North Dakota Medicaid Pharmacy Program Quarterly News

Published Quarterly by Kepro

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Welcome to the "North Dakota Medicaid Pharmacy Program Quarterly News," a pharmacy newsletter presented by the North Dakota Department of Human Services and published by Kepro. This newsletter is published as part of a continuing effort to keep the Medicaid provider community informed of important changes in the North Dakota Medicaid Pharmacy Program.

The North Dakota Department of Human Services has contracted with Kepro to review and process prior authorizations (PAs) for medications. For a current list of medications requiring a PA, as well as the necessary forms and criteria, visit www.hidesigns.com/ndmedicaid, or call Kepro at (866) 773-0695 to have this information faxed. An important feature on this website is the NDC Drug Lookup, which allows you to determine if a specific NDC is covered (effective date), reimbursement amount, MAC pricing, copay information, and any limitations (prior authorization or quantity limits).

This newsletter provides information about buprenorphine-naloxone metabolism, adverse reactions, and use in pregnancy.

The North Dakota Medicaid Pharmacy Program team appreciates your comments and suggestions regarding this newsletter. To suggest topics for inclusion, please contact Kepro at 1-800-225-6998, or e-mail us at ND_Info@kepro.com.

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Inside this issue:

Helpful Numbers

PA Help Desk	866-773-0695
To fax PAs	855-207-0250
To report adverse reactions	800-FDA-1088

Visit Kepro's North Dakota Department of Human Services Prior Authorization Webpage, *www.hidesigns.com/ndmedicaid*.

Overview

Buprenorphine-naloxone is a combination product commonly used for patients who are diagnosed with opioid use disorder. Buprenorphine is a partial mu-opioid agonist, and naloxone is a pure mu-opioid antagonist. Currently available formulations include buccal film, sublingual film, and sublingual tablet.

Metabolism of Buprenorphine-Naloxone

Buprenorphine: primarily metabolized hepatically via N-dealkylation by CYP3A4, which is then converted to norbuprenorphine (the active metabolite).

Naloxone: primarily metabolized hepatically via glucuronidation. Taken orally, naloxone undergoes significant hepatic first-pass metabolism which, in turn, causes very low (<2%) systemic bioavailability.

Adverse Drug Reactions of Buprenorphine-Naloxone

Adverse drug reactions include withdrawal syndrome, anxiety, irritability, depression, and dental problems. Fortunately, withdrawal and behavioral effects occur at very low incidences (1 to 5%) when taken as prescribed. The combination taken orally does not cause withdrawal symptoms, but rather, deters patients from using the agent inappropriately. When misused by injecting or snorting, naloxone can cause severe opioid withdrawal symptoms in patients who are physically dependent on full opioid agonists. When snorted, the bioavailability of naloxone increases to 42% to 54% which can cause severe side effects.

In January 2022, the U.S. Food and Drug Administration (FDA) issued a warning about dental problems that have been associated with using buprenorphine orally. These dental problems include tooth decay, cavities, loss of teeth, and oral infections. Such issues can be serious and may occur in those without a history of dental problems. Regular checkups, dental cleanings, and proper dental hygiene should be recommended to all individuals using buprenorphine products orally. Switching between the different oral formulations or between buprenorphine/naloxone combination and buprenorphine monoproduct has not been shown to decrease the risk. However, to avoid such dental problems, Sublocade, a long-acting subcutaneous injection, may be utilized in eligible members, as it is a preferred agent.

Buprenorphine-Naloxone Versus Naloxone in Pregnancy

Buprenorphine monoproduct has historically been recommended during pregnancy to avoid severe withdrawal and prenatal exposure to naloxone in the case of misuse. Transferring a pregnant patient to buprenorphine alone, which has a higher potential for misuse and diversion, may not be necessary. Recent studies have found no adverse effects and similar outcomes when using the combination product versus buprenorphine alone while pregnant. The use of combination therapy in pregnant patients will likely expand over time. If the provider finds it necessary to prescribe buprenorphine alone, then the patient may need to be monitored more closely for misuse and diversion.

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Visit http://www.hidesigns.com/ndmedicaid for information on prior authorization. Helpful links include PA Forms, PA Criteria (outlined in the Preferred Drug List), and NDC Drug Lookup.