid overdose.
    - To patients NOT receiving a prescription for an opioid analgesic or a medicine to treat OUD, but who are at increased risk of opioid overdose
    - When a patient has household members (e.g. children) or other close contacts at risk for accidental ingestion or opioid overdose.
- Familiarize with the options for obtaining naloxone as permitted by their individual state/U.S. territory dispensing and prescribing requirements or guidelines for naloxone.
- Provide education to patients and caregivers on:
    - How to recognize signs and symptoms of opioid overdose (e.g. breathing problems, severe sleepiness, or not being able to respond or wake up).
    - How to administer naloxone.

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  - How to properly store and dispose opioids.
  - Options for obtaining naloxone as permitted by their individual state/U.S. territory dispensing and prescribing requirements or guidelines for naloxone.
  - The importance of calling 911 or getting emergency medical help right away, even if naloxone is administered.
- Report adverse events or side effects involving naloxone, opioids, or other medicines at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:
  - Complete and submit the MedWatch Online Voluntary Reporting Form online.
  - Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Additional information can be found at FDA's Drug Safety and Availability portal and FDA's Press Announcements portal.

PharmPix is committed to the health and wellness of our members. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

References:

- Discuss naloxone with all patients when prescribing opioids. U.S. Food and Drug Administration. (2020). Retrieved 30 July 2020, from https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommends-health-care-professionals-discuss-naloxone-all-patients-when-prescribing-opioid-pain.
- FDA Requiring Labeling Changes for Opioid Pain Medicines, Opioid Use Disorder Medicines Regarding Naloxone. U.S. Food and Drug Administration. (2020). Retrieved 30 July 2020, from https://www.fda.gov/news-events/press-announcements/fda-requiring-labeling-changes-opioid-pain-medicines-opioid-use-disorder-medicines-regarding?utm_campaign=072320_PR_FDA%20Requiring%20Labeling%20Changes%20for%20Opioid%20Pain%2C%20Use%20Disorder%20Medicines&utm_medium=email&utm_source=Eloqua.

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