Incorporating Long-Acting MOUD Formulations into Clinical Practice

Additional Prescribing Information

Injectable Buprenorphine

Injectable Buprenorphine is administered in-office, not prescribed or dispensed. Because of safety issues, it requires both providers and dispensing specialty pharmacies to participate in an FDA-mandated, manufacturer-developed Risk Evaluation and Mitigation Strategy (REMS) program.

Drug details, including warnings, storage, dosage, administration, etc., can be found at the National Library of Medicine's Daily Med site.

FDA information notes the following about the REMS:

SUBLOCADE is available only through a restricted program called the SUBLOCADE REMS Program because of the risk of serious harm or death that could result from intravenous self-administration. The goal of the REMS is to mitigate serious harm or death that could result from intravenous self-administration by ensuring that healthcare settings and pharmacies are certified and only dispense SUBLOCADE directly to a healthcare provider for administration by a healthcare provider.

Notable requirements of the SUBLOCADE REMS Program include the following:

- *Healthcare Settings and Pharmacies that order and dispense SUBLOCADE must be certified in the SUBLOCADE REMS Program.*
- *Certified Healthcare Settings and Pharmacies must establish processes and procedures to verify SUBLOCADE is provided directly to a healthcare provider for administration by a healthcare provider, and the drug is not dispensed to the patient.*
- *Certified Healthcare Settings and Pharmacies must not distribute, transfer, loan, or sell SUBLOCADE.*

Further information is available at http://www.SublocadeREMS.com or call 1-866-258-3905.

The REMS site, mandated by the FDA, provides access to the REMS program for both providers and specialty pharmacies. A list of specialty pharmacies that dispense injectable buprenorphine is available at the site.

Implantable Buprenorphine

Implantable Buprenorphine is administered in-office, not prescribed or dispensed. Because of safety issues, it requires both providers and dispensing specialty pharmacies to participate in an FDA-mandated, manufacturer-developed Risk Evaluation and Mitigation Strategy (REMS) program.

Drug details, including warnings, storage, dosage, administration, etc., can be found at the National Library of Medicine's Daily Med site.

FDA information notes the following about the REMS:

PROBUPHINE is available only through a restricted program under a REMS, called the PROBUPHINE REMS Program, because of the risk of complications of migration, protrusion and expulsion, and nerve damage associated with the insertion and removal of PROBUPHINE.

Notable requirements of the PROBUPHINE REMS Program include the following:

- *Healthcare Providers who Prescribe PROBUPHINE must be certified with the program by enrolling and completing live training*
- *Healthcare Providers who Insert PROBUPHINE must*
    - *meet the prerequisite requirements be certified with the program by enrolling and completing live training, including demonstrating competency in PROBUPHINE procedures*
- *Patients must be monitored to ensure that PROBUPHINE is removed by a healthcare provider certified to insert PROBUPHINE implants*
- *PROBUPHINE will only be distributed to certified prescribers through a restricted distribution program*

Further information is available at https://probuphinerems.com/ or 1-844-859-6341.

The REMS site, mandated by the FDA, provides access to the REMS program for both providers and specialty pharmacies. A list of specialty pharmacies that dispense injectable buprenorphine is available at the site.

Injectable Naltrexone

Injectable Naltrexone is administered in-office, not prescribed or dispensed. Drug details, including storage, dosage, administration, etc., can be found at the National Library of Medicine's Daily Med site. There is no black box warning for injectable naltrexone, and the FDA has not mandated a REMS for this medication.