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First Script Prescription Benefit News
for Workers' Compensation

February 2019

Drug of the Month

Yupelri™ (revefenacin)

Yupelri (revefenacin) was approved by the FDA on November 9, 2018, for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Yupelri is a type of anticholinergic medication, also known as a long-acting antimuscarinic antagonist (LAMA), that helps the muscles around the airways in the lungs to stay relaxed thereby preventing symptoms associated with COPD such as wheezing, cough, chest tightness, and shortness of breath. Specifically, Yupelri's active ingredient binds to muscarinic receptors in the airways and blocks their action on smooth muscle which leads to bronchodilation or less restricted airflow.

Yupelri is available as an inhalation solution in a dose of 175 mcg within a 3 mL unit-dose vial for nebulization. The approved recommended dosing of Yupelri is for one 175 mcg vial (3 mL) to be inhaled once daily via nebulizer. The most common adverse reactions reported with Yupelri include cough, swollen nasal passages, upper respiratory tract infection, headache, and back pain. Yupelri may exacerbate conditions such as glaucoma, prostate or bladder problems, or difficulty passing urine. It is also not recommended for use in individuals with any degree of liver impairment.

COPD is a pulmonary (i.e., lung-related) disorder that can present as a work-related condition depending on the underlying cause (e.g., occupational exposure to dust or chemicals). The definition of COPD heralded by the Official Disability Guidelines (ODG) is based on the National Heart, Lung, and Blood Institute and the World Health Organization's guidelines as reported through the Global Initiative for Chronic Obstructive Lung Disease (GOLD). The 2019 GOLD report defines COPD as a "preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases."

Drug therapy for management of COPD is aimed at reducing symptoms, decreasing the frequency and severity of exacerbations, and improving exercise tolerance and overall health status. While LAMAs are supported by both ODG and GOLD as evidence-based drug therapy options for COPD, a first-line choice within the anticholinergic drug class is not clarified. Another once daily inhaled LAMA, tiotropium (Spiriva®), is listed and recommended for management of work-related COPD; however, Yupelri is not yet specifically addressed. A cost comparison based on Medispan AWP between Spiriva HandiHaler and Yupelri is summarized in Table 1. Both are single-source brand products with no generics currently available. An additional point for consideration is that Yupelri would also have the added cost of a nebulizer device which would need to be obtained in order to administer the medication.

Table 1: Cost Comparison

Brand	Active Ingredient	Strength/Dosage Form	Cost/Day*
Spiriva HandiHaler	tiotropium	18 mcg capsule for inhalation	$17.18
Yupelri	revefenacin	175 mcg/3 mL vial for inhalation	$41.20

**Based on AWP for once daily FDA-approved dosing schedule*

A careful evaluation of work-relatedness is recommended prior to considering COPD coverage. The two primary causative factors of COPD are individual susceptibility (i.e., genetic abnormality) and exposure to inhaled agents. World-wide, one of the most common causes of COPD is cigarette smoking. Other agents include fumes, chemical agents, and indoor/outdoor air pollution. Once an accurate diagnosis is established, management of the disease requires a partnership between the patient and the physician in order to achieve optimal treatment outcomes. Lifestyle modifications are often involved, such as avoiding or minimizing exposure to the causative agent. Drug therapy with a LAMA is recommended; however, the choice of treatment should be individualized preferably with the most cost-effective options within a drug class tried first wherever possible.

References:
www.accessdata.fda.gov/scripts/cder/daf/
www.odg-twc.com
www.goldcopd.org

Ask The Pharmacist

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

Is naloxone going to be made available for purchase without a prescription?

In October of last year, Food and Drug Administration (FDA) Commissioner Scott Gottlieb, M.D., released a statement describing efforts the agency is taking to make naloxone more readily available for the reduction of opioid overdose deaths. Some of the major points of interest under discussion by the FDA advisory committee included consideration of co-prescribing naloxone for all or some prescription opioid patients, draft guidance to the industry supporting development of generic naloxone hydrochloride nasal spray, development of over-the-counter (OTC) naloxone products, and a review of the work that organizations and communities have done nationwide to facilitate programs supporting naloxone access. Just last month, Gottlieb made an additional announcement specifically addressing a new pathway for OTC naloxone product development.

Today, naloxone is available in an injectable form for use in a health care setting and as two prescription products for use by laypersons, namely, auto-injector (Evzio®) and intranasal (Narcan® Nasal Spray) naloxone. The FDA believes an OTC version may remove barriers for obtaining naloxone such as for those who are not under the care of a physician or who may be hesitant to admit to issues with opioid abuse. Additionally, the FDA cites another barrier to the development of OTC naloxone products: the requirement for a consumer-friendly Drug Facts Label (DFL). The DFL is to be submitted with any new drug application or supplement for an OTC drug product along with required studies demonstrating consumer understanding. As a result, the FDA has taken some unprecedented steps in an effort to encourage drug companies to enter the OTC market with an over-arching goal of increasing access to naloxone.

For the first time in its history, the FDA has created and tested a model DFL containing easy-to-understand pictograms demonstrating how to use naloxone. The required label comprehension consumer testing for the model DFL was conducted through an independent research contractor. The test involved over 700 participants representing potential OTC naloxone users (e.g., adults [age 18 or older] who use prescription or illicit opioids; adult family and friends of people using opioids; and the general public [adults and adolescents age 15 or older]). The study results have already been reviewed by an independent FDA team not directly involved in conducting the study and were deemed satisfactory.

The model DFL was created in two versions, one for use with naloxone nasal spray and one for naloxone auto-injector, with placeholders in each for product-specific information and instructions that would need to be added and tested where necessary by the product sponsor. This pathway is intended to make it easier for drug companies to pursue OTC naloxone development, and the FDA is urging manufacturers to take note and submit applications as soon as possible. Coventry and First Script will continue to monitor for progress and the introduction of any such OTC naloxone products.

Safe delivery of mail-order medications no matter what the season

Whether the thermometer is falling or rising, temperature control of mail-order medications en route to injured workers is an important consideration. While most drugs are temperature stable across a broad range and do not degrade during shipping, extreme temperature and humidity must still be accounted for when mail order is preferred.

Our mail-order service incorporates state-of-the-art shipping control technologies and predictive algorithms to protect medications from extreme cold and heat. It begins with predicting daily temperature patterns based on zip codes to determine the best timing and packaging for temperature-sensitive medications. If a medication is identified as time or temperature sensitive, it is shipped from a facility closest to the mailing address on a weekday to avoid additional storage days in a shipping facility.

When temperature-sensitive medications are shipped, we determine the best shipment method, including coolers and ice packs when necessary to ensure proper care, timely delivery, and protections designed to accommodate the unique stability of each shipped medication. Depending on specific package requirements, delivery time typically ranges from just one to two days, and shipments requiring arrival in a refrigerated state only ship under strictly controlled criteria.

The First Script mail-order program strives to ensure that every prescribed medication dispensed is appropriately and carefully packaged and delivered for the safety of each injured worker.

Regulatory Update

California

The California Division of Workers' Compensation has updated the Medical Treatment Utilization Schedule (MTUS) Drug List. Changes are effective February 15, 2019 and relate to drugs addressed in the Traumatic Brain Injury Guideline.

Kentucky

Rule 803 KAR 25:270 regarding a workers' compensation drug formulary adopts the current edition, and any future updates, of the ODG formulary. These rules were adopted on an emergency basis due to KY HB 2 which required the commissioner of the Kentucky Department of Workers' Claims to adopt a drug formulary before December 31, 2018. Changes to the rule outline claim effective dates, utilization review, and preauthorization requirements. A public hearing is scheduled for February 22, 2019 and written comments will be accepted through February 28, 2019.

Minnesota

Bill MN SF 751 proposes to establish an opiate epidemic response, including a limit to the quantity of opiates and narcotics that can be prescribed for acute pain. When used for the treatment of acute pain, prescriptions for opiates or narcotic pain relievers listed in Schedules II through IV shall not exceed a seven-day supply. If, in the professional clinical judgement of a practitioner, more than the limit is required to treat a patient's acute pain, the practitioner may issue a prescription for the quantity needed to treat the patient's acute pain.

Montana

The Montana Department of Labor and Industry has adopted new rules related to the workers' compensation prescription drug formulary. Montana ARM 24.29.1601, .1607, .1616, .1624, .1631, .1645, and .1648 adopted new rules, with additional amendments to ARM 24.29.1401A, 24.29.1591, 24.29.1595, and 24.29.1596. Changes include the adoption of the October 2018 edition of the ODG Drug Formulary and rules outlining prior authorization requirements. It also consolidates medical utilization and treatment guideline rules into a new subchapter in order to adopt drug formulary rules as part of overall workers' compensation medical utilization and treatment guidelines. The rules become effective January 1, 2019 but does not apply to new claims until April 1, 2019.

New York

Pursuant to Subject No. 046-1133, the New York Workers' Compensation Board has announced a second revision to its proposed drug formulary, dated January 23, 2019. Changes to the regulation include restructuring the formulary phases and preauthorization requirements. Comments will be accepted until February 22, 2019.

Ohio

Rule 4123-6-21.3 amendments the Ohio outpatient medication formulary. New rules address outpatient medication formulary requirements for state fund claims. Self-insured employers may also utilize the formulary but are not required to do so. Changes include a complete list of medications approved for reimbursement by the Bureau of Workers' Compensation (BWC) and prescribing and dispensing restrictions. The rule was published on December 13, 2018 and became effective January 1, 2019.

Utah

R156-37f regarding the Controlled Substance Database Act updates' requirements for access, data collection, and reporting on the dispensing of Schedule II-V drugs. Changes include new registration requirements for access to opioid prescription information, and how employees of licensed practitioners can access the data. This rule was published on January 15, 2019 but became effective December 27, 2018.

Virginia

Rules 16 VAC 30-16-10 through -80 establishes electronic medical billing standards for health care providers and insurers for products and services provided to injured workers. It requires health care providers to accept electronic medical bills in accordance with the adopted standards, and to be able to exchange electronic data by July 1, 2019. The rules become effective February 6, 2019 and apply to all medical products and services provided after July 1, 2019.

Pharmaceutical prices increased in January

According to an analysis by Rx Savings Solutions, in January, 60 pharmaceutical companies announced price increases for approximately 300 prescription medicines, and more manufacturers are anticipated to follow suit. Announced medication cost increases in workers' compensation include leading sole-source brand medications such as Lyrica® (5%), OxyContin® (9.5%) and Nucynta® (9.9%).