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Update on Sublocade and Long-Acting Opioid Treatments in 2025

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Optimum Re Life Research and
Development – Biometric Risk



Introduction

In 2025, several new and updated long-acting opioid treatments have emerged, primarily targeting opioid use disorder (OUD) and chronic pain management. These innovations aim to improve patient adherence, reduce withdrawal symptoms and cravings, and minimize the risks associated with fluctuating plasma drug levels seen in daily dosing regimens.

This update is intended to inform underwriters and actuaries about current developments in long-acting opioid therapies, focusing on improved outcomes in opioid use disorder treatment.

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Sublocade --Long-Acting Injectable Buprenorphine

The U.S. Food and Drug Administration (FDA) approved significant labeling changes for monthly long-acting injectable buprenorphine products, including Sublocade and newer generics, in early 2025. This approval expanded clinical guidance and practical use for treating moderate to severe OUD. Sublocade, first approved by the FDA in 2017, is a controlled drug subject to special regulations in prescribing and dispensing, requiring providers to have specific training and certification in the Risk Evaluation and Mitigation Strategy (REMS) program. Sublocade releases buprenorphine steadily over four weeks, helping to reduce opioid cravings and withdrawal symptoms, thereby improving adherence compared to daily oral or sublingual products (buprenorphine/naloxone). Health Canada has also approved Sublocade for OUD. Clinical data show high patient satisfaction due to lifestyle stability and decreased opioid misuse.

Key Advances in Sublocade Use in 2025

- FDA-approved rapid initiation protocol enabling treatment start just one hour after a single 4 mg transmucosal buprenorphine dose, eliminating the prior requirement for at least seven days of transmucosal dosing before transitioning. This accelerates access to long-acting treatment and reduces relapse risk during induction, particularly valuable for emergency and high-risk patients.
- Expanded injection site options now allow subcutaneous administration in the abdomen, thigh, buttock, or back of the upper arm, enhancing patient comfort and provider flexibility.
- Clinical studies involving over 500 patients transitioning to injectable buprenorphine demonstrated general tolerability, with mild adverse events such as injection site pain or nausea and few withdrawal symptoms.
- Therapeutic plasma concentrations (>2 ng/mL) are typically achieved after the second injection, supporting steady opioid receptor activation and lowering relapse risk.
- Treatment initiation protocols now include patients actively using **fentanyl**, with monitoring for withdrawal symptoms during induction.



Other Long-Acting Opioid Treatments

- Brixadi (also a long-acting buprenorphine) is available for either weekly or monthly injections to treat OUD. Approved by the FDA in 2023, it offers a weekly start-up for faster stabilization at the initiation of therapy.
- Nor-LAAM, an experimental monthly therapy developed at Virginia Commonwealth University, is a reformulated version of levo-alpha-acetylmethadol that provides sustained therapeutic levels via biodegradable microparticles. Early preclinical data indicate promise for long-acting OUD treatment, though it remains in prehuman testing.
- Established extended-release opioids, like oxymorphone ER and oxycodone ER, continue FDA approval for chronic pain management, providing steady drug levels over 12–24 hours and allowing individualized dosing.
- The FDA has issued updated safety labeling across all extended-release opioids to emphasize addiction, misuse, and overdose risks during long-term use, recommending cautious use primarily for severe, persistent pain refractory to non-opioids.



Conclusion

Sublocade stands as the most advanced and widely clinically adopted long-acting opioid treatment in 2025 for OUD. Its rapid initiation protocol and expanded injection sites significantly enhance patient access and convenience, contributing to improved adherence, reduced overdose risk, and sustained recovery support. Novel therapies like nor-LAAM represent the next generation of long-acting OUD treatments under development, offering future promise.

These therapeutic advances combined with comprehensive psychological treatment and enhanced clinical protocols elevate the standard of care for opioid dependence and chronic pain management in 2025.



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