

## 17 Questions to Ask When Considering Compounded Medications

The practice of compounding medications is an age-old process used by pharmacists to create personalized medications for patients in need. A great amount of chemistry, mathematics and skill goes into creating compounded medications. Although controversial in both workers' compensation and group health, there is a valid need for compounded medications. Manufacturers will never be able to produce every medication in every strength and dosage form that a patient may require. Medications may be temporarily unavailable or the injured person may have an allergy precluding their use of oral medications. In recent years, however, some pharmacists, doctors and businesses discovered great potential for generating extra income by dispensing compounded medications, tarnishing the practice.

Presently, most compounded medications fall outside of state fee schedules and are billed using the National Drug Code (NDC) of the highest price ingredients. While legislators contemplate ways to normalize the cost of the practice, workers' compensation payers are evaluating the use of compounded medications based on the specific needs of the injured person. In doing so, there are a few things to understand and several questions to ask when determining if the use of a compounded medication is appropriate.

### **Types of Compounded Medications**

Many times, physicians introduce compounded medications into the therapy regimen because a patient is having problems taking a commercially prepared medication. He/she might be experiencing adverse side effects, allergies, difficulty swallowing or absorption issues. In workers' compensation, most compounded medications are in the form of a topical preparation (cream) for skin or local use. Ophthalmic agents and injectable compounded medications are used in the absence of commercial preparation, in order to avoid adverse reactions, and when sterility is of high importance. To a lesser extent, oral compounded medications, such as a capsule, solution, suspension or lozenge, are used if there is no commercially available strength, the patient requires a unique combination of agents or if ensuring no impurities is essential.

### Topical Compounded Medications in Workers' Compensation

Medical guidelines consider compounded medications, particularly those administered topically, as second- or third-line therapy. Primarily physicians recommend their use for neuropathic pain when trials of antidepressants and anticonvulsants have failed or when an injured worker is allergic to certain inactive ingredients in oral medications. Often, compounded topical medications in workers' compensation include four to five individual ingredients. Those commonly used include:

Therapeutic Classes	Commonly used agents
NSAIDs	Ibuprofen, diclofenac, ketoprofen, flurbiprofen
Opioids	Tramadol
Local anesthetics	Lidocaine, benzocaine, ketamine
Antidepressants	Amitriptyline, nortriptyline
Anticonvulsants	Gabapentin
Muscle relaxants	Cyclobenzaprine, baclofen
Other topical analgesics	Capsaicin, menthol, methyl salicylate, clonidine

### Injectible Compounded Medications in Workers' Compensation

Injectable compounded medications are used in workers' compensation to deliver pain medications in implantable pumps. They are typically administered in clinics, outpatient centers and physician's offices. Medication examples include morphine, hydromorphone, fentanyl, clonidine and baclofen. Since 2012, there has been much publicized concern over injectable compounded medications due to sterility issues that led to many illnesses and deaths. In response, guidelines and standards for compounded sterile products have been designed to reduce harm to patients from:

- Microbial contamination and excessive bacterial endotoxins
- Variability in the intended strength of correct ingredients
- Unintended chemical and physical contaminants
- Inappropriate quality of ingredients

According to best practices, injectable compounds should be avoided unless the following conditions exist:

- Commercially manufactured products are unavailable, on back-order or recalled
- Injured worker understands the risks and benefits of injectable compounds
- Other medications have failed
- Medication is obtained from a reputable and experienced pharmacy that is licensed for sterile product compounding
- Clinical resource consultant states otherwise

## Evaluating Appropriateness of Compounded Medications

As a payer, you may be hearing a good deal of rhetoric, as well as seeing increased use, of compounded medications. To help you evaluate their use, consider the following 17 questions:

- **Has an adequate trial of first-line, oral medications been completed?** If you're seeing a compounded medication as the first prescription for a patient, investigate why. Sometimes we see compounded medications come through without any trial of first-line, oral medications. There may be legitimate reasons for the compound versus the first-line medication but it's safest to find out why.
- **Are first-line oral agents available?** There could be a shortage of commercially available first-line oral agents, or perhaps none exist. In either of these situations, the compounded medication may be appropriate until the oral agent becomes available.
- **Why is the patient unable to use oral medicines?** It's helpful to know why the patient cannot tolerate the oral medicines. If, for instance, the patient has trouble swallowing, this would also be important to note for future care.
- **Are there any comorbid conditions that might prevent the use of oral formulations?** A patient may have a history of severe gastroesophageal reflux disease (GERD), making the use of oral nonsteroidal anti-inflammatory drugs (NSAIDs) less desirable. Underlying cardiac conditions or uncontrolled high blood pressure may further necessitate the use of a topical approach to pain management rather than using oral NSAIDs.
- **Does the patient have any allergies that might prevent the use of oral formulations?** A patient may have an allergy to NSAIDs when taken orally but may not experience problems with a topical formulation. If it's an allergy, is there another oral medication that would perform as well, if not better, than the compounded medication that doesn't contain that allergen?
- **Have other non-compounded, topical medications been tried?** Many commercially available and over-the-counter topical medications may provide the same relief as the compounded medication. For example, if the compound is mostly an NSAID, Voltaren® gel is a non-compounded topical formulation in the same class. If the compounded medication contains an anesthetic, perhaps a lidocaine patch will work.
- **Is the condition being treated compensable?** What is the purpose of the compounded medication? Confirming compensability for the condition requiring the compounded medication is a good check.
- **Are all the ingredients appropriate for the condition being treated?** Consider the actual injury and look at the ingredients in the compounded medication. Does it make sense from a therapeutic class standpoint? If the ingredients were all oral medications, would it still make sense for the treatment of that injury? For example, a prescription for anticonvulsants wouldn't make sense for an injury that doesn't involve neuropathic pain. It therefore follows that anticonvulsant ingredients in the compound would be unnecessary.
- **Are the ingredients effective according to evidence-based guidelines?** What do the Official Disability Guidelines (ODG) and American College of Occupational and Environmental Medicine (ACOEM) say about the ingredients of the compounded medication in relation to the injury? Since compounded medications are created for individual use and not subject to clinical trials, guidelines applying to individual ingredients offer some evidence of efficacy.

- **Does the prescriber have any literature to support the use of the compound?** Perhaps the prescriber has a clinical study or other information that supports the use of the ingredients in the compound medication.
- **Is there therapy class duplication with current oral medications?** Is the patient taking an oral anti-inflammatory agent and using a topical compound which also includes an anti-inflammatory? This therapeutic duplication increases the risk of drug-drug interactions, over-medicating and other complications
- **Is there ingredient duplication within the compounded medication itself?** Lidocaine and Benzocaine, for example, are both local anesthetics. Are both necessary ingredients in one compounded medication?
- **Has there been an associated decrease in opioid utilization? If the goal is to reduce opioid use by utilizing a specific compounded medication, is this working?** If the opioid level has remained the same—or increased—because of the ingredients included in the compounded medication, it may not be meeting this goal.
- **Has the patient demonstrated improvement in function and/or quality of life?** If the patient has reported improvement or has returned to work, even doing light duty, this is an indication that the medication therapy is working. No reported improvement is a red flag that the medication therapy is in need of review.
- **How long does the prescriber plan on prescribing the compound medication?** There must be a treatment plan in place. If there are not specific goals and a clear plan of care, the medication therapy could go on indefinitely. Moreover, the patient, payer and physician should be aligned in their understanding of the treatment plan, its intended duration and objectives.
- **Will a compounded medication cost less long-term than multiple oral medications?** If commercially available medications and the compounded medication can equally and adequately address the patient's specific needs, look at the overall costs and determine what the safest, most cost-effective approach is.
- **How does the pricing of the compounded medication compare with the cost to create it?** Look at the NDC for each of the ingredients in the compounded medication and compare it to the price paid for the compounded formulation.

Having started a dialogue with the physician, you may find that more questions arise or additional guidance is necessary. In such situations, a pharmacy benefit manager can be a valuable resource. Reach out to their clinicians to discuss your concerns. Require the physician to provide documentation that the compounded medication is medically necessary. Ask a nurse case manager or medical director for a consult. Most importantly, keep the conversations going. When you generate a conversation with the patient, physician and pharmacist, you open the door to understanding the specific needs of that patient, leading the way to better outcomes.

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For more information, contact us:

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#### About Optum for Workers' Compensation

The workers' comp division of Optum collaborates with our clients to deliver value beyond transactional savings while helping ensure injured workers receive safe and effective clinical care. Our innovative and comprehensive medical cost management programs include pharmacy, ancillary and managed care services from first report of injury to settlement.

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