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First Script Prescription Benefit News
for Workers' Compensation

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Ask The Pharmacist

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

What is the difference between MED and MME?

The acronym MED stands for "morphine equivalent dose" and MME is short for "morphine milligram equivalents." Essentially, these terms are interchangeable and mean basically the same thing. Both provide us with a consistent measure representing the cumulative amount of opioids that are being taken in a time period. Usually, this is determined on a per day basis. In the case of MED thresholds or measures against risk, the morphine equivalent daily dose is represented and may use the abbreviations MEDD or MME/day to emphasize the *daily* measurement, but in general, MED refers to the 24-hour morphine equivalent dose unless otherwise indicated.

Why do we need MED?

The idea behind MED is that various opioids have different potencies; i.e., different amounts or measures of the various drugs might be required to achieve the same analgesic activity or effect. Put another way, more potent does not mean more effective, it simply refers to the equivalent dose needed to attain equivalent pain control. Calculating a person's total opioid dose is often done by first converting all opioids to a standard unit of measure (i.e., MED): the amount they would be if they were morphine.

It may be helpful to use currency as an analogy to help explain this concept of MED conversion. Think of all of the different currency measures in the world: Yen, Rubles, Pesos, Pounds, Francs, etc. If you live in America and are familiar with the U.S. dollar, it might be difficult for you to conceptualize how much cumulative value you might be discussing if you have several amounts in many different currencies. Comparisons are difficult. However, if you were to apply the exchange rate to convert each of those currencies to what their values would be in U.S. dollar equivalents, suddenly it is easier to understand the full amount. In that example, the currency exchange rate is like the opioid morphine equivalent conversion factor. The general concept of converting many different measures to one uniform standard of measure is basically the same.

How is MED used?

MED is perhaps most useful as a risk indicator and a signal that an injured worker may benefit from education, outreach, or additional monitoring. High MED warrants extra precaution as increasing levels have been shown to be more associated with an increased risk of overdose and death. Studies have shown, in general, that risk can be present starting as low as 20 MED, with MED greater than or equal to 50 showing up to a four-time increased risk of death from overdose compared to those at lower MED levels, and MED greater than or equal to 100 being associated with up to a nine-time increased risk of death from overdose. Overall, MED values can be used to guide meaningful discussions with the medical treatment providers and/or the injured workers receiving these medications aimed at reducing risk through dose reductions, therapy changes, increased frequency of monitoring, referrals to additional resources or providers, and considerations for discontinuing opioids, decreasing doses, and/or offering the opioid overdose reversal agent naloxone.

If you have any questions related to MED or how to calculate, interpret, or apply it, feel free to contact our team of clinical pharmacists at askthepharmacist@cvty.com.

Drug of the Month

Lyrica® CR (pregabalin)

A new, extended-release version of the anticonvulsant medication Lyrica® was approved by the FDA last month. Lyrica® CR (pregabalin) is indicated for the management of pain from damaged nerves related to diabetes (i.e., diabetic peripheral neuropathy) and following the viral condition shingles (i.e., postherpetic neuralgia). The medication is available as 82.5 mg, 165 mg, or 330 mg extended-release tablets, and is intended to be dosed once daily following the evening meal. Oral tablets should be swallowed whole (do not split, crush, or chew). The most common side effects reported with Lyrica CR are dizziness, drowsiness, headache, fatigue, swelling of the limbs (i.e., legs, feet, hands), nausea, blurred vision, dry mouth, and weight gain.

Lyrica (the original version) was first FDA-approved in 2004, and is one of the more commonly used drugs in workers' comp. It has historically been among the top 10 medications by utilization and spend for First Script. Lyrica is typically prescribed "off-label" for chronic and/or general neuropathic (i.e., nerve-related) pain conditions found in injured workers. Off-label essentially means that the drug was originally FDA-approved for various types of seizure disorders as well as a few specific types of nerve pain (e.g., diabetic neuropathy, postherpetic neuralgia), but has been found to be useful in other similar types of pain conditions as well. It is important to recognize that while many off-label uses are well accepted, they have not been evaluated by the FDA. Consideration should always be given to the risks and benefits of any off-label treatment with a drug, and alternative anticonvulsants (e.g., gabapentin) are recommended to be tried prior to using Lyrica CR for pain.

FDA spurs new interest in expediting generic drug opportunities to market

In an effort to save patients money by offering a wider variety of more affordable generic drugs, the U.S. Food and Drug Administration (FDA) has stepped back to review the patent rules used, and misused in some cases, that delay generic drug approvals beyond the period the law intended. The FDA website states, "In the United States, 9 out of 10 prescriptions filled are for generic drugs. Increasing the availability of generic drugs helps to create competition in the marketplace, which then helps to make treatment more affordable and increases access to healthcare for more patients."[1]

How the FDA will make this a reality

The FDA has a two-step approach to getting more generics to the market. It's the start of what the FDA is referring to as the "Drug Competition Action Plan."

First, they publically released a list of off-patent, off-exclusivity branded drugs without approved generics.[2] This alerts pharmaceutical companies of the opportunity to submit their own generic version of these medications for distribution. In the industry this is known as an Abbreviated New Drug Application (ANDA). The FDA has also promised to update the list to ensure continued transparency.

Second, for the first time ever, the FDA enacted a new policy to expedite the review of generic drug applications where competition is limited.[3] They will, "expedite the review of generic drug applications until there are three approved generics for a given drug product."[4] The idea is that once there are multiple generics competing within the market, there will be competitive pricing as well. The FDA also had a public meeting in July that welcomed input on their rules for drug approvals.

Why this matters now more than ever

It seems as though the drug companies have unlimited resources when it comes to avoiding generic production. For example, Allergan has found a loophole around patent laws by selling their patent for Restasis®, a popular eye medication, to the Saint Regis Mohawk Tribe in upstate New York to retain their patent.[3] In doing so, the Mohawk tribe can now claim sovereign immunity on the patent and dismiss the patent challenge through the United States Patent and Trademark Office. The tribe collected $13.75 million up front and will lease the patent to Allergan annually for $15 million for as long as the patent is valid.

One of our resident Account Pharmacists, Craig Prince, weighed in on this saying, "This is a transparent workaround for standing patent laws. Allergan and Restasis is just the first of many others that could step through the same loophole. It would appear a call for legislation is needed to prevent the obvious anti-competitive implications."

Cameron Hannum, another Account Pharmacist at First Script adds, "If not appropriately addressed legislatively, the common law precedence would be established for other brand manufactures to implement similar work-arounds with tribal nations."

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Given the arrangement Allergan has with the Mohawk tribe for the brand-name drug, a cheaper generic can't be made available to the market. Allergan argues that Restasis is their most profitable medication, and by selling the patent to the Mohawk tribe, they are allotted more time to put together a compelling argument for retaining the patent.

Dr. Scott Gottlieb, the Director of the FDA, has stated they intend on pursing legislative action to close loopholes like this.[5] He wrote in his blog, "Our plan has a number of different domains… [including] a group of policies aimed at closing loopholes that allow branded drug companies to game our rules in ways that forestall the generic competition that Congress intended."

How this will affect you

The most recent list of drugs will have a gradual positive impact on the general market as generic drug companies release new medications. However, this list contains only a few workers' comp medications. While we may not see immediate gratification from lower cost work comp drugs now, we remain cautiously optimistic about future drugs that are on the verge of expiration. A few examples scheduled to expire in 2017 or early 2018 are Norvir® capsules, Sustiva®, Prevacid® Solutab, and Fentora®. While we anticipate these patents to expire in the near future, the dates are subject to change.

1 https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm
2 https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM564441.pdf
3 https://www.nytimes.com/2017/09/08/health/allergan-patent-tribe.html
4 https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm564725.htm
5 https://blogs.fda.gov/fdavoice/index.php/2017/10/reducing-the-hurdles-for-complex-generic-drug-development/