Sublocade® (buprenorphine extended-release) – Updated indication

- On February 24, 2025, Indivior announced the FDA approval of Sublocade (buprenorphine extended-release), for the treatment of moderate to severe opioid use disorder (OUD) in patients who have initiated treatment with a **single dose of a transmucosal buprenorphine product** or who are already being treated with buprenorphine.
    - Sublocade was previously approved for the treatment of moderate to severe OUD in patients who have initiated treatment with a buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.
- The updated indication allows for use of Sublocade as a part of a rapid initiation protocol.
- The approval of Sublocade for the updated indication was based on data from a randomized, open-label study in 723 treatment-seeking patients with moderate to severe OUD and high-risk opioid use. Patients were randomized to Sublocade rapid induction or standard induction. The primary endpoint was the participant retention at the second injection.
    - The proportion of participants who received the second injection was 66.4% in the rapid induction arm and 54.5% in the standard induction arm; the estimated retention rate difference in the overall population was 11.8% with a lower bound of multiplicity adjusted two-sided 95% CI greater than the pre-specified non-inferiority margin of -10%.
    - This demonstrated non-inferiority of rapid induction to standard induction.
- Sublocade carries a boxed warning for risk of serious harm or death with intravenous administration
    - Sublocade is only available through a restricted program called the Sublocade REMS program.
- The most common adverse reactions (≥ 5%) with Sublocade use were constipation, headache, nausea, injection site pruritus, vomiting, increased hepatic enzymes, fatigue, and injection site pain.
- Sublocade is administered subcutaneously and is for healthcare provider preparation and administration only.
    - Sublocade must be injected into the subcutaneous tissue of the abdomen, thigh, buttock, or back of the upper arm.
    - Refer to the Sublocade drug label for complete dosing and administration recommendations.