North Dakota Medicaid Pharmacy Program

Buprenorphine Utilization

Buprenorphine Use in Pregnancy

- When taken correctly, a baby will have little to no absorption of naloxone due to very low (<2%) systemic bioavailability when taken by transmucosal route.
- Studies show that combination use during gestation does not negatively affect newborn outcomes.
- Substance Abuse and Mental Health Services (SAMHSA) guidance states that pregnancy alone is not an indication to change a member who is stable on an opioid agonist and a change in medication represents a period of vulnerability to return to substance use.
- Effective August 1, 2023, to align with SAMHSA guidance, ND Medicaid removed pregnancy or breastfeeding as criteria for prior authorization approval of transmucosal buprenorphine mono-product.

Transitioning to Extended-Release Injectable Buprenorphine

- Considerations for individuals to be on injectable extended-release buprenorphine include:
 - Inability to stabilize on transmucosal buprenorphine
 - Extensive exposure to highly potent synthetic opioids (e.g., fentanyl)
 - Unsafe living environments
 - Multiple opioid overdoses.
- Studies have also shown superior results for extended-release injectable buprenorphine in achieving no illicit opioid use.
- Extended-release buprenorphine at steady-state offers less fluctuation and higher sustained plasma levels of buprenorphine the transmucosal buprenorphine.
- Sublocade is a monthly subcutaneous formulation of buprenorphine which can be initiated following induction with another buprenorphine-containing product for 7 days.
- Brixadi is a weekly or monthly subcutaneous formulation which can be initiated following a single dose of a transmucosal buprenorphine product.

References:

- Debelak K, Morrone WR, O'Grady KE, Jones HE. Buprenorphine + naloxone in the treatment of opioid dependence during pregnancy-initial patient care and outcome data. Am J Addict 2013;22:252–4.
- 2. Wiegand SL, Stringer EM, Stuebe AM, Jones H, Seashore C, Thorp J. Buprenorphine and naloxone compared with methadone treatment in pregnancy. Obstet Gynecol 2015; 125:363–8.
- 3. Substance Abuse and Mental Health Services Administration. (2018). Clinical guidance for treating pregnant and parenting women with opioid use disorder and their infants. HHS Publication No. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration. Available from https://store.samhsa.gov/sites/default/files/d7/priv/sma18-5054.pdf
- 4. Substance Abuse and Mental Health Services Administration (SAMHSA). Medications for opioid use disorder. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2021. Available from https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP21-02-01-002.pdf
- 5. Suboxone (buprenorphine/naloxone) sublingual film [prescribing information]. North Chesterfield, VA: Indivior Inc; March 2021.
- 6. Buprenorphine and naloxone sublingual tablets [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries; April 2022.
- 7. Smith K, Hopp M, Mundin G, et al. Low absolute bioavailability of oral naloxone in healthy subjects. Int J Clin Pharmacol Ther. 2012;50(5):360-367.[PubMed 22541841]
- 8. ACOG Committee on Health Care for Underserved Women and American Society of Addiction Medicine. ACOG Committee opinion no. 524: opioid abuse, dependence, and addiction in pregnancy. Obstet Gynecol. 2012;119(5):1070-1076.[PubMed 22525931]
- 9. Buprenorphine sublingual tablets [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc; May 2022.
- 10. "FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain." U.S. Food and Drug Administration. January 2022. Available from: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-dental-problemsbuprenorphine-medicines-dissolved-mouth-treat-opioid-use-disorder
- 11. Substance Abuse and Mental Health Services Administration. Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants. HHS Publication No. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018. Transitioning from Buprenorphine-Naloxone SL to Sublocade
- 12. Product Information: SUBLOCADE(R) subcutaneous extended-release injection, buprenorphine subcutaneous extended-release injection. Indivior Inc (per FDA), North Chesterfield, VA, 2021.



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