



Formulary Fundamentals

A Powerful Tool for Workers'
Compensation Change
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Introduction

Patient care and safety standards stand at the forefront of conversation in workers' compensation as we tackle the opioid crisis, physician dispensing and compounding medications, among other issues. Curtailing the impact of these challenges requires comprehensive changes to the system, and drug formularies are one of the tools that many states are beginning to employ. These lists of approved medications work in conjunction with other guidelines and requirements to improve the overall outcomes of workers' compensation claims.

Although drug formularies are not a new concept and have been utilized by pharmacy benefit managers for years, those specific to workers' compensation and enforceable at the jurisdiction level are relatively new.

State-mandated workers' compensation formularies now exist in a handful of states and provide more clarity to all stakeholders on what medications to approve for workers' compensation claims. Though many of these formularies are still in the developmental stage, preliminary results have shown that they are effective at addressing major problems in each state's workers' compensation system.

This whitepaper will explore how drug formularies address major issues in workers' compensation, what successes states have seen in their own workers' compensation systems, and what the future might hold for drug formularies.



What is a Formulary?

To understand how formularies improve workers' compensation systems, we must first understand what they are and how they work.

A drug formulary is a list of preferred medications that physicians can prescribe without prior authorization. This means that a prescribed drug that is proven to be effective, is low risk and low cost, such as ibuprofen, will be automatically approved, as long as the medication is appropriate for the injury.

A formulary also includes other medications or combinations of medications that require additional authorization before they can be prescribed or dispensed. For instance, many states require that larger doses of opioids receive additional authorization. This authorization comes from the claims examiner or trained medical staff and is based upon medical guidelines.

If this designated person has questions about authorization, he or she can contact a pharmacist, nurse or physician with specialized experience with workers' compensation or auto accident injuries and the related prescriptions. This portion of a formulary puts an additional control in place to ensure that the injured worker is not receiving inappropriate, risky or unnecessarily expensive medication.

Most importantly, the purpose of a formulary is to ensure that injured workers are receiving the most appropriate care for their injuries. Formularies are developed through extensive research on proven and effective medical therapy and are more extensive than merely reducing costs. When complex issues such as opioid prescribing arise, formularies can provide direction for prescribers, pharmacists, claims examiners, PBMs and all other stakeholders.



Formulary Quick Facts

- 7 states have formularies specific to workers' compensation
- 6 states are considering new formulary legislation
- 2 commercially-available guidelines

Formularies Provide Guidance

A recent study by the Workers' Compensation Research Institute (WCRI) points to the issue of longer recovery times for injured workers when an opioid is prescribed. Workers who receive a long-term opioid take three times longer to return to work as those who do not receive opioid prescriptions. Formularies can help address this by restricting both the types of opioids allowed for certain injuries and the length of opioid prescriptions.

For instance, Arizona only allows for a 5-day initial prescription of opioids. Again, this puts a check on the system to ensure that the medications prescribed are what the patient actually requires for their injury (not more and not less).

Formularies also help physicians with prescribing. With thousands of medications available to prescribe, it can be difficult to discern what is best for an injured worker, especially since these cases can be complex. Formularies help guide physicians with proven, effective medication for a particular injury. Since the formulary is created with physician input, it is a helpful tool for prescribing guidelines. This guidance in turn can help reduce the impact of issues such as over-prescribing, opioid use and costs. We will look at these issues more closely in upcoming sections.

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The Difference Between Formularies

Workers' compensation drug formularies differ from Medicaid, Medicare and commercial health formularies in a few ways. The major difference is the type of care provided. While the other types of formularies address a wide range of medical conditions, workers' compensation formularies focus on injuries and the type of care necessary to adequately treat these injuries.

Injured workers can face many challenges, including extensive time away from work, difficulty recovering, pain and the psychological struggles that accompany these challenges. Formularies for workers' compensation focus on the specific injury or injured workers' experience, as well as the best clinical guidelines available to address these injuries.

As states look to adopt workers' compensation-specific formularies, there are several things to consider and steps to take.

1. What is the current status of medication prescribing in the state? What prescribing behaviors stand out? Which drugs are being utilized the most?
2. Research other states and compare data to those states
3. Review national guidelines to see why a state may be over-utilizing in specific areas
4. Select a national guideline or develop a committee to create a formulary based on best clinical practice
5. Publish a draft of the formulary to a wider audience and provide a way to accept comments
6. Evaluate comments and incorporate those deemed relevant
7. Publish final formulary
8. Continue to evaluate on an ongoing basis and adjust as needed.



Workers' Compensation Formularies

When developing a formulary, states have a few options. Some states have opted to create their own guidelines, while others have chosen to follow commercially available formularies. The Official Disabilities Guidelines (ODG) is one set that states such as Texas have opted to follow. The American College of Occupational and Environmental Medicine is the second set that California has adopted and New York has proposed in a draft rule. States can also create their own custom program.

Official Disability Guidelines (ODG)

One commercially available formulary is the Official Disability Guidelines (ODG) drug formulary. This formulary is evidence-based and "...[provides] a listing of the different medications used in workers' compensation cases, in table format, with populated categories for Drug Class, Generic Name, Brand Name, Generic Equivalent, Cost, and ODG's proprietary Preferred Drug Status." The Preferred Status indicates whether a drug is approved without additional authorization (a Y drug) or requires additional authorization (an N drug).

Overall, these guidelines have shown to be effective in addressing major issues in workers' compensation systems. Texas, in particular, has shown considerable improvement and the state's results will be addressed in an upcoming statistics section.

ACOEM

The Reed Group's American College of Occupational and Environmental Medicine (ACOEM) guidelines are also commercially available. The formulary is less widely used than ODG, but has been adopted in California and is being considered in New York.

The ACOEM formulary is somewhat more complex than ODG, because it focuses on not only specific body parts but also specific injury types when addressing what medications are approved. For instance, a wrist fracture would potentially have different authorized medication than a wrist sprain. Because the formulary is very specific, it can often be difficult to administer, since PBM's don't necessarily have access to specific injury diagnoses beyond the basic body part impacted.

Since California's drug formulary is still in its early stages, it is difficult to determine if the ACOEM guidelines will prove as successful as ODG has.

State-Specific Formularies

States can also develop their own formularies based on medical research and expertise. Several states have developed a mixture of guidelines that include portions of ODG or ACOEM guidelines and are focused on specific issues within the state.

Colorado and Washington have developed their own formularies. Arkansas is the most recent to approve a state-specific formulary, which will be effective July 1, 2018.

ODG

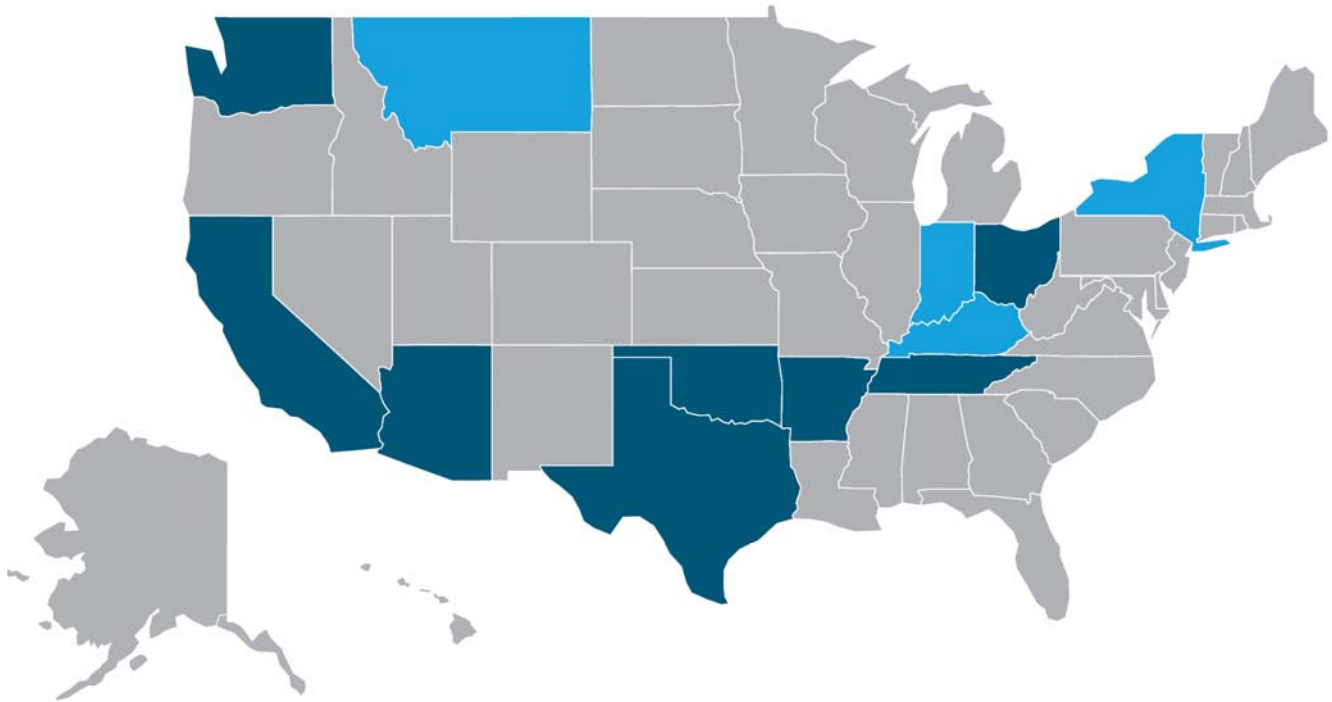
Listing of different medications used in workers' comp cases

ACOEM

Focuses on specific body parts and specific injury types

State-by-State Laws

To date, a handful of states have adopted workers' compensation drug formularies. Several more are considering or have recently passed new legislation to establish formularies. The map below gives an overview of these states.



Formularies implemented in California, Washington, Arizona, Texas, Oklahoma, Tennessee and Ohio.



Formulary legislation being considered or recently passed in Montana, Nebraska, Louisiana, Indiana, Pennsylvania and New York.



Major Issues in Workers' Compensation

There are several major issues in workers' compensation today. Opioid-related overdose deaths in 2016 totaled more than 64,000; the cost of drugs is expected to rise 4–7% through 2021; physician-dispensing and compounding medications continue to cost the industry and challenge patient safety standards. Formularies address these issues as well as over-prescribing and workers' compensation-specific treatment.

Let's take a closer look at the specifics of these issues.

Opioids

The opioid epidemic is top of mind for many across the United States. Today, one in four people receiving long-term opioid prescriptions becomes addicted and nearly forty Americans die every day from prescription opioid-related drug overdoses. In 2016, synthetic opioids such as fentanyl were the leading drug in opioid overdose deaths, overtaking heroin and prescription painkillers.

Opioids are especially important in workers' compensation, since a high percentage of injured workers receive medication to treat pain. Opioids have typically been the type of medication prescribed, but recent years have shown the inability of opioids to effectively treat pain for certain types of injuries. It is this disconnect and public health crisis that has prompted the formulary discussion in many states.

As mentioned earlier, WCRI's recent study shows that injured workers who had multiple opioid prescriptions took three times longer to return to work than those without any

opioid prescriptions. Additionally, the region where the worker resides can often affect the length of opioid prescriptions that patients receive. Those living in areas that prescribe more long-term opioids are more likely to be prescribed opioids for a longer time. While this may seem straight forward, it can have devastating regional effects. Certain states such as West Virginia have been disproportionately impacted by the opioid epidemic where the death rate from prescription opioids is 37.7 per 100,000 citizens (based on 2016 data).

A recent study from the American Action Forum sheds light on how acutely opioids affect the workforce. The study found that in 2015, over 900,000 working-age individuals were not working due to opioids. Additionally, labor force participation "cumulatively cost the economy 12.1 billion work hours" between 1999 and 2015. It's clear from these studies that opioids are a major issue costing the workers' compensation industry time, money and lives.



Injured workers who received multiple opioid prescriptions took 3x longer to return to work than those without any opioid prescriptions.

WCRI study, 2017

Rising Costs

The rising cost of medications is another big issue in workers' compensation. Depending on the state, anywhere from 11% to 17% of the medication portion of workers' compensation costs can be attributed to prescriptions.

The following issues contribute to the rise in overall drug and pharmacy costs.

Physician Dispensing

Physician dispensing causes several issues for workers' compensation systems. This practice often raises costs for the system, especially if the physician opts for brands or compounds over generics. A 2016 study by NCCI showed that in states where physician dispensing was not highly regulated, the allocation of costs of prescription drugs to physician dispensing exceeded 20% in 2014. In contrast, those states that had strict regulations on physician dispensing saw only 2% of total costs being attributed to physician dispensing.

Additionally, the cost of a drug can be as much as 500%, or more, in a physician-dispensed setting than in a pharmacy for the same medication. For instance, a study by WCRI found that "injured workers in Florida, Georgia, Illinois and Maryland paid physicians on average \$4 to \$7 for a pill of ranitidine (Zantac), when they could have bought it at Walgreens for 33 to 42 cents, depending on the strength and quantity."

The cost of a drug can be as much as 500% more in a physician-dispensed setting than in a pharmacy for the same medication.

Physician dispensing can also create a problem for the injured worker. The patient could be receiving medications from multiple sources or may be taking medication that would interact with the newly prescribed medication. The controls typically put in place to prevent this dangerous pattern of prescribing, like those used by PBMs, are undermined when the patient receives medication from several different physician-dispensing locations.

A physician may have no way of knowing this and, even with best intentions, could provide the patient with a harmful prescription. Additionally, the insurer would likely not

know about these medications until at least a month later when the bill is received. By then, the overall cost and risk of the claim may be considerably higher.

When a patient fills prescriptions at a pharmacy, he or she typically utilizes the same pharmacy for all prescriptions. This gives the pharmacist and other stakeholders better insight into the medications the patient is taking. When a patient instead is filling prescriptions at one or multiple physicians' offices, the ability of stakeholders to monitor and balance these costs and additional prescriptions and to ensure patient safety is ultimately hindered.





Compounding

Compounding medication is typically cited as a way to adapt medication to the needs of a specific patient by combining two or more drugs (often in the form of a topical cream). Outside of the workers' compensation system, a prescription compound is a rare event and happens only when there is clear medical justification for the use of a compound.

Inappropriate compounded medications inflate costs for workers' compensation systems. The two or more separate drugs are typically inexpensive and when combined can be remarketed at a much higher price. Some compounds can cost hundreds to thousands of dollars, while their ingredients cost is minimal when purchased separately. Additionally, costs of these drugs continue to rise.

For instance, Texas saw the average price of compounding scripts more than double between 2010 and 2014, from \$356 to \$829.

Compounding also presents an issue in the form of patient safety. These compounded drugs are not approved by the Food and Drug Administration (FDA). There is no testing or approval process after they are compounded. This means that, though the active ingredients may have evidence to show their safety and efficacy, the compounded versions have little or no such data. FDA research has shown that compounded medications may only show benefit in cases where patients are unable to swallow pills or are allergic to part of the commercially available drug.

Over-Prescribing

A patient may not report every medication he or she is taking, which can lead to inadvertent and sometimes dangerous over-prescribing. Additionally, certain medications, including opioids, come with side effects that some physicians try to solve by prescribing additional medications to counteract these side effects. Often, instead of trying to solve the cause of these issues, the strategy has been to treat various symptoms with additional medications. With these additional prescriptions comes both higher risk for the injured worker and higher costs. If the worker is on multiple medications, there can be risk for greater debilitation and prolonged recovery time, dangerous drug interactions, and addiction.

Workers' Compensation-Specific Treatment

Ultimately, workers' compensation cases need specific treatment methods and medications. Without guidelines and practices that address the unique needs of injured workers, the entire system is subject to prolonging the above issues.

The next section will cover how formularies address these pressing workers' compensation issues.



How Do Formularies Address Major Workers' Compensation Challenges?

Workers' compensation-specific formularies have shown impressive results when it comes to addressing major issues in the workers' compensation industry. From reducing opioid utilization to restricting physician dispensing, formularies have improved several states' workers' compensation systems.

Opioids

Many workers' compensation formularies take an aggressive stance on opioids by limiting prescription quantities and doses, prohibiting physician dispensing and enacting more prior authorization controls. For instance, Arizona's formulary focuses specifically on opioids, and their recent Opioid Act prohibits physicians dispensing of Schedule II opioids, limits initial opioid prescriptions to five days and limits new opioid prescriptions to 90 MME's (Morphine Milligram Equivalent). Other states have enacted similar legislation and controls.

Texas and Ohio have both seen impressive decreases in opioid utilization since implementing their formularies, with opioid costs dropping from 27% to 18% in Texas and opioid dependence decreasing by 59% in Ohio.

Rising Costs

Formularies can address rising costs by requiring the use of generic medication over brand medication (or requiring pre-authorization for brand medications). Additionally, by reducing physician dispensing, over-prescribing, opioids and compounded medications, formularies can significantly reduce the workers' compensation system drug spend while ensuring appropriate and effective drug therapy is prescribed. These individual savings groups will be addressed next.

NCCI's study estimated that implementing an ODG formulary could reduce workers' compensation-related pharmacy costs by 10%. Much of these savings could be attributed to the tightening of opioid restrictions with the implementation of this formulary. While safety and patient welfare is the primary goal, choosing wisely can also have beneficial financial implications.

Physician Dispensing

Many states have made reforms to their workers' compensation systems since discovering the problems with physician dispensing. Some states have completely banned the practice of physician dispensing while others have limited what physicians are allowed to dispense. A study by WCRI showed that post-reform states saw a decrease in physician dispensing. South Carolina, for instance, saw a 63% decrease. The study also showed that these reforms initially showed cost savings, but physicians have found ways around these limitations. Some are continuing to dispense drugs repackaged at different strengths that are not included in restrictions, which are expensive and have made overall cost savings plateau.

Formularies combat this issue by continuing to put limits on what physicians are allowed to dispense and how much they can be reimbursed for the prescriptions. This continues to be an issue that future formulary creation and reforms can hopefully address.



Compounding

Formularies also limit the use of compounded medications in workers' compensation claims. Texas, for instance, passed an amendment in 2018 to its formulary to place all compounded medications on the prior-authorization list. Prior to the 2018 change, the state saw a 46.4% increase in compound drug prescriptions and an average cost increase from \$356 to \$829 between 2010 and 2014. Compounding pharmacies who were taking advantage of the loophole learned that by creating a compound with all "Y" or approved ingredients they could avoid the prior authorization requirement. In closing this loophole, Texas is hoping to see these numbers drop significantly.

New York and Arkansas are following similar paths with their new formularies, which will require prescribers to prove medical necessity of the compounded medications before injured workers receive the medication.



63%

decrease in physician-dispensing since South Carolina reformed its workers' compensation guidelines.



10%

potential decrease in costs if an ODG formulary is implemented, according to an NCCI study

Over-Prescribing and Polypharmacy

Because formularies limit the use of medications that cause serious side effects, such as opioids, the issue of over-prescribing is subsequently reduced. When patients are not prescribed these medications in the first place, they will not be prescribed the subsequent medications to address side effects.

Opioids, in particular, have been shown to increase the cost of claims significantly. A 2015 study from Accident Fund Holdings and John Hopkins University found that claims with the presence of long-acting opioid medications were nearly 3.9 times more likely than a claim with no prescriptions to have a total cost of over \$100,000. Claims with short-acting opioids were 1.76 times more likely to have a total cost of over \$100,000. Claims with non-opioid prescriptions, in comparison, showed no significant risk of totaling over \$100,000.

The study, additionally, found that the cost of the opioid medication itself was only a minor contributor in these total costs. The need for additional medications and prolonged treatment are likely contributors to these increased total costs.

Every state that has implemented a formulary has seen a reduction, not just in the medications not recommended by the formulary, but also in all prescription drugs. The adoption of a drug formulary creates more focus on appropriate prescribing and the guidelines help physicians choose the best medications early in the claim process, resulting in better, long-term outcomes.

Workers' Compensation-Specific Treatment

Workers' compensation-specific drug formularies are able to focus on which treatments and medications are best for workers' compensation cases. For instance, pain medications are more prevalent in workers' compensation claims, which would place them at the forefront of formulary creation.



State Successes

The results from states that have adopted workers' compensation formularies have given credence to the ability of these formularies to address major workers' compensation concerns. From reducing costs to preventing opioid overdoses, these states have shown that formularies can be successful. Let's take a look at Texas, Ohio and Washington.

Texas

As one of the first states to implement a workers' compensation-specific formulary, Texas has shown much success. Several statistics stand out from a 2016 review of the data.

- Between 2011 and 2014, the number of injured employees receiving "N" drugs (drugs requiring additional authorization) fell by 83%. Those receiving any other drugs fell by 12%.
- In this same time frame, the number of "N" drug prescriptions decreased by 85% and other drug prescriptions fell by 14%. The associated costs dropped by 80% and 14%, respectively.
- Opioid costs as percentage of pharmacy costs dropped from 27% in 2009 to 18% in 2015.
- "The number of claims receiving N-drug opioids with 90+ MMEs/day decreased from almost 15,000 in 2009 to less than 500 in 2015."

These statistics give impressive support for the use of formularies in workers' compensation.



Texas saw an 85% decrease in "N" drug utilization in the first three years after its formulary was implemented.

Ohio

Ohio has also seen success with its drug formulary.

- Since implementing, the state has seen a 59% decrease in opioid dependence, which can in large part be contributed to the measures taken with the formulary.
- Overall, the average medical cost per claim decreased by 60% and average lost time per claim decreased by 66%.



Ohio has seen a 59% decrease in opioid dependence since implementing its workers' compensation drug formulary.

Potential for Other States

Several studies by WCRI have shown potential savings if states implement similar formularies. Louisiana, for instance, could see non-formulary drug use drop to somewhere between 6–17% of all drug prescriptions in the state. Additionally, the cost reductions of overall medication in Louisiana could be as large as 27–28% or around \$2.3 million over the course of 18 months.

As more states adopt formularies and more data is gathered, the workers' compensation system as a whole can work toward optimizing these formularies and improving overall outcomes.

Considerations for Stakeholders and the Future of Workers' Compensation

As more states move to implement workers' compensation drug formularies, there are a few things for stakeholders to be considering.

- How do formulary changes affect workflow? What company-wide changes need to be made? Consider what education needs to be developed and deployed for both employees and claimants.
- How are costs going to change? (More?)
- What do patients need to know? How will their prescriptions and treatments change with changes in legislation? Will they need additional support as formularies are implemented?
- How can Pharmacy Benefit Managers help in the transition process? What support are you getting from your PBM?

The future of workers' compensation is sure to continue to evolve. As formularies develop in more states, we are hopeful to see more success stories.

As we addressed at the beginning of this paper, the ultimate goal of a workers' compensation drug formulary is to ensure that injured workers are receiving appropriate care for their injuries. As several states have already seen, this goal is achievable with the help of comprehensive drug formularies.



Current Legislation

To stay up-to-date with the most recent legislation relating to formularies, follow our news feed at mitchell.com/mitchellnews

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Brian Allen is a nationally recognized policy expert for workers' compensation and insurance issues across the country. Allen currently serves as Vice President of Government Affairs for Mitchell's Pharmacy Solutions team.

Allen lobbied nationally for workers' compensation issues for over 14 years and has over 25 years of political experience. During his time in the government, Allen was actively engaged in the development of the Texas Drug Formulary Rule, the Tennessee Drug Formulary Rule and other critical rulemakings around the country. Additionally, he was a member of a special working group helping Assembly Member Perea in California draft the drug formulary legislation (AB1124). Allen is currently engaged in California, New York, Pennsylvania, Montana, Louisiana and Arkansas on drug formulary proposals and is working with other states on managed care and reimbursement issues.



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Freeman is a frequent guest speaker and author. Freeman is a graduate of Florida A&M University where he received his doctorate of pharmacy.

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