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First Script Prescription Benefit News
for Workers' Compensation

October 2018

What is REMS?

REMS stands for "Risk Evaluation and Mitigation Strategy" and represents an effort put forth by the U.S. Food and Drug Administration (FDA) back in 2011 to address safety of prescription medication. Legislation passed in 2007, namely the FDA Amendments Act (FDAAA, U.S. Public Law 110-85), opened the door by allowing the FDA to require a REMS from drug or biologic product manufacturers to ensure benefits outweigh risk. A list of currently approved REMS and drug or biologic products can be found online at REMS@FDA.

According to a statement on the FDA's website, "REMS are designed to help reduce the occurrence and/or severity of certain serious risks, by informing and/or supporting the execution of the safe use conditions described in the medication's FDA-approved prescribing information."[1] While all prescription medications contain guidance from the manufacturer such as prescribing support and package inserts addressing FDA-approved dosing and uses as well as safety information, only a few medications require a REMS. Opioid analgesics, a drug class of which we see plenty in workers' comp, is one such medication category for which a REMS is mandatory.

Interestingly, a REMS was only required for extended-release or long-acting (ER/LA) opioid products starting in 2012, with immediate-release opioid products just recently added to the requirement in September 2018. The opioid analgesic REMS includes a REMS document as well as materials for patients and health care providers (see REMS Materials), including counseling points, continuing education resources, guidance for reporting adverse events, and general pain management education. To this end, the FDA also approved the new Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain. While opioid prescribers are strongly encouraged to utilize these resources and complete REMS-compliant Accredited Continuing Education (CE), they are not currently required to do so.

Reference: https://www.fda.gov/Drugs/DrugSafety/REMS/default.htm

Drug of the Month

Emgality™ (galcanezumab-gnlm)

Emgality was approved by the FDA on September 27, 2018, for the preventative treatment of migraine in adults. The once-monthly injectable biologic agent produced by Eli Lilly joins a similar product developed by Amgen, Aimovig™ (erenumab-aooe), which was approved this year in May. Like Aimovig, Emgality works by blocking the activity of calcitonin gene-related peptide (CGRP), one of the molecules involved in migraine attacks.

Emgality is available as 120 mg/mL solution in either a single-dose pre-filled pen or syringe for subcutaneous use. The approved recommended dosing for Emgality includes an initial "loading dose" of 240 mg (administered as two injections of 120 mg each), followed by doses of 120 mg once monthly. The product is intended for self-injection into the abdomen, thigh, upper arm, or buttocks.

Clinical studies showed that Emgality is generally well-tolerated with the most commonly reported adverse effects being injection site reactions. Emgality is not yet addressed in the Official Disability Guidelines, however, it is comparable in pricing to another injectable migraine product supported as a second-line treatment option for chronic migraine sufferers: Botox® (onabotuinumtoxinA). According to Medi-Span, the cost (based on AWP) for a single-dose Emgality product (either pre-filled pen or syringe) is $690 (the same as Aimovig). First-line oral preventative migraine medications including select antidepressants, anticonvulsants, or antihypertensive agents are recommended to be tried before consideration for Emgality.

Furthermore, biologic medications like Emgality fall in the "specialty" drug category, and additional oversight is recommended due to the complex or costly nature of these types of drugs. The appropriateness for use of Emgality in relation to the work injury, as well as prior treatment history, should be determined prior to coverage consideration.

Reference: https://www.accessdata.fda.gov/scripts/cder/daf/

Regulatory Update

Alaska

House Bill 79 includes various changes to the Alaska Workers' Compensation Act. The bill expands the list of materials the Department of Labor and Workforce Development may incorporate into future amendments or regulation effective November 22, 2018. It also establishes a workers' compensation working group to review the workers' compensation system, including procedures, compensable injuries, treatment guidelines, and monitoring of controlled substances.

Colorado

7 CCR 1101-3, Rule 16 has adopted utilization standards including requiring opioids classified as Schedule II or Schedule III controlled substances prescribed for treatment lasting longer than seven days be provided through a pharmacy. The adopted revisions also include amendments to the Colorado Medical Fee Schedule (Rule 18) which apply to services rendered after January 1, 2019.

California

The California Division of Workers' Compensation (DWC) has updated the Medical Treatment Utilization Schedule (MTUS) Drug List effective October 1, 2018.

The DWC has also posted proposed amendments to the Pharmaceutical Fee Schedule. Amendments include establishing rules for repackaged and compounded drugs, increasing dispensing fees for pharmacies, and revising payment methodology for drug ingredients. The first comment period was held on October 8, 2018.

Georgia

Rule GAC 360-38-.01, .02 through .05 adopts new rules related to the Prescription Drug Monitoring Program (PDMP). The rules establish definitions for "Prescriber" and "Controlled medication" and require prescribers to enroll as PDMP users for the prescribing of controlled substances, along with other requirements, which became effective on September 3, 2018.

Massachusetts

The Massachusetts Executive Office of Health and Human Services (EOHHS) has published a Notice of Public Hearing and proposed amendments to 101 CMR 346.00 regarding certain substance-related and addictive disorders (SRAD) programs. The proposed changes include increases in ambulatory and supportive case management rates, and the removal of certain medication rates. A public hearing is scheduled for October 12, 2018.

Mississippi

Rule CMSR 30-026-2640 adopts changes relating to prescribing, administering, and dispensing medications. New requirements include how physicians utilization the Mississippi Prescription Monitoring Program (MPMP) and how opioid therapy is used for acute and chronic pain. The rule also establishes guidelines for point-of-service drug testing, and becomes effective October 28, 2018.

Rhode Island

The state of Rhode Island has published their 2018 Medical Fee Schedule effective October 1, 2018. This legislation includes the newly enacted "Opioid Reduction Act," and amends sections dealing with various programs including pharmacy fee schedule rates, compound medication rates, and medical provider, hospital, and mail-order procedures.

Washington

The Washington State Dept. of Labor & Industries announced changes to their Outpatient Drug Formulary and Selected Preferred Drug list effective October 1, 2018.