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Drug of the Month

Sublocade™ (buprenorphine extended-release)

The Food and Drug Administration (FDA) approved a new dosage form of buprenorphine on November 30, 2017, for patients with opioid use disorder. Sublocade (buprenorphine extended-release) is the first once-monthly injection product that is indicated for the treatment of moderate to severe opioid use disorder as part of a complete treatment program that includes counseling and psychosocial support for patients who have started treatment with a transmucosal buprenorphine-containing product such as Belbuca® (buprenorphine) oral dissolving film, Subutex® (buprenorphine) sublingual tablet, Suboxone® (buprenorphine and naloxone) sublingual film, Bunavail® (buprenorphine and naloxone) buccal film, or Zubsolv® (buprenorphine and naloxone) sublingual tablet. Buprenorphine is a mixed opioid agonist-antagonist, meaning that it stimulates opioid receptors and elicits a response similar to full agonists (e.g., morphine, hydrocodone, etc.); however, this medication exhibits a ceiling to its pharmacological effects. In other words, buprenorphine can offer pain relief and keep opioid withdrawal symptoms at bay, but potential for overdose, abuse, and toxicity from buprenorphine may be less than that of full opioid agonists. Buprenorphine is a schedule III controlled substance.

Sublocade will be available as a pre-filled syringe in two strengths: 100 mg/0.5 mL and 300 mg/1.5 mL, and is intended to be administered monthly as a subcutaneous injection into the abdominal region. The recommended dose is to be initiated at 300 mg monthly for the first two months followed by 100 mg monthly maintenance doses with a minimum of 26 days between doses. Due to the risk of withdrawal in patients on full opioid agonists, Sublocade should only be initiated in patients who are clinically stable on transmucosal buprenorphine delivering the equivalent of 8 to 24 mg of buprenorphine daily following dose adjustments for a minimum of seven days. All other opioid products, including alternative forms of buprenorphine, should be discontinued during treatment with Sublocade.

The most commonly-reported adverse reactions associated with Sublocade were constipation, headache, nausea, vomiting, fatigue, injection site itching and pain, and elevated liver enzymes. Patients should be monitored with liver function tests prior to beginning treatment and throughout therapy, and the self-administration (i.e., at-home use) of other CNS depressants such as benzodiazepines (e.g., Xanax®, Ativan®, Valium®) should be avoided while the patient is undergoing treatment with Sublocade. Patients should also be evaluated for treatment effectiveness and signs of tampering with the injection site or depot – a lump under the skin at the injection site that will decrease in size over several weeks.

Practitioners who wish to prescribe Sublocade for opioid use disorder must obtain a special waiver under the Drug Addiction Treatment Act of 2000 (DATA 2000), and the product should only be prepared and administered by a health care provider (i.e., it cannot be dispensed to the patient). Further, providers wishing to administer Sublocade must adhere to specific risk evaluation and mitigation strategy (REMS) requirements and be certified through a restricted "SUBLOCADE REMS Program." The product is expected to be available on the market in the first quarter of 2018.

Reference: www.accessdata.fda.gov/scripts/cder/drugsatfda/

Ask The Pharmacist

To suggest a topic, send an email to: AskThePharmacist@cvty.us.com

I've heard about pills with digital trackers inside. What are these and how do they work?

The concept of so-called "self-tracking pills" or oral medications with trackers inside has been in development for some time, but just recently we saw one of these drug products approved by the FDA. On November 13, 2017, the FDA approved Abilify MyCite® – the first drug in the United States with a digital ingested tracking system. Abilify MyCite, the drug-device combination product containing aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor, is indicated for the treatment of adults with schizophrenia, bipolar I disorder, or as adjunctive treatment in adults who are taking medications to manage Major Depressive Disorder (MDD).

The technology behind digital pill tracking was first approved by the FDA in 2012. Proteus was the first to develop medicine technology with an ingestible sensor in a system they call "Proteus Discover." The drug-device system works through the interplay of three main components: an ingestible tracker, a wearable sensor patch, and an application on a mobile device or provider portal. Once the medication with digital tracker is swallowed and reaches the stomach, a signal is sent to the wearable patch worn on the patient's torso. The patch then transmits information to the patient's mobile device and stores a record in the "Proteus cloud" where the patient can give permission to share this with health care providers or other caregivers through their portal.

There are several statistics and many research studies surrounding the prevalence of non-adherence to medication and the resultant projected burdens on health care costs and outcomes. Non-adherence has certainly been shown to impact the challenges faced in providing optimal care, thus it is reasonable to hope that tracking the ingestion of medication may be useful for some patients with any variety of chronic diseases where drug therapy compliance can be crucial. However, the technology is still relatively new, and many have raised concerns about patient privacy, security of health information, and bioethics. Some are concerned that such technology is too likened to surveillance or being watched vs. self-tracking and have cited potential legal implications or penalties for missed doses in the case of court-mandated treatment, for example. Medical privacy laws such as HIPAA are intended to protect against the sharing of medical data and health information outside of those entities directly involved in patient care; however, insurers and health care providers would have access to this information and some have wondered if it will be used to enforce compliance in ways that may violate patients' rights.

Further, the factors that lead to non-compliance or non-adherence with a medication regimen are often multi-faceted. Simple forgetfulness is often a common reason; however, patients may also be non-compliant as a result of not understanding their dosing instructions, having difficulty obtaining refills (e.g., inability to get to the pharmacy), payment complications (e.g., insurance coverage delays), or having multiple medications with multiple dosing schedules to manage throughout the day. While digital trackers may represent one approach for improving adherence through ingestion tracking, this does not solve for every piece of the puzzle.

The ethical arguments and usefulness of digital medication tracking will likely remain to be sorted out as the technology becomes more commonplace; nevertheless, the FDA has determined that Abilify MyCite has met the standards for safety and efficacy that go into the approval of all drug products, and thus it is now an available treatment option. However, Abilify MyCite is not without limitations. According to the FDA's recent press release: "It is important to note that Abilify MyCite's prescribing information (labeling) notes that the ability of the product to improve patient compliance with their treatment regimen has not been shown. Abilify MyCite should not be used to track drug ingestion in "real-time" or during an emergency because detection may be delayed or may not occur."

It is also important to keep in mind that while Abilify is seen in the workers' comp book of business, the mental health conditions that the medication treats should be carefully evaluated for relatedness to the work injury or illness from a compensability standpoint. Also, while the technology is interesting and exciting, such drug-devices will not typically be considered first-line treatment for most patients. If the medication contained within the product is indicated and determined to be appropriate for treatment of the work-related condition, consideration of the comparable costs and benefits for Abilify MyCite with digital tracking technology vs. regular Abilify (aripiprazole tablets) or other drug treatments in the same or similar category should always be weighed carefully. Questions related to place in therapy for this product or any medications requested for your injured worker may be directed to our team of clinical pharmacists at askthepharmacist@cvty.com.