

## 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 than 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:

1. 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](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, Munda 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-problems-buprenorphine-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.