The Trouble With Compounds

Do These Specialty Medications Have a Place in the Workers' Compensation Arena?

By Niki T. Ingram, Esq.

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As many in our industry know, compounded medications have become an increasing driver of costs in workers' compensation cases. Over the course of the past few years, there have been exponential increases in both the use of these medications and the payouts. The cost of compound medication was 30 percent higher in 2013 than it was in 2012, and it was 36 percent higher in 2015 than in 2014. Neither the usage nor the costs show any signs of abating.

However, in recent months, the insurance industry and compounding pharmacies have engaged in serious attacks and counterattacks over the pricing of these medications. At press time, a number of compounding pharmacies have filed suit in federal district court in St. Louis against the largest pharmacy benefit managers (PBMs), alleging that these companies have violated their antitrust rights by drastically cutting payments to the vendors. What happens as these behemoths fight about payments will be determined by the courts, but until the legal process is concluded, it is essential that workers' compensation insurance professionals understand what compounded medications are, why their usage and costs increased so dramatically, and how to develop strategies to control these costs.

What Is a Compound Medication?

In its simplest terms, a compound medication is the creation of a pharmaceutical product by combining two or more medications to fit the specific needs of an individual patient. The medication is prescribed by a licensed health care provider and created by a licensed pharmacist.

The explosion of costs for compounds is recent, but the compounding process actually has been in existence for centuries. Compounding was used in ancient civilizations when herbs and powders were combined to create healing ointments. In historical accounts of life in colonial America, there are frequent references made to compounding. Its actual usage in the U.S. was steady until the post-World War II era, when large pharmaceutical companies began mass producing medications and compounding then slowed down. In the last few years, providers began to realize that there is much money to be made from compounding medications for carriers, and they have followed the market.

Why Use Compounded Medications?

There are valid medical reasons for compounding medications, such as when an individual is allergic to a medication or cannot take a medication orally. It may allow flavoring so that a medication can become palatable. It may also be of benefit to someone who is taking a number of different medications and wants to reduce the impact of those medications on the gastrointestinal system. They also are indicated for certain systemic diseases, such as multiple sclerosis, as they can ensure that a medication is free of preservatives. Generally speaking, however, these reasons do not usually exist in the context of the workers' compensation system.

While compounding has some benefits, the large-scale use of this practice in the workers' compensation system is costly and problematic.

Compounded medications are not regulated by the federal government, and there are some valid concerns as to how beneficial they actually are. Prescriptions that are manufactured by large pharmaceutical companies must be approved by the Federal Drug Administration (FDA) before they can be sold to the public. Each product must be tested, and this testing takes place in stages and includes clinical trials, which must follow very specific guidelines. This process can take several years and is costly for pharmaceutical companies. Additionally, once a drug does make it to the marketplace, it must continue to meet FDA standards of sterility and efficacy. Failure to meet government standards may result in a drug manufacturing plant being closed down until it meets FDA regulations. Either of these scenarios is very costly for the pharmaceutical company.

By contrast, compounds do not require FDA approval. Compounded medications are created individually, and there are no requirements of sterility, consistency or quality of production. In practical terms, this means that each batch of the medication is different, even though the patient, the prescribing provider, the prescription, the prescription amount and the pharmacy are the same. Compounding pharmacies essentially have become large manufacturers of drugs without the burden of conducting drug trials or providing evidence to support their claims of efficacy. Because this lack of regulation causes an abundance of problems, a number of states are beginning the process of regulating these sales, which will help to ensure uniformity of production.

The lack of regulation of compounded medication is one of the primary reasons that pharmacists have been able to charge so much for them. These pharmacies have learned that, in the workers' compensation system, they can charge for each drug in a compound. Some companies include more than 10 different medications. Previously, pharmacists submitted claims by listing the main ingredient of the compound and charging some markup. However, in the last few years, pharmacists have begun to list each ingredient and bill for them. This can result in multiple opioids being used, as well as nonsteroidal inflammatory ingredients, in one compound. In many instances, compounding pharmacies have been found to charge hundreds or thousands of dollars per gram of bulk product, whether that product is a cream, powder or ointment. These multiple components can then cost thousands of dollars for each prescription.

Additional Cost Drivers

The other primary reason for the high cost of compounded medication in the workers' compensation system is the process that exists. Most large private insurers or the government agencies like the Centers for Medicare & Medicaid Services have structures in place which ensure some degree of cost containment. These structures may be provisions that require higher deductibles, pre-authorization for certain conditions or procedures, or limitations on the payment of nongeneric medications. None of these controls exist in the workers' compensation system, where carriers generally have been required to make prescription payments unless there has been some type of utilization review process that has been fully adjudicated. The inherent nature of the workers' compensation system means that the providers will use it whenever possible, as its structure allows higher rates of reimbursement. This is basic economics.

What's an Insurer to Do?

Insurers are not without some resources. There are steps that can be taken when confronted with a bill from a compounding pharmacy.

All compounding prescriptions should be automatically reviewed. Insurers should limit initial approval to known problems that would benefit from the use of a compound, and they

should get letters of medical intent from the prescribing provider that offer a clinical rationale as to why the compound is necessary.

That provider should offer information on whether conventional therapy has been tried and failed. If that is indeed the case, then it should be asked how and why the compound will now work. If the same medication has been used or has been tried orally and failed, then the carrier should ask why the medication is now being topically tried. The providers also should ask who is manufacturing the product in order to make sure that there is no self-referral. Also, ask how it will be determined that the correct dosage will be administered.

There also should be questions about what steps are being taken to ensure that the injured worker will use the medication properly. A determination must be made as to whether medical literature suggests the compound substance can be properly absorbed into the body and on which part of the body the medication will be applied.

Insurers should avoid approving compounds with multiple controlled substances. Question the health care provider about why these substances are necessary and whether they should be combined. The provider should be asked if the molecular configuration of the component is such that it can only be absorbed by the patient.

It is worthwhile to fight back on these prescriptions as many carriers that ho require letters of medical intent have found that the providers often do not want to provide the necessary information, opting instead to change the prescription to a more conventional drug.

Initially, it seemed that the letter of medical intent was the most efficacious way for insurers to combat these cases, but that changed when the largest PBMs decided that they would create internal prescription management plans. According to the PBMs, those who need compounds will be able to get them; however, the companies are "actively" looking for ways to reduce the costs of these medications. The PBMs decided to revolutionize the process of paying for compounded medication and began reviewing all of the ingredients in the compound. This included more than 1,000 ingredients and resulted in many of these companies simply declining to pay the charges. This refusal resulted in the first glimmer of reducing the cost of compounded medication; however, the pharmacies have fought back with the filing of the aforementioned antitrust suit.

The Road Ahead

It is much too early to know if the PBMs will hold the line on paying for compounded medications given the fact that the lawsuit was filed by the pharmacies. There is also no indication as to how the courts will view the lawsuit that has been filed by the compounding pharmacies.

In the interim, compounding pharmacies will continue to dispense compounded medications, which will result in tremendous costs for carriers. The PBMs probably will not pay for as many of these as they did, but it largely will be business as usual until the courts make a decision. The amount of money at issue here is significant, and it appears the fight has just begun.

Niki T. Ingram is the Director of the Workers' Compensation Department at CLM member company, Marshall Dennehey Warner Coleman & Goggin. She may be reached at ntingram@mdwcg.com.