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First Script Prescription Benefit News
for Workers' Compensation

April 2019

Ask The Pharmacist

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

What is levorphanol, and why is it so expensive?

Levorphanol is a long-acting, Schedule II opioid analgesic that has been around since the 1950s. The medication originally was marketed under the brand name Levo-Dromoran® as both an injectable and oral tablet; however, those products have long since been discontinued. While generic levorphanol is available today, it carries a relatively high price tag and has limited availability. Up until September 2015, levorphanol generic was available under the manufacturer Hikma at an average wholesale price (AWP) of $2.14 per tablet. Following the Hikma product's exit from the market, a new manufacturer, Sentynl Therapeutics, picked up the drug that same year but raised the Average Wholesale Price (AWP) by over 2,000%. Currently, levorphanol is available from two manufacturers, Sentynl and Virtus Pharmaceuticals (see Table 1).

Table 1: Levorphanol Product Information

Product Name	NDC	Package Size	Manufacturer	AWP/tablet*
levorphanol 2mg tablet	42358-0102-10	100-count	Sentynl Therapeutics	$53.40
levorphanol 3mg tablet	42358-0103-10	100-count	Sentynl Therapeutics	$80.10
levorphanol 2mg tablet	69543-0412-10	100-count	Virtus Pharmaceuticals	$53.40

**Based on MediSpan AWP as of 4/4/2019*

Like other drugs in its class, levorphanol exerts its analgesic effects through activity at the mu-opioid receptor. However, unlike most opioids, levorphanol also carries additional mechanisms of action and is known to increase norepinephrine and block N-methyl-D-aspartase (NMDA) receptors, both of which are associated with neuropathic pain relief, similar to the opioid medications tramadol, methadone, and Nucynta® (tapentadol). Levorphanol has a long half-life (up to 16 hours) and thus is considered a long-acting opioid. The FDA-approved labeling recommends a dosing schedule of every 6 to 8 hours.

The Official Disability Guidelines (ODG) list levorphanol as and "N" drug and indicate use is not generally recommended. Levorphanol is not considered a first-line option among opioids in part due to the drug's long half-life which can lead to possible drug accumulation. These factors, along with its limited availability and comparatively high price tag, should be weighed against other lower cost long-acting opioid alternatives that may provide similar efficacy including morphine ER (brand name MS Contin®), tramadol ER (brand name Ultram® ER), OxyContin® (oxycodone ER), methadone, and Nucynta® ER (tapentadol ER).

National Prescription Drug Take Back Day is April 27

National Prescription Drug Take Back Day will be Saturday, April 27, 2019. National Take-Back Day is a safe, convenient, and responsible way to dispose of unused or expired prescription drugs.

The last Take Back Day brought in more than 900,000 pounds of unused or expired prescription medications, bringing the total amount of prescription drugs collected by the DEA since the fall of 2010 to 10,878,950 pounds.

Check the DEA's official Take Back Day website for more information and to find year-round collection sites near you.

Quiz: Test your knowledge on proper drug disposal.

Drug of the Month

Motegrity™ (prucalopride)

Motegrity (prucalopride), a selective serotonin-4 receptor agonist approved in December 2018 by the FDA for the treatment of chronic idiopathic constipation (CIC) in adults, became available in February. Chronic idiopathic constipation essentially refers to ongoing symptoms of constipation with no known or identifiable cause. Other FDA-approved prescription drugs for CIC include Linzess® (linaclotide), Trulance® (plecanatide), and Amitiza® (lubiprostone). Motegrity works differently from these medications by stimulating colonic peristalsis (i.e., a series of involuntary muscle contractions in the digestive tract) which leads to increased bowel motility.

Motegrity is available as a 1 mg or 2 mg tablet and is intended to be taken by mouth once daily with or without food. The recommended daily dose is 2 mg, with the 1 mg once-daily dose reserved for those patients with severe renal (kidney) impairment. The most common side effects reported with Motegrity are headache, abdominal pain, nausea, vomiting, diarrhea, abdominal distension, dizziness, flatulence, and fatigue. Because Motegrity affects serotonin levels, the label carries an added precaution similar to that included with other serotonergic drugs that addresses suicidal ideation, especially in patients with existing depression. The label warning recommends that patients be monitored for worsening depression and the emergence of suicidal thoughts and behavior. Patients should be instructed to discontinue Motegrity immediately and contact their health care provider if these symptoms occur.

The Official Disability Guidelines (ODG) do not specifically address chronic idiopathic constipation, likely because by definition, the cause is unknown. However, ODG does provide guidance for medication-assisted management of constipation caused by opioids, or opioid-induced constipation (OIC). That being said, ODG does not consider specifically-targeted OIC medications to be first-line treatment. Instead, ODG recommends changes to diet (such as increasing fiber and fluid intake), increasing mobility, establishing a toileting regimen, reducing opioid use if possible, and starting with trials of over-the-counter (OTC) laxatives such as polyethylene glycol, lactulose, senna, bisacodyl, or docusate prior to considering FDA-approved OIC prescription medications (i.e., Amitiza®, Relistor®, Movantik®, and Symproic®). Questions related to Motegrity or any medications requested for your injured worker may be directed to our team of clinical pharmacists at askthepharmacist@cvty.com.

OxyContin® Maker Purdue Pharma Exploring Bankruptcy

Purdue Pharma LP, the makers of OxyContin, is exploring bankruptcy in the midst of addressing almost 2,000 lawsuits alleging the drug maker contributed to the opioid crisis sweeping the United States. Opioids, including prescription painkillers, heroin, and fentanyl, were involved in 47,600 overdose deaths in 2017, six times the amount in 1999, according to data from the U.S. Centers for Disease Control and Prevention.

Purdue and its owners, the Sackler family, are facing mounting litigation accusing the company of misleading doctors and patients about the risks associated with prolonged use of its prescription opioids. The company is denying the allegations, saying that the labels for its opioids, approved by the U.S. Food and Drug Administration, carried warning cautioning of the risk of abuse and misuse associated with the pain treatments.

A filing is not certain at this time; however, filing for Chapter 11 protection would halt lawsuits and allow Purdue to negotiate legal claims with plaintiffs under U.S. bankruptcy judge supervision. It was reported in August by Reuters that Purdue hired law firm Davis Polk & Wardwell LLP for restructuring advice, fueling concerns that the company might seek bankruptcy protection before the trial.

Purdue stated its longstanding policy to decline comment on financial or legal strategy but added, “We are, however, committed to ensuring that our business remains strong and sustainable. We have ample liquidity and remain committed to meeting our obligations to the patients who benefit from our medicines, our suppliers and other business partners.”

Reuters also reported in May that Purdue CEO Craig Landau cut hundreds of jobs, stopped marketing opioids to physicians, and moved the company toward developing medications for sleep disorders and cancer. In addition, Mortimer D.A. Sackler is no longer seated on Purdue’s board.

On March 26, it was reported that the pharmaceutical company agreed to a $270M opioid settlement with Oklahoma to fund addiction research and treatment in the state and pay legal fees. It is thought this deal is the beginning of many more throughout the nation.

Governmental Activity by State

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

Florida

Proposed House Bill 1399 would require the adoption of statewide workers' compensation schedules of maximum reimbursement allowances, extend timeframes employees receive certain workers' compensation benefits, provide conditions under which employees may receive permanent impairment benefits, and require a good faith effort to resolve dispute. The proposed changes also include provider authorizations for prescribed medical supplies with a reimbursable value of less than $500, and requirements related to physician dispensing of prescription medications.

Georgia

Proposed Senate Bill 232 would establish the Controlled Substances Therapeutic Relief Act, which would create a process for patients to apply to the Department of Public Health for an identification card for a debilitating medical condition. The bill would define a "debilitating medical condition" to include cancer, hepatitis C, PTSD, and other conditions, and would include rules governing medical marijuana dispensaries.

Proposed Rule GAC 430-10-.03, regarding amendments to pharmaceutical agents used by doctors of optometry (O.D.) under the Board of Optometry, would add to the list of therapeutic agents that may be used by an O.D. for treatment purposes. The Georgia Board of Optometry will hold a public hearing on the matter on April 17, 2019.

Indiana

Introduced Senate Bill 146, regarding controlled substance prescriptions, would require a controlled substance prescription be issued electronically, and for prescribers to obtain three hours of opioid medication prescribing continuing education every two years in order to continue prescribing opioids, otherwise face a Class B infraction for failure to comply.

Introduced Senate Bill 310, regarding outpatient-based opioid treatment providers, proposes that a health care provider prescribing in an office-based opioid treatment setting must meet with the patient during treatment, as well as perform an initial assessment, history, physical, provide education on treatment risks, and be able to refer for substance abuse counseling and support. The provider will also need to establish patient consent to treat in the office and maintain records and treatment plans including progress of treatment goals, drug monitoring testing, and results from random pill count testing.

Kansas

Adopted changes to KAR 51-9-7, regarding fees for medical and hospital services and the adoption of the 2019 fee schedule, enacts fees for medical, surgical, hospital, dental, and nursing services, medical equipment, medical supplies, prescriptions, medical records, and medical testimony rendered pursuant to the Kansas workers compensation act. The rules and subsequent fee schedule were adopted and have an effective date of March 3, 2019.

Massachusetts

Proposed House Bill 1713 would require practitioners to assess and inform patients prior to prescribing certain opioid medications. The act would require a practitioner, before issuing an extended-release long-acting opioid for the first time, to:

- Evaluate the patient's current condition, risk factors, history of mental health or substance use disorder, and whether the patient has taken/is currently taking medications to treat these disorders;
- Discuss with the patient the risks of addiction and overdose associated with the medication and the risk of concurrent use of alcohol or other central nervous system depressants; and
- Obtain the patient's written informed consent indicating that the practitioner consulted with and informed the patient as required.

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Montana

Enacted Senate Bill 83 establishes allowable and prohibited practices for pharmacy benefit managers (PBMs) by establishing fees to pharmacies by a PBM, the rights of pharmacies that a PBM cannot prohibit the pharmacy from engaging, and adds a provision stating this also applies to workers' compensation policies. The bill becomes effective January 1, 2020.

Effective October 1, 2019 enacted House Bill 86, regarding opioid prescribing limitations and the Montana Prescription Drug Registry (MPDR), revises the prescription drug law as follows:

- Provides for the positive identification of potential recipients of controlled substances
- Restricts prescriptions for opioid-naïve patients to a 7-day supply
- Requires certain professionals who prescribe and dispense prescriptions to review the prescription drug registry

Nebraska

Proposed Legislative Bill 487 would adopt an evidence-based drug formulary which would include drugs listed in Schedules II, III, IV, and V that are prescribed or dispensed for outpatient use. It would also establish that recommended formulary prescription drugs be prescribed and dispensed without prior authorization and allow all parties to request an independent medical examiner review if payment or preauthorization is denied for a prescription drug not included in the formulary.

Proposed Legislative Bill 110 would adopt the Medical Cannabis Act to create a list of qualifying medical conditions for the use of medical cannabis, and would establish a patient registry that requires a participating health care practitioner to provide certification that a patient suffers from a qualifying medical diagnosis.

Proposed Legislative Bill 316 would enact the Pharmacy Benefit Fairness and Transparency Act, which would include requirements that a pharmacy benefit manager not exclude a Nebraska pharmacy from its specialty pharmacy network, and must also obtain a certificate of authority as a third-party administrator (TPA) under the TPA Act.

Nevada

Proposed Assembly Bill 239, governing the prescribing for controlled substances, would authorize a practitioner to prescribe an initial prescription of a controlled substance for the treatment of acute pain for a longer amount of time if the practitioner determined it was medically necessary. It would also limit evaluation and risk assessment requirements prior to issuing an initial controlled substance prescription and would require informed written consent for the use of a controlled substance.

Ohio

Introduced changes to Rule OAC 4123-6-21.3, regarding the outpatient medication formulary for state fund claims, proposes to revise the rule by developing a new formulary. In addition, in cases of medical necessity and evidence of need the BWC may reimburse for new drugs and new indications approved by the FDA for a period not to exceed 180 days. The Ohio Bureau of Workers' Compensation plans to hold a public hearing on Tuesday, April 23, 2019.

Oklahoma

Proposed House Bill 2632 would create the Patient's Right to Pharmacy Choice Act, and includes changes that would restrict a PBM as follows:

- A PBM could not require patients to use pharmacies that are directly or indirectly owned by the PBM.
- A PBM could not reimburse an independent pharmacy an amount less than the amount the PBM reimburses a pharmacy owned by a PBM for providing the same covered services.
- A PBM could not deny a pharmacy the opportunity to participate in any pharmacy network at preferred participation status if the pharmacy is willing to accept the established terms and conditions set forth for other pharmacies.
- A PBM could not impose on a covered individual a monetary advantage or penalty, including a higher cost-sharing or additional fee which would affect a covered individual's choices of network pharmacy.

Oregon

Senate Bill 572 proposes new requirements on PBMs registered in the state, and would include dispensing requirements for specialty drugs, drug lists be provided in a searchable electronic format, and increase the appeal period for network pharmacies.

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Proposed House Bill 2840, relating to PBMs, would establish that a PBM not prohibit a pharmacist or pharmacy from providing a patient with information regarding their cost share for a prescription drug or the clinical efficacy of a lower cost alternative drug.

Utah

Adopted House Bill 191 amends the Utah Controlled Substances Act regarding opioid education, and requires a prescriber to discuss the risks of using an opiate with a patient or the patient's guardian before issuing an initial opiate prescription. The bill becomes effective May 5, 2019.

Virginia

Enacted House Bill 2557 classifies gabapentin as a Schedule V controlled substance. Current law lists gabapentin as a drug of concern. The bill also removes the list of drugs of concern from the Code of Virginia and provides that any wholesale drug distributor licensed and regulated by the Board of Pharmacy and registered with and regulated by the U.S. Drug Enforcement Administration shall have until July 1, 2020 to comply with storage requirements for Schedule V controlled substances containing gabapentin.

West Virginia

Adopted House Bill 2768 makes changes to opioid prescribing limitations and establishes new definitions for "prescribe," "referral," "Schedule II opioid drug," and "surgical procedure," and clarifies that opioids are Schedule II opioid drugs. It also specifies that a pharmacist is not responsible for enforcing opioid prescribing limitations and may not be disciplined for filling a prescription in violation of the limitations. The bill was adopted on March 9, 2019 and has an effective date of June 7, 2019.

Wyoming

Senate Bill 46, relating to controlled substances, establishes a limit for opioid prescriptions and provides authority to establish exemptions effective July 7, 2019.

Clinical Updates

Authorized Generic for Flector® Patch launched in U.S.

On March 1, 2019, Teva Pharmaceuticals announced the introduction of an authorized generic for Flector Patch 1.3% (diclofenac epolamine), a topical nonsteroidal anti-inflammatory drug (NSAID), indicated for the treatment of acute pain. Topical analgesic medications are frequently prescribed in workers' compensation treatment settings and are included in the top 10 drug categories for spend at First Script.

New Montana Drug Formulary Rule Adoption

Effective January 1, 2019, the Montana Department of Labor and Industry has adopted new workers' compensation formulary rules which incorporate the October 2018 edition of the Official Disability Guidelines (ODG) "N" & "Y" drug list. The new rules apply to dates of injury on or after April 1, 2019. The First Script Smart Prior Authorization process has been configured to address these state formulary rules and will provide authorization guidance for identified drugs falling under the new requirements.

FDA Approves Spravato® for Treatment-Resistant Depression

On March 5, 2019, the U.S. Food and Drug Administration (FDA) approved Spravato® (esketamine) nasal spray for adult patients with treatment-resistant major depression (TRD), which refers to patients who have tried and failed to respond adequately to at least two other drugs. Topical analgesic medications are frequently prescribed in workers' compensation treatment settings and are included in the top 10 drug categories for spend at First Script.