Kansas Drug Utilization Review Newsletter

Health Information Designs, LLC **1st Quarter 2020**

Welcome to the Quarterly edition of the "Kansas Drug Utilization Review Newsletter", published by Health Information Designs, LLC (HID). This newsletter is part of a continuing effort to keep the Medicaid provider community informed of important changes in the Kansas Medical Assistance Program (KMAP).

Helpful Web Sites

KMAP Web Site
https://www.kmap-state-ks.us/

KDHE-DHCF Web Site
http://www.kdheks.gov/hcf/

KanCare Web Site
http://www.kancare.ks.gov/

Fee-For-Service (FFS) Helpful Numbers

Provider Customer Service (Provider Use Only)
1-800-933-6593

Beneficiary Customer Service
1-800-766-9012

KMAP PA Help Desk
1-800-285-4978

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Emergency Opioid Antagonists

The opioid epidemic has been present for several years and continues as one of the most urgent public health priorities. Continued efforts to mitigate this issue have resulted in position statements, opioid guidelines, amendments to law, and approval of new medications. Regardless of the maintenance and prevention regimens available to support patients from relapsing back to opioids, there is a current need for access to emergency treatment for acute opioid overdose.

Injectable (intravenous [IV], intramuscular [IM], subcutaneous [SQ]) and intranasal naloxone are indicated for the complete or partial reversal of respiratory and/or central nervous system (CNS) depression induced by natural and synthetic opioids.[1,2] The U.S. Food and Drug Administration (FDA)-approved labeling of the injectable form of naloxone states that the medication should be administered in a healthcare setting. The FDA has clarified that all formulations of the medication are not excluded from being dispensed by pharmacies or by community distribution programs.[3]

Effective on July 1, 2017, the state of Kansas announced that naloxone may be dispensed by pharmacists under the Statewide Protocol. Information can be found at https://pharmacy.ks.gov/resources-consumer-info-2/naloxone. The Kansas Board of Pharmacy notified pharmacists of this protocol which includes the following steps:

1. Read relevant laws and regulations (HB 2217 and KAR 68-7-23).
2. Download the official, pre-signed Statewide Protocol. Available at: https://www.pharmacy.ks.gov/docs/default-source/Naloxone/naloxone-statewide-protocol---official.pdf?sfvrsn=c709a601_6.
3. Review and sign the official Statewide Protocol.
4. Send a copy of the last page of the Statewide Protocol to the Board (mail, fax, or email).
5. Dispense to the patient, bystander, first responder agency, or school nurse.

In general, all formulations of naloxone continue to require a prescription for access, whether written by the patient's provider or by a statewide protocol. However, the Kansas Board of Pharmacy Statute 68-7-23 addresses the dispensing and administration of emergency opioid antagonists without a prescription. The need for a prescription exposes some access limitations. For example, some patients do not have a provider and there are patients who are hesitant to discuss substance abuse with a health care provider.

Emergency Opioid Antagonists, cont.

In response to this issue, the FDA is considering an important public health advancement by encouraging naloxone to become an over-the-counter (OTC) product.[3,4] As an incentive for drug companies to enter the OTC market, the FDA has developed a consumer-friendly Drug Facts label (DFL) model, which is required for OTC drug products and is a key component for OTC availability.[4] This is a responsibility for the manufacturer and requires a time investment. The FDA has created and tested a DFL to support the development of naloxone as an OTC product. Typically, this is the manufacturer's responsibility; however, for the first time, the FDA has proactively developed a DFL.[4] Additionally, the FDA has granted priority review for all generic applications for agents used in the treatment of opioid overdose in the emergency setting.[2]

Formulation	Price	Dosage‡
Injection	Generic 0.4 mg vial: $12* per vial	0.4 mg to 2 mg IV, IM, or SQ; may repeat every 2 to 3 minutes until emergency medical assistance becomes available.[1]
	Evzio 2 mg autoinjector: $4,920** per 2-count kit	2 mg IM or SQ; may repeat every 2 to 3 minutes until emergency medical assistance becomes available.[10]
Nasal Spray	Narcan 4 mg: $60* per nasal spray	2 mg or 4 mg (contents of 1 nasal spray) intranasally in one nostril as a single dose; may be repeated every 2 to 3 minutes in alternating nostrils until emergency medical assistance becomes available.[2]

*Price based on NADAC
**Price based on AWP
‡There is no universally recommended dosage. Total dosage depends upon the amount, type, and route of administration of the opioid being antagonized and is based on the response. This newsletter is not meant to override any specific training and education for opioid antagonists.

Although advancements are being made, including attempts at increasing access (e.g., state protocols, considerations of allowing naloxone to become OTC, etc.) and prioritizing generic applications as mentioned above, there are still many factors to consider, which may include naloxone availability, pricing barriers, and dispensing barriers. Reported concerns from pharmacists include the following: a) lack of ongoing education and/or training to improve pharmacists' knowledge about the use of naloxone and how to identify patients who may benefit from this medication, b) policies or regulations governing naloxone prescribing and dispensing and practice logistics (e.g., time, legalities, reimbursement), and c) patient trust and safety.[5]

Opioid E-Prescribing

In an era of widespread opioid abuse, some states are actively taking measures to prevent further harm and improve patient safety. Currently, opioid overdose is the cause of more deaths than motor vehicle crashes, leading to more than 399,000 deaths from 1999 to 2017.[11] The number of opioid overdose deaths were six times higher in 2017 than it was in 1999, and it includes natural opioids, semi-synthetic opioids, synthetic opioids, methadone, which are all available as prescriptions, and heroin, which is an illicit opioid synthesized from morphine. Per the Centers for Disease Control and Prevention (CDC), the annual rate of opioid prescribing has declined by 19% from 2006 to 2017, suggesting prescribers are more cautiously choosing these agents, but more can still be done. Although this decline is reported during this timeframe, opioid prescribing rates peaked and leveled off between 2010 and 2012. At peak prescribing, there were 81 opioid prescriptions written for every 100 Americans.[6]

Opioid E-Prescribing, cont.

Electronic prescribing of controlled substances (EPCS) is legalized nationally and many states have mandated or are considering mandating the use of EPCS for all controlled substances.[8] With the progression of technology, electronic-prescribing software is available for use in both physician offices and pharmacies, but may be cost prohibitive for some. Organizations must comply with the U.S. Drug Enforcement Agency's (DEA's) specific requirements in the Interim Final Rule and obtain the proper software for this process.[9] The DEA estimates there are nearly 100 provider systems and 20 receiving pharmacy systems available.[9] Although electronic prescribing is an option in all states per the DEA ruling in 2010, it is still not a requirement.[7] Currently, 11 states mandate EPCS, 17 have passed legislation for EPCS, and 6 states have pending legislation.[8] Kansas has an EPCS mandatory requirement that has a future enforcement date of July 1, 2021.[13]

As another resource to handle the opioid epidemic, prescription drug monitoring programs (PDMPs) are operated at the state level to ensure prescribers have a supporting resource to identify patients who are addicted to or at risk of becoming addicted to controlled substances.[8] Kansas has a mandatory PDMP dispenser enrollment in place, integrating the Kansas Tracking and Reporting of Controlled Substances (K-TRACS). A "dispenser" is a pharmacist or any other practitioner who provides a drug of concern or scheduled substance to a user. Each dispenser is required to submit information required by the board through electronic means. However, "the board may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or other means, provided that all information required by rules and regulations is submitted in this alternative format." [12]

References:

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12. KS Stat § 65-1683 (2015).
13. KS HB2119 | 2019-2020 | Regular Session. (2019, May 01).

Generic Medications

Recently Approved Generic Drugs:

November 2019	December 2019	January 2020
Mesalamine capsule (Apriso®) Vilazodone tablet (Viibryd®)	Apixaban tablet (Eliquis®) Deferasirox tablet (Jadenu®) Etonogestrel/EE vaginal ring (Nuvaring®) Fingolimod capsule (Gilenya®) Mirabegron ER tablet (Mirbetriq®)	Hydrocodone bitartrate extended-release capsule (Zohydro®)

Upcoming Generic Drugs:

Generic Name	Brand Name	Anticipated Launch
Doxepin tablet	Silenor®	January 1, 2020
Insulin Aspart Recombinant	Novolog®	January 2, 2020
Insulin Aspart Protamine Recombinant, Insulin Aspart Recombinant	Novolog® Mix 70/30 (10 mL vial and Flexpen)	January 2, 2020
Everolimus	Zortress®	March 10, 2020

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