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First Script Prescription Benefit News
for Workers' Compensation

March 2019

Is tramadol an opioid? Some prescribers seem to consider it one and others do not.

Tramadol, the active ingredient in several analgesic medications available on the market today, is classified by the Food and Drug Administration (FDA) as an opioid agonist. There are, however, a few characteristics that make this particular opioid unique among its class, and these may contribute to the confusion some providers and consumers have as to whether or not the drug is considered an opioid. For example, while the majority of opioid analgesic medications such as oxycodone, hydrocodone, morphine, and codeine have activity on opioid receptors within the body to exert their effects, tramadol has a dual mechanism of action on both the mu opioid receptor and as a weak inhibitor of norepinephrine and serotonin reuptake. These secondary mechanisms may lead to better activity in certain types of pain conditions, such as neuropathic pain, where norepinephrine and serotonin are thought to play a role.

The Controlled Substances Act (CSA) of 1970 created five schedules for drugs based on medical use, safety, potential for abuse, and dependence liability. Determinations as to which drugs are assigned to each category is largely handled by the U.S. Drug Enforcement Administration (DEA); however, the FDA and Congress can also schedule drugs. Classifications of controlled substances range from the most restricted Schedule I representing drugs with a high potential for abuse and dependence with no accepted medical use and a lack of safety information (e.g., heroin, LSD) to Schedule V including drugs with a low potential for abuse, extremely low potential for physical and psychological dependence, and currently accepted medical use (e.g., Lomotil® [diphenoxylate/atropine], cough medicines containing codeine).

Unlike most opioid agonists, tramadol falls in a less restrictive scheduling category per the CSA. In fact, the drug was unscheduled (no restrictions) at the federal level from 1995 until August 18, 2014, when tramadol and all its forms we placed in Schedule IV controlled substance status in all 50 states. By comparison, most opioids are Schedule II controlled substances. Schedule IV classification, by category definition, indicates tramadol is considered to have less potential for abuse compared to other opioids along with low or limited physical or psychological dependence. Logistically, while Schedule II prescriptions cannot be refilled and cannot be transmitted to a pharmacy in any form other than paper hard copy original written in ink and manually signed by the prescriber or via certified electronic prescription, Schedule IV prescriptions may be written with up to five refills within a six-month period and may be transmitted to a pharmacy via written/hard copy, electronic, fax, or oral (phoned in directly by the prescriber's office) means.

Tramadol is, however, very much still an opioid and carries the same black box warnings as all drugs in this class. Due to tramadol's classification in a lower Scheduling category vs. other opioids, many people are led to believe that tramadol is not habit-forming. When tramadol is used as intended, true physical and/or pharmacological dependence is rare, but psychological dependence and abuse is not uncommon, especially in those with substance abuse history. In other words, tramadol can still be abused and may lead to opioid overdose. Interestingly, additional precautions exist with tramadol overdose treated with the opioid overdose reversal agent, naloxone. Due to tramadol's unique mechanisms of action compared with other opioids, the drug has a potential for seizures among its labeled warnings and precautions. Naloxone may not reverse all effects of opioid overdose from tramadol (e.g., seizures), and the risk of seizures may be increased with naloxone administration, thus requiring additional anti-seizure treatment.

While caution is warranted with the use of any opioid medication, including tramadol, opioid analgesics continue to be considered the next logical step in the management of pain after the use of nonsteroidal anti-inflammatory drugs (NSAIDs)/non-opioid analgesics has either failed to produce sufficient pain control or is believed to be inadequate for a specific pain condition from the start. In these instances, tramadol is well-suited for patients with no history of substance abuse where contraindications to NSAIDs or concerns about NSAID's cardio-renal and gastrointestinal effects are present. As will all opioid medications, tramadol use should be coupled with adequate treatment monitoring and patient follow-up to manage predictable side effects that naturally occur (e.g., constipation, sedation, nausea); tolerance (i.e., need for escalating doses over time with continuous, regular use); and the potential for addiction, misuse and abuse, overdose risk, and withdrawal.

Drug of the Month

Tosymra™ (sumatriptan)

The FDA has approved a new nasal spray product for acute treatment of migraine with or without aura in adults. Tosymra, approved on January 25, 2019, introduces a 10 mg strength of single-dose sumatriptan nasal spray manufactured by Dr. Reddy's Laboratories. The product joins nasal spray formulations of sumatriptan already on the market as 5 mg/spray and 20 mg/spray. Of note, the new product, Tosymra, is available as brand-only while the 5 mg and 20 mg strength products are available as generic sumatriptan.

The intended dosing of Tosymra is a single spray (of 10 mg) in one nostril. The dose may be repeated if needed, with doses separated by at least one hour. The maximum total dose that may be given in a 24-hour period is 30 mg (no more than three doses per day). If another sumatriptan product is used, Tosymra may be given at least one hour following a dose of that product. Other sumatriptan products include nasal (spray or powder), oral (tablet), and injectable formulations with brand names such as Imitrex®, Onzetra Xsail™, and Zembrace™ SymTouch™. The most common adverse effects are tingling; dizziness/vertigo; feeling warm or hot; a burning sensation; a feeling of heaviness, pressure, or tightness; flushing; numbness; application site (nasal) reactions; abnormal taste; and throat irritation.

Pricing information is not yet available for Tosymra. However, as with most brand-only products, the Average Wholesale Price (AWP) can be expected to be higher than the generic nasal spray formulations that are available today. While the dosage strength is different, careful consideration should be given to cost-effective alternatives to brand sumatriptan products where generics are available. The Official Disability Guidelines (ODG) support use of triptans such as sumatriptan as effective and well-tolerated at marketed doses for the pharmaceutical management of migraine where the head is an accepted body part and migraines are believed to be causally related. Questions pertaining 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.

New Study Finds Compounded Topical Pain Creams and Placebo Equivalent in Pain Relief

A newly released clinical trial of compounded topical pain creams vs. a placebo, published in the Annals of Internal Medicine, February 2019[1], reports no significant difference in measured pain relief. In recent years, utilization of opioid pain medications across all U.S. health care delivery channels, including workers' compensation treatment settings,[2] have been declining in response to heightened public awareness of their risks and targeted efforts to reduce their use. In contrast, non-opioid analgesics, especially pre-manufactured and compounded topical medications for pain, have seen dramatic growth and now lead in both use and spend.

Utilization review professionals charged with evaluating the use of these prescriptions rely on available evidence to form recommendations that support "best effectiveness" in the relief of pain, patient safety, and value. Compounded pain creams, in particular, represent a distinct evaluation challenge because they are not FDA reviewed or approved, and adequate studies regarding their effectiveness, safety, and value are not prevalent.

This new study was conducted at Walter Reed Medical Center and looked at 399 patients with pain from an identifiable injury or pain stimulus (nociceptive), pain caused by damage or disease affecting the nervous system (neuropathic), and mixed types of pain. The study concluded "compounded pain creams were not better than placebo creams and their higher costs compared with approved compounds should curtail routine use,"[1] which offers added support for the recommended denial of their use.

Dr. Steven Cohen, lead investigator on the study and pain researcher at Walter Reed National Military Medical Center in Bethesda, Maryland and Johns Hopkins Medicine in Baltimore remarked that, "We know from other studies that some of the agents (lidocaine, non-steroidal anti-inflammatory drugs) may be effective for certain types of acute and chronic pain, so it is surprising that the difference here did not reach statistical significance in any of the pain types. This matters because compounded pain creams are much more expensive than prescribed (lidocaine, diclofenac) or over-the-counter (capsaicin) pain creams, but they didn't provide meaningful benefit compared to placebo cream."[3]

Studies like this one provide important evidence as prescribers seek and choose opioid treatment alternatives that balance the needs of chronic pain patients with the substantial health and social risks of opioid analgesics. Choosing an alternative to opioid pain medications should proceed from the "best available," clearest assessment of effectiveness, safety, and value.

1. Compunded Topical Pain Creams to Treat Localized Chronic Pain: A Randomized Controlled Trial: Accessed at https://annals.org/aim/article-abstract/2724041/compounded-topical-pain-creams-treat-localized-chronic-pain-randomized-controlled on 2-28-2019
2. First Script 2017 Drug Trends-Part 3, Assessing Opioids and Compounds – published August 2018. Accessed at https://coventrywcs.com/content/Menu/Home/News_Insights/Drug_Trends.html on 2-28-2019
3. Study Shows No Value to Topical Compounded Pain Creams. Workers Compensation.com 02-05-19. Accessed at : https://www.workerscompensation.com/news_read.php?id=31571 on 02-28-2019

Governmental Activity by State

Find out more about the governmental updates and potential changes currently being proposed in your state

Idaho

Proposed Senate Bill 1068 would establish definitions for "entity" and "pharmacy benefit manager" and would require all pharmacy benefit managers to register annually with the director of the Idaho Department of Insurance before providing services to any entity.

Illinois

Effective immediately, new House Bill 2587, enacts written agreements between injured workers and prescribers regarding pain management, and includes various other physician reimbursement and utilization review requirements.

Proposed House Bill 2795 would establish a drug formulary by September 1, 2020. If enacted, the Illinois Workers' Compensation Commission and the Workers' Compensation Medical Fee Advisory Board would put forth an evidence-based drug formulary and the rules necessary for its administration.

Proposed House Bill 2792 would establish a new workers' compensation fee schedule, and render the existing medical fee schedules inoperative after August 31, 2020. The bill proposes the Illinois Workers' Compensation Commission establish new medical fee schedules applicable on and after September 1, 2020 in accordance with specified criteria.

Indiana

Proposed Senate Bill 40 was introduced in the Indiana General Assembly, and would require pharmacy benefit managers to register with the state Board of Pharmacy and restrict medications included in the drug list.

Proposed Senate Bill 631, regarding drug classifications and drug schedules, would update the definition of "synthetic drug" which would add numerous drugs to the list. It would also define "fentanyl related substance" and move them from a Schedule ll to a Schedule l controlled substance.

Proposed House Bill 1130, regarding out-of-state drug prescriptions, would establish that patients legally obtaining a drug containing marijuana, hash oil, hashish, or salvia in a state other than Indiana may possess these substances subject to certain requirements and limitations.

Proposed House Bill 1384 would establish a medical marijuana program to permit the cultivation, processing, testing, transportation, and dispensing of medical marijuana, permit the use of medical marijuana by persons with serious medical conditions, and require an in-person visit prior to a physician issuing a certification to use medical marijuana.

Iowa

Rule IAC 645-222.3, 223.5 and 224.2, regarding prescribing opioids and the Prescription Drug Monitoring Program, becomes effective April 3, 2019. These rules require a podiatrist to review a patient's information within the prescription monitoring program database prior to prescribing opioids unless the patient is receiving inpatient hospice care or long-term residential facility care. It also establishes penalties for practitioners (Podiatrist, orthotist, prosthetist or pedorthist) who overprescribe opioids.

Proposed House Bill 140 would introduce changes to the Iowa Prescription Monitoring Program and includes medical marijuana. Changes would expand reporting to include controlled substances of schedules III, IV, and V, in addition to substances considered addictive or fatal when not taken under the direction of a prescribing practitioner. In addition, certain language referring to medical marijuana programs would be removed, making penalties applicable, and including effective date provisions.

Proposed House Bill 86, regarding choice of doctor, would allow employers to choose care unless the employee was predesignated by a physician. If enacted, the bill would also provide additional employer and employee guidelines for care.

Kansas

Proposed House Bill 2303 would establish the Kansas Safe Access Act to provide the safe, legal, humanitarian, and therapeutic use of cannabis for medical conditions. The Act would also provide registration, functions, and provide administration by the department of health and environment.

(Continued on page 4)

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Nevada

Proposed Senate Bill 187, regarding the prescribing of controlled substances, proposes that a physician conduct an evaluation and risk assessment before issuing an initial prescription for a controlled substance. This bill would also contain similar stipulations for dentists and optometrists, as well as guidelines for renewal of controlled substance prescriptions.

Ohio

The Ohio Bureau of Workers' Compensation will hold a public hearing on Friday, March 22, 2019 to consider the following proposed Rules:

- Rule 4123-6-08 regards the 2018 BWC Professional Provider Medical Services Fee Schedule
- Rule 4123-6-37.2 regards the payment of Hospital Outpatient Services
- Rule 4123-6-37.3 regards the payment of Ambulatory Surgical Center Services

Effective March 15, 2019 new rules OAC 4729:8-1-01, 2-01-05, 4-01-02 regarding drug database reporting will be adopted. These rules require controlled substances and distributed dangerous drugs to be transmitted in an electronic format to the State Board of Pharmacy within 24 hours.

Oklahoma

Proposed House Bill 2315, regarding the Patient's Right to Pharmacy Choice Act, would establish a retail pharmacy network access standard and prohibit any entity that manages prescription drug plans from restricting choice of pharmacy.

Rhode Island

Proposed House Bill 5537, regarding opioid prescribing limitations, would restrict a practitioner from issuing an opioid prescription for more than a 7-day supply with additional guidelines for exceptions based on professional medical judgment.

Texas

Proposed Senate Bill 865, regarding the use of cannabis for medical purposes, would authorize the possession, use, cultivation, distribution, transportation, and delivery of medical cannabis, establish licensing requirements for dispensing organizations, and provide physicians with the authority to recommend medical cannabis for qualified medical conditions.

Virginia

New Rule 18VAC 60-21-101 through 106, relating to opioid prescribing limitations applicable to dentists, replaces an emergency rule currently in place. The rule establishes definitions for acute and chronic pain and provides various requirements for initiating treatment of an opioid for acute and chronic pain. The Final Rule becomes effective March 6, 2019.

Wyoming

Proposed Rule WCWR 053-0021-10 includes payment by the division for compound prescription medications per the Wyoming Workers' Compensation formulary, National Drug Code (NDC), and listed fee schedule. It would also add requirements for home health nursing services regarding prescriptions. Comments can be submitted until March 29, 2019.

Claim Management Updates

Arizona

Out-of-State Adjuster Authorization Program: Generally, self-insured employers and insurance carriers that have or are underwriting workers' compensation policies in Arizona are required to process and pay workers' compensation claims in an Arizona claims office. Under R20-5-130(B) carriers and self-insured employers may request authorization from the Industrial Commission of Arizona (ICA) to maintain an out-of-state claims office. A variety of training is available for the program.

Washington

The Self-Insurance program is continuing to prepare for changes related to thirteen Washington Administrative Codes (WACs) that will become effective July 1, 2019. Training, new forms, and templates are underway, in addition to changes in requirements to become and maintain claims administrator certification. For more information visit this site.

FDA Approves First Generic for Advair Diskus® for Treatment of Asthma and COPD

On Jan. 30, 2019, the FDA announced their approval of the first generic for Advair Diskus (fluticasone proprionate and salmeterol inhalation powder). Advair Diskus, marketed by GSK (GlaxoSmithKline) is a respiratory medication, with approved labeling for the twice-daily treatment of asthma and Chronic Obstructive Pulmonary Disease (COPD). Metered Dose inhalers, like Advair Diskus are known as "combination products" because they consist of medication and delivery device components. The development of generics for combination products has historically been more challenging than for simpler, solid oral dosage forms. The FDA has committed to speed the movement of products like these to market by providing specific guidance and prioritizing their review.

"Today's approval of the first generic drug product for one of the most commonly prescribed asthma and COPD inhalers in the U.S. is part of our longstanding commitment to advance access to lower cost, high quality generic alternatives," said Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research. Today's approval will bring more competition to the market which will ultimately benefit the patients who rely on this drug."[1]

Mylan Laboratories is expected to market the new generic product called Wixela Inhub® in February 2019 at introduction prices approximately 70% below those of Advair Diskus. Branded respiratory medications like Advair Diskus and others are infrequently prescribed in a workers' compensation setting but carry a high cost per treatment. They are included on the First Script formulary and injury-specific drug lists.

1. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630151.htm?utm_campaign=FDA/