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First Script Prescription Benefit News
for Workers' Compensation

November 2018

What will the newly signed opioid legislation do for pharmacy and opioid risk management?

In October 2018, Congress passed H.R.6, the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" (also known as **SUPPORT for Patients and Communities Act**). At over 650 pages, the bill takes a comprehensive approach in addressing the opioid epidemic while looking to improve the prevention and treatment resources available throughout the health care system. It also makes several statutory changes that impact the administration of Medicare Advantage, Part D, and state Medicaid Managed Care Organizations (MCOs). As a high-level overview, the legislation contains provisions that seek to encourage alternative forms of pain management, restrict the importation of illegal substances into the United States, reduce excess opioid prescriptions, promote safe disposal of prescription drugs, and bolster prescription drug monitoring programs.

Over the past few years, growing government support has continued to evolve in the fight against opioid abuse. In the prior Congress, the **Comprehensive Addiction and Recovery Act (CARA)** was the first major piece of legislation focused on addition recovery. Following this in 2016, the **21st Century Cures Act** provided addiction support for behavioral health and opioid abuse treatment, including provisions for research and expanded drug and medical device development. The **Bipartisan Budget Act of 2018** allocated $6 billion in additional funding over two years to combat the opioid epidemic, including enhanced state grants, public prevention programs, and law enforcement activities related to substance abuse and mental health programs.

Some of the key provisions of the "SUPPORT for Patients and Communities Act" that can reasonably be expected to advance efforts related to opioid risk management programs include components related to Medication Assisted Treatment (MAT) and better information sharing related to substance use disorder records.

Expanded access to MAT through broadening the types of providers and practitioners that can dispense MAT as well as increasing the number of patients a qualified practitioner can treat with MAT are included in the new legislation. The Act orders the Secretary of the Department of Health and Human Services (HHS) to evaluate the extent to which Medicare Advantage plans are offering MAT and covering non-opioid alternative treatments not covered under traditional Medicare as part of supplemental benefits. While current legislation is limited to Medicare Advantage plan requirements specifically, the provision sets a precedent that could influence broader coverage for pain management alternatives.

According to data from the Substance Abuse and Mental Health Services Administration's (SAMHSA) most recent National Survey on Drug Use and Health, an estimated 2.1 million people aged 12 and older met the criteria for having an opioid use disorder (OUD) in 2016. Today, under the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM-5), a diagnosis of OUD would likely be seen on a patient's chart if he or she was struggling with addiction but may also cover those who demonstrate risky use of a substance or physical drug-related manifestations such as tolerance or withdrawal. The new legislation removes barriers to sharing patient information about substance use disorder (including OUD), and requires the HHS to develop best practices for prominently displaying SUD treatment information in electronic health records, when requested by the patient.

Drug and medical device development efforts have also shifted in response to these regulations. According to a recent Reuters article, business intelligence gathered from Informa indicates there are 120 non-opioid drug applications under FDA review this year, which represents a 650 percent increase since 2013. This is in alignment with recent legislation such as the Cures Act enabling the FDA to accelerate medial product development and allow for new innovations in pain treatment.

These legislative advances are an encouraging step forward in the effort to combat the opioid epidemic, and we will continue to monitor opportunities to enhance our programs and policies to align with best practice recommendations and to capitalize on expanding treatment information and resources. For additional information related to available programs or for questions related to a specific injured worker's care, please reach out to your Account Manager or our team of clinical pharmacists at askthepharmacist@cvty.com.

Drug of the Month

Dsuvia (sufentanil)

The U.S. Food and Drug Administration (FDA) has approved a new formulation of a potent opioid medication amid controversy on November 2, 2018. Dsuvia (sufentanil) sublingual tablet, made by AcelRx Pharmaceuticals Inc., will now be available as the first under the tongue (sublingual) form of the drug approved for acute severe pain in health care settings with a launch expected in the first quarter of 2019. The debate over the FDA's recent approval decision centers on the nature of this powerful medication as another potential concern in the fight against the opioid epidemic.

Sufentanil is an opioid reported to be as much as 10 times more potent than fentanyl, a drug associated with a rising number of cases involving death from overdose. The active ingredient of Dsuvia, sufentanil, has been around since the 1980s for intravenous (IV) and epidural use as an analgesic and anesthetic in medically supervised settings. According to the manufacturer's website, this novel product was created in collaboration with the Department of Defense as an innovative approach to pain management that "was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with IV administration." The new, single-dose sublingual tablet system comes to market with several restrictions that the FDA has asserted will mitigate the drug's risks while offering unique benefits to patients in need of pain control who may not be able to receive IV medication or are unable to swallow a pill.

Dsuvia is not for home use and may only be administered by a health care provider for no more than 72 hours. It will not be available at retail pharmacies or for outpatient use and instead will be limited to short-term treatment for adult patients within a certified medically supervised health care setting (such as hospitals, surgical centers, and emergency departments). One dose (30 mcg) of Dsuvia may be may be administered by the health care provider as needed with a minimum of one hour between doses for a maximum of 12 tablets (360 mcg) in 24 hours. Each 30 mcg tablet is housed in a disposable, single-use applicator and is placed under the patient's tongue at the floor of the mouth for delivery of the tablet to the sublingual space by pressing a button on the end of the applicator.

The most commonly reported adverse reactions associated with Dsuvia include nausea, vomiting, headache, dizziness, and a drop in blood pressure. The drug product also carries several black box warnings indicative of the opioid drug class including the potential for life-threatening respiratory depression; addiction, abuse, and misuse; and drug-drug interactions such as with inhibitors or inducers of the CYP3A4 liver enzyme or central nervous system depressants such as benzodiazepines.

Due to the risks associated with this particular drug, the product will only be available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), dubbed the "DSUVIA REMS Program," the goal of which is to ensure that Dsuvia is only administered to patients in certified medically supervised health care settings. Certification requires that such health care settings be able to manage opioid overdose, that all applicable staff are trained in the administration of Dsuvia and understand that the drug may not be dispensed for outside or take-home use, and that processes and procedures are in place to verify that no such dispensing occurs. Supplemental requirements are placed on wholesalers who distribute Dsuvia obliging them to establish processes and procedures to limit distribution only to certified medically supervised health care settings.

Dsuvia may present an additional challenge as it will not go through live transaction retail settings where pre-dispensing safety edits and point-of-sale rules can apply. The requirements limiting its use to specific health care settings will instead result in billing channels submitting post-dispense requests. Dsuvia is not considered first-line treatment and, per the manufacturer's labeling, should be reserved for those patients with pain severe enough to require an opioid and for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products) are not tolerated, are not expected to be tolerated, or have failed to provide adequate pain relief. In addition, use of Dsuvia should not exceed 72 hours of treatment. These and other considerations can help guide payment decisions for Dsuvia requests. Questions related to this product or any medications requested for your injured worker may be directed to our team of clinical pharmacists at askthepharmacist@cvty.com.

References:
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/
ir.acelrx.com

National Workers' Compensation and Disability Conference — Discounted Tickets with Coventry Code

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National Workers' Compensation and Disability Conference
December 5 – 7, 2018
Mandalay Bay, Las Vegas

Regulatory Update

Colorado

7 CCR 1101-3, Rule 16, regarding utilization standards includes rules allowing a clinical pharmacist review for medications without Level I or Level II accreditation, and requires opioids classified as Schedule II or Schedule III controlled substances to be provided through a pharmacy. The rules become effective January 1, 2019.

Montana

The Department of Labor and Industry has posted proposed rules for the adoption of New Rules I through VII, the amendment of ARM 24.29.1401A, the amendment and transfer of ARM 24.29.1591, 24.29.1595, and 24.29.1596, and the transfer of ARM 24.29.1593 and 24.29.1599. The rules pertain to workers' compensation utilization and treatment guidelines and a drug formulary. A public hearing is scheduled for November 9, 2018, and written comments are being accepted until November 16, 2018.

New Jersey

AB 4505 changes requirements to include coverage for costs associated with the use of medical marijuana for workers' compensation.

New Mexico

The Workers' Compensation Administration (WCA) has posted its proposed 2019 Health Care Provider Fee Schedule & Billing Instructions. Comments can be submitted until November 16, 2018.
