A DISCUSSION ON THE USE OF A FORMULARY IN WORKERS’ COMPENSATION

IAIABC Medical Issues Committee

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ABOUT THE IAIABC

Founded in 1914, the International Association of Industrial Accident Boards and Commissions is a not-for-profit association representing most of the government agencies charged with the administration of workers’ compensation systems throughout the United States, Canada, and other nations and territories, as well as other workers’ compensation professionals in the private sector. Its mission is to advance the efficiency and effectiveness of workers’ compensation systems throughout the world. It is governed by a Board of Directors made up of jurisdictional agency leaders, and maintains a staff headquarters in Madison, Wisconsin, USA. Learn more at www.iaiabc.org.
# Table of Contents

**Executive Summary** .......................................................... 4  
**Introduction** ........................................................................ 5  
**Jurisdictional Considerations** .................................................... 111  
**State Snapshots** .................................................................. 11  
  - North Dakota ...................................................................... 11  
  - Ohio .................................................................................. 24  
  - Tennessee .......................................................................... 29  
  - Texas ................................................................................ 32  
  - Washington ....................................................................... 37  
**Additional Resources** .............................................................. 40  
**References** ........................................................................ 44
EXECUTIVE SUMMARY

Over the last several years, the workers’ compensation industry has become increasingly interested in solutions to address inappropriate prescription use in the treatment of injured workers. At the same time, widespread attention has focused on the damaging effects of increased opioid use by Americans for pain treatment. Federal and state policymakers are implementing a variety of strategies to address these issues including treatment guidelines, prescription drug monitoring programs, provider education, and formularies.

Several states have used a workers’ compensation formulary as one tool to successfully reduce the use of potentially harmful prescription drugs and decrease prescription drug costs. A formulary in workers’ compensation is a list of drugs, where each drug has a status indicator, noting if the drug is approved or requires pre-authorization by the claims administrator.

This resource paper was developed by the IAIABC Medical Issues Committee for workers’ compensation policymakers, regulators, and industry stakeholders to understand what a formulary is and how it can be used in workers’ compensation. In workers’ compensation, formularies are commonly described as:

- **Open**: An open formulary is a list of all FDA approved prescription drugs but does not indicate a status of any drug. In practice, an open formulary would not have any effect on utilization or cost of prescription drugs.

- **Closed**: A closed formulary is a list of all FDA approved prescription drugs with a drug status indicated for all drugs.

- **Preferred Drug List (PDL)**: A PDL is a list of prescription drugs that are preferred in workers’ compensation. Drugs on the PDL must be used before prescribing a non-PDL drug.

The paper describes the differences between each of these approaches. In addition, the paper includes a section on jurisdictional considerations and decision points when implementing a formulary. Discussions should include formulary design and maintenance, implementation of the formulary for legacy claims, the dispute resolution process, stakeholder engagement and education, and integration of the formulary in the dispensing process.

The final section includes descriptions of formulary implementation in North Dakota, Ohio, Tennessee, Texas, and Washington. These snapshots are rich in practical insight and meaningful real-world experience.

The IAIABC is hopeful this resource is valuable to those jurisdictions seeking to understand the impact of a formulary in workers’ compensation and looking for guidance to successfully implement. The experiences offered by experts from both jurisdictions and industry will further knowledge and enhance medical treatment to injured workers’ across the country.
INTRODUCTION

The increasing use and rising cost of prescription drugs across U.S. workers’ compensation systems is a continued concern for the industry.\(^1\) Improper utilization of prescription drugs can result in medical side effects, delayed or no return to work, and higher claims costs.\(^2\) Especially troublesome is the inappropriate use of opioids in the treatment of injured workers.

This paper is intended as a resource for jurisdictions interested in understanding the use of a drug formulary for workers’ compensation claims. This resource was developed for jurisdictional policymakers to share knowledge and experience among industry stakeholders, but is appropriate for anyone interested in learning about:

- Formulary composition
- Creation of a formulary
- Formulary outcomes
- Jurisdictional updates

Inappropriate use of prescription drugs negatively affects patient health and return to work and can have lasting consequences on an individual’s life. A California Workers’ Compensation Institute (CWCI) report found that workers who took high doses of opioid painkillers to treat injuries like back strains stayed out of work three times longer than those with similar injuries who took lower doses (Swedlow, Gardner, Ireland, & Genovese, 2008). Delayed return to work reduces the likelihood an injured worker will ever return to productive employment.\(^3\)

The rising share of prescription drugs as a workers’ compensation cost driver is also a concern. According to the National Council on Compensation Insurance (NCCI) medications represent 18% of the costs for a workers’ compensation claim (Lipton, Colón, & Robertson, 2013). In 2014, the total workers’ compensation pharmacy drug spend ranged between $5 and $7 billion (Paduda, 2015) and prescription drug costs increased 10.2% from the 2013. In 2014, the average pharmacy drug cost per injured worker was $1,583 (2014 Drug Trends Analysis).

Over and above the cost of prescription drugs, administrative expenses related to unnecessary or inappropriate prescriptions are expensive. A 2014 study found that 44% of all utilization reviews and 48% of independent medical reviews in California were for pharmaceutical requests, and that the majority of those were for opioids and compound drugs (Swedlow & Ramirez, 2014).

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\(^1\) Leading workers’ compensation research organizations including CWCI, NCCI, and WCRI have documented that prescription drugs make up a higher percentage of medical costs in the past ten years.


\(^3\) Research shows that individuals who are out of work for longer than six months have very little chance of returning to work. The American College of Occupational and Environmental Medicine (ACOEM) calls this the decay curve and is discussed in Preventing Needless Work Disability by Helping People Stay Employed: A Report from the Stay-at-Work & Return-to-Work Committee of ACOEM.
A number of jurisdictions\(^4\) have adopted or are currently examining the use of a drug formulary to reduce inappropriate use of prescription drugs and/or reduce prescription drug costs. Applied to workers’ compensation, a formulary is a list of prescription drugs that indicates which are automatically authorized for the treatment of work injuries. A formulary may also indicate those prescription drugs that require review or pre-authorization before being dispensed to an injured worker.

North Dakota, Ohio, Texas, and Washington were early formulary adopters and have seen impressive results in the reduction of cost and utilization of some prescription drugs. When implemented in coordination with other medical management strategies, including utilization review and treatment guidelines, a formulary can facilitate injured workers’ receiving prescription drugs appropriate to their recovery needs.

Policymakers should understand that a formulary can work with other medical management techniques to improve the quality of medical treatment to injured workers. However, a formulary cannot, on its own, reduce harmful prescribing patterns. An effective formulary strategy should be carefully considered by policymakers.

**BACKGROUND**

Formularies were first introduced by private healthcare insurers in the 1970s, following the rise of pharmaceutical research in the 1950s (Catamaran, Formulary Management Best Practices, 2013). According to the Academy of Managed Care Pharmacy, “Formularies have evolved into a tool for assuring the selection of medications demonstrated to be safe, effective and affordable while maintaining or improving quality patient care” (Formulary Management, 2009).

Health plan formularies look to balance drug safety, efficacy, and cost. In group health, a formulary is structured as a hierarchy, defining classes of medications and drugs within each class that are covered by the health plan.

Most group health insurers create their own formulary, which is developed and maintained by a committee of physicians, nurses, and pharmacists (often referred to as a Pharmacy & Therapeutics (P&T) Committee). Determinations for drug inclusion or exclusion are based on a number of factors including efficacy, internal rules, and cost. Some formularies allow wider choice of brand drugs while others are more selective in eliminating inappropriate therapies or encouraging generic substitutes when available.

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\(^4\) As of December 2015, Delaware, North Dakota, Oklahoma, Ohio, Tennessee, Texas, and Washington have adopted a formulary. California has statutory authority to adopt a formulary and is in the rule-making process. Arizona, Arkansas, Georgia, Louisiana, Maine, and New York are evaluating a formulary.
How Formularies Work

Formularies have been adopted by several jurisdictions to address prescription drug management, including utilization and cost. Formularies are only one component of this effort; states also use fee schedules, treatment guidelines, prescription drug monitoring programs (PDMPs), utilization review, and other regulatory tools to help an injured worker obtain the best medical care at an affordable cost to the employer. The cost and utilization of prescription drugs is influenced by many factors. These include:

- Type of injury and medical treatment options available;
- Expanding choice and use of drugs;
- Dramatic increase in the use of pain management therapies; and
- Physician dispensing and prescribing practices.

Prescription drugs in a workers’ compensation claim are usually administered by a pharmacy benefit manager (PBM) on behalf of an insurer or third party administrator. PBMs are retained by most payers who seek to manage their drug spend, ensure appropriate utilization, clinical oversight, and prescriber education. More discussion about the PBM role in the formulary process is found on page 15.

The earliest adopters of a workers’ compensation formulary were North Dakota, Texas, and Washington. In North Dakota, Texas, and Washington, a formulary was implemented to reduce inappropriate prescription drug use and also reduce prescription drug costs. In many states, the formulary is used to complement existing strategies including treatment guidelines and utilization review to promote better outcomes for injured workers. All three early adopters have seen a reduction in prescription drug costs and a decrease in the use of certain drugs following formulary adoption.

Formularies have more recently been adopted in Delaware, Oklahoma, Ohio, and Tennessee and enabling legislation was passed in California. Mark Sektnan, President of the Association of California Insurance Companies commented “Governor Brown should be applauded for signing AB 1124. This bill will put California on track to create a scientifically valid, evidence-based formulary and will control the overprescribing of opioids.” (Insurance Journal, 2015)

Drug formularies used for workers’ compensation injuries work by requiring specific authorization to dispense certain drugs. Drugs that require pre-authorization are generally those with the highest abuse potential and can include long-acting opioids, benzodiazepines, neuroleptics, skeletal muscle relaxants, and investigational medications.

Formularies have been described as open, closed, and preferred drug lists (PDLs). In the general healthcare context, the terms are defined as:

Open: An open formulary includes coverage status for all formulary and non-formulary drugs. The payer may require additional out-of-pocket expenses for use of a non-formulary drug.

Closed: A closed formulary includes coverage status for only formulary drugs. The payer does not require additional out-of-pocket expenses for use of a non-formulary drug.

Preferred Drug List (PDL): A preferred drug list includes coverage status for all formulary drugs and certain non-formulary drugs. The payer may require additional out-of-pocket expenses for use of non-PDL drugs.

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Closed: A closed formulary includes coverage status for only formulary drugs. The payer does not require additional out-of-pocket expenses for use of a non-formulary drug.

Preferred Drug List (PDL): A preferred drug list includes coverage status for all formulary drugs and certain non-formulary drugs. The payer may require additional out-of-pocket expenses for use of non-PDL drugs.

Footnote:

5 High abuse potential is based on medical evidence. The formulary publisher should clearly document evidence used to determine the status of each drug.
Closed: Non-formulary drugs are not reimbursed by the payer.

These terms have been used slightly differently in workers’ compensation, which can lead to confusion. These terms are described for workers’ compensation below:

Open: An open formulary is a list of all FDA approved prescription drugs but does not indicate a status of any drug. In practice, an open formulary would not have any effect on utilization or cost of prescription drugs.

Closed: A closed formulary is a list of all FDA approved prescription drugs with a drug status indicated for all drugs.

Preferred Drug List (PDL): A PDL is a list of prescription drugs that are preferred in workers’ compensation. Drugs on the PDL must be used before prescribing a non-PDL drug.

These descriptions do not address other differences in formulary implementation across jurisdictions. A significant difference between formulary adoption in Texas and Washington is the scope of the formulary.

Texas adopted the Official Disability Guidelines – Treatment in Workers’ Comp (ODG)/Appendix A, ODG Workers’ Compensation Drug Formulary which lists approximately 300 prescription and non-prescription drugs that can be prescribed and dispensed for outpatient use. Each drug is classified as a “Y” or “N” drug. “Y” drugs can be prescribed and dispensed with no restrictions. “N” drugs can be prescribed but are subject to prospective utilization review to confirm the drug is medically necessary for treatment of the injured worker before being dispensed. There are some drugs which have both a “Y/N” status depending on the purpose of the prescription. The utilization review process is defined by the state.

Washington’s formulary was adopted as a part of a larger state-wide initiative to consolidate prescription drug purchasing among public programs in 2003. The Preferred Drug List (PDL) applies to the state’s Medicaid, public employees’ Uniform Medical Plan, and Labor & Industries (L&I) for workers’ compensation. The state contracts with the Drug Effectiveness Review Project (DERP) to review and report on the evidence of comparative effectiveness and safety of the drugs within a given drug class. The Pharmacy & Therapeutics (P&T) Committee reviews the report and makes recommendations to the state.

L&I participates in only a subset of the statewide PDL because the workers’ compensation benefit is different from that of public employees and Medicaid recipients. L&I uses other methods to manage the remainder of the drug classes on the formulary such as using rebate vendor’s national formulary, evaluating drugs with high utilization, assessing newly available drugs for formulary consideration based on their safety, efficacy, and cost relative to therapeutic alternatives, and developing treatment guideline and coverage or payment policies to ensure appropriate drug utilization.

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6 For example, benzodiazepines (anti-anxiety drug) can be prescribed for treating anxiety but are not indicated for treating pain.
A DISCUSSION ON THE USE OF A FORMULARY IN WORKERS’ COMPENSATION

A workers’ compensation formulary can be an effective check and balance in the system. Through a formulary, a medical provider understands which medications are excluded or require preapproval, and the payer, typically through the PBM, is alerted when a therapy with high abuse potential is initiated.

FORMULARY OUTCOMES

Jurisdictions interested in formulary implementation should clearly define the desired outcomes and implement appropriate tools to measure success. Possible goals include:

- Reducing prescriptions of potentially dangerous drugs to injured workers
- Decreasing length of disability and increasing return to work rates
- Cost savings
- Reduction in litigation

Research has shown a formulary can be an effective tool in decreasing potentially harmful prescription drugs and reducing prescription drug costs. The following is a summary of results seen in some jurisdictions that have adopted a formulary. More information about specific outcomes is detailed in the jurisdictional case studies.

NORTH DAKOTA
Implementation of a formulary has allowed the state the ability to restrict medication use to those medications which have clinically demonstrated safety and efficacy while also demonstrating cost effectiveness.

OHIO
Ohio benefited from a 27.8% decline in opioid prescriptions and a 72.9% decrease in skeletal muscle relaxant prescriptions in the year following formulary implementation (Insurance Journal, 2014).

TEXAS
Texas has seen significant reductions in the use of “N” drugs since formulary implementation. For example, “N” drug costs reduced by 82% for new claims, and after one year, only 53% of legacy claims still had an “N” drug included in the regimen (Lee, 2015).

WASHINGTON
A 2011 study from the Workers’ Compensation Research Institute (WCRI) found that Washington’s prescription drug payments per claim were 40% lower than the median of the other 17 states studied. The main reasons for lower prescription costs included lower prices per pill paid to pharmacies, more frequent use of cheaper generic drugs in place of brand name drugs and infrequent physician dispensing. (Wang & Lui, 2011).

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7 “N” Drugs are those drugs that require preauthorization before dispensing.
In addition to results seen by these states, two workers' compensation research institutions have studied the potential impact of formulary adoption in workers' compensation.

**WCRI STUDY**

A Workers Compensation Research Institute (WCRI) study published in June 2014 evaluated potential savings of implementing a formulary, like Texas, for 23 states.\(^8\) The findings indicated that prescriptions could be reduced between 3% and 13% and prescription costs could be reduced by 2% to 29%. (Thumula & Lui, 2014).

**CWCI STUDY**

A study by the California Workers' Compensation Institute (CWCI) published in October 2014 evaluated potential savings if a closed formulary, like Texas, or a preferred drug list, like Washington, was implemented in California. For the Texas model, prescription drug costs could potentially be reduced by 18% ($182M). For the Washington model, prescription drug costs could potentially be reduced by 45% ($459M) (Swedow, Hayes, & David, 2014).

As discussed earlier, inappropriate prescription drug use can impede health and return to work outcomes, therefore, a decrease in potentially harmful prescription drugs should result in improved outcomes for injured workers. Jurisdictions need to clearly define desired outcomes and how they will measure and monitor results.

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\(^8\) Alaska, California, Connecticut, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, North Carolina, Pennsylvania, South Carolina, Tennessee, Virginia and Wisconsin
JURISDICTIONAL CONSIDERATIONS

A jurisdiction evaluating a formulary must consider the following:

- Goal of formulary implementation and intended impact on stakeholders;
- Existing statutory and regulatory structure;
- Formulary design and maintenance;
- Implementation strategy;
- Administrative costs to implement, maintain, educate, and evaluate;
- Current or needed review or pre-authorization process;
- Medical dispute resolution process; and
- Stakeholder input and priorities.

A jurisdiction’s goals and unique environmental factors will influence their decisions regarding each of the items noted above. The following sections include general information on these considerations, more specific responses can be found in the state snapshots included in the State Snapshots Section of this paper.

STATUTORY AND REGULATORY AUTHORITY

Workers’ compensation policymakers will find it useful to examine the controlling statutes to confirm their ability to implement a formulary. If there is any ambiguity as to the statutory authority to promulgate such a rule, new legislation may be necessary to effectively adopt, implement, and minimize the impact of legal challenges. These challenges could include:

- Applicability of the formulary;
- Compliance;
- Oversight;
- Enforcement; and
- Ability to measure effectiveness.

Analysis of existing regulatory framework on medical decision making and medical dispute resolution is necessary to support effective formulary implementation. Most jurisdictions that have adopted a workers’ compensation formulary had existing treatment guidelines in place, so the statutory and regulatory authority was already in place.
FORMULARY DESIGN AND MAINTENANCE

Key: A formulary should be based on medical evidence and be regularly maintained.

There are many factors to consider when evaluating formulary design. A jurisdiction will want to adopt a formulary based on medical evidence. Some factors to consider in this area include:

- Proprietary, commercial, or hybrid formulary;
- Efficacy of the drug to treat the injury or illness;
- Safety of the drug;
- First line therapy;
- Non-pharmacological treatment options that should be tried in advance of prescription medication; and
- Drugs that require additional evaluation before prescribing.

Jurisdictions will want to consider whether to build a proprietary formulary or buy a commercial product. Development of a proprietary formulary should be done by a group of credentialed and credible healthcare providers (e.g., pharmacists, doctors, and nurses) with pharmacy experience. The formulary should be based on objective medical evidence.

Commercial guidelines should be evaluated on their evidence base, ease of use, cost, maintenance schedule, and other factors important to stakeholders. There are currently two commercial formularies that serve the workers’ compensation market:

**Official Disability Guidelines Treatment in Workers’ Compensation, Appendix A, ODG Workers’ Compensation Drug Formulary.** The ODG Drug Formulary 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 Drug status is derived from the evidence-based recommendations in the chapters from *ODG Treatment in Workers’ Comp (ODG Website)*. More information can be found at [http://www.worklossdata.com/drug-formulary.html](http://www.worklossdata.com/drug-formulary.html)

**ACOEM Formulary: The ACOEM Formulary** is based on the *ACOEM Practice Guidelines* and is published by Reed Group on the MDGuidelines website. This formulary is condition specific and provides evidence support for therapeutic agents in the acute and chronic phases. More information can be found at [http://www.mdguidelines.com](http://www.mdguidelines.com)

Adopting a proprietary formulary can be as simple as stating that any drug covered for a previous period (e.g., 3 years, as in Ohio) will be initially considered as a formulary drug. Then going forward, payment for any drug not previously covered will require a review by the P&T Committee, for formal admission to the formulary.

After the formulary is adopted, the P&T Committee can begin a systematic review of the drugs covered within each drug class based on current clinical standards and best practice guidelines. As drug
classes are evaluated, individual drugs can be deleted from the formulary, and specific electronic edits, such as step therapy requirements or quantity limits, can be implemented.

All new drugs coming to market must be reviewed by the P&T Committee before being permitted as a part of the formulary. The formulary rule must provide for an expedited process to allow for the payment of therapeutically unique or clinically critical medications. Examples of these situations would be the introduction of the new class of oral anticoagulant agents and the anti-viral medications that treat Hepatitis C.

The formulary must include a process for prescribers to request that a drug be reviewed for addition to the formulary. The P&T Committee must be an integral part of this process and must be made aware of such requests from prescribers. Acceptance of a formulary by the various stakeholders depends on the P&T Committee being seen as a body of clinicians whose decisions are driven by best prescribing practices and best therapeutic outcomes for injured workers.

Jurisdictions will also want to consider the scope of their formulary. For example, do they want an inclusive formulary that includes a status for all FDA drugs or a restrictive formulary that prohibits certain drugs or classes of drugs? An inclusive formulary offers more prescribing choice. However, an inclusive formulary may increase the prescribing of other drugs. Additionally, an inclusive formulary offers no guidance on whether a specific drug is indicated as an effective treatment for a given condition.

A formulary must be regularly maintained in order to be effective. Formulary regulations need to allow for updates on a regular basis as new medicines and new research on existing medicines will impact the benefit status of medications within a formulary. A jurisdiction may want to specifically indicate “current edition” of any adopted commercial formulary.

For example, when drug manufacturer Zogenix introduced a new long acting opioid, Zohydro ER to the market, many in the medical community were opposed to this medications’ approval by the FDA because it was developed without an abuse deterrent formulation and because the majority of votes from the FDA approval panel were against approving this medication. As a result of the controversy surrounding Zohydro ER, the drug was added to a commercial vendor’s “N” or not recommended drug. The states who had adopted the commercial vendor’s formulary did not have to engage in rulemaking, as existing rules allowed the state to bypass any additional approval process.

Similarly, when new medical evidence supports the removal of a drug from a formulary, there must be a mechanism to ensure patients are safeguarded from being unilaterally cut off from medications, especially where there may be a risk of adverse reaction.

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9 After the implementation of the formulary in Texas, PBMs reported an increase in prescriptions not indicated by the treatment guideline as appropriate for a particular condition (Helios Report, Working Together to Achieve Better Outcomes, How Using a State-Specific and PBM Formularies is a Benefit).
**Step Therapy**

Step therapy is a utilization management strategy that is frequently used to ensure dispensed medications are both cost effective and medically appropriate as a first line of treatment. Effective lower cost medications are suggested to be used initially, before the patient can be prescribed a higher cost medication. Step therapy plans take several factors into consideration: the availability of multiple therapeutically equivalent drugs, over-the-counter medications for the accepted medical condition, and the cost. Some step therapy programs may also factor in the risk of side effects to the patient and, in some states, drug rebates can be a consideration.

PBM systems are programmed with coverage rules, called “edits”, which can be used to flag medications that are prescribed out of sequence. These edits are based on the insurer’s coverage rules, or the state’s specific formulary or preferred drug list. They are applied at the point of sale so the pharmacist is made aware that the payer or state rules require the patient to first try a more cost effective medication prior to the drug which was initially prescribed.

An example of a common step therapy is the use of the medication Celebrex.

_Celebrex is one of the highest cost non-steroidal anti-inflammatories (NSAIDs) and it has some properties that protect against stomach ulcers, a common side effect of long term NSAID use. Step therapy is often incorporated for Celebrex because there may be only a small subset of NSAID-using patients who require the ulcer protection offered by Celebrex, and if this feature is not needed, a lower cost medication may be as effective at a significant savings. Step therapy edits may message back to the pharmacy that a more cost effective NSAID should be tried first. The pharmacist will then contact the prescriber to determine if the lower cost medication can be substituted._

This utilization management strategy is incorporated into the state formularies adopted in Delaware, North Dakota, Ohio, and Washington.

**Legacy Claims**

**Key: New and legacy claims should be required to use the formulary, but a grace period for legacy claims should be considered.**

Legacy claims are those claims with dates of injury prior to the effective date of a formulary. Legacy claims will likely have existing prescription drug use and immediate application of a formulary may create dangerous medical situations. For example, cutting off a long-time opioid drug user without a tapering program could lead to serious withdrawal symptoms including anxiety, abdominal cramping, nausea, diarrhea, and even death. A claim with drug(s) used for years will likely require additional intervention, including a tapering program and/or cognitive behavioral therapy (CBT). A remediation period for addressing legacy claims is paramount for success.

Texas had a two-year delay before implementing the formulary for legacy claims. This gave providers and payers ample time to work on treatment plans to wean injured workers off drugs that would not be
allowed under the formulary. Other jurisdictions have considered a one-year remediation period before requiring legacy claims to be subject to the formulary.

A workers’ compensation drug formulary, just like those in private healthcare settings, should be implemented to accelerate the delivery of appropriate medications to the patient. A critical component to meeting this objective is stakeholder education. It is important that all system stakeholders understand how the formulary will be used, what the pre-authorization process is, and the timeline for implementation.

**DISPUTE RESOLUTION**

**Key:** Dispute resolution process should be based on evidence based medicine and be timely.

There must be a formal mechanism for physicians, pharmacies, and claims administrators to communicate and resolve medical disputes for accepted claims, and timely intervention by the regulator when the parties involved cannot agree.

The exclusion of a drug from the formulary may not mean it cannot be prescribed, rather it could require the prescriber to validate its medical necessity. The prescriber may then be required to provide evidence as to why this particular drug is required for the patient at the time. This process may already be in place within a jurisdiction’s existing utilization or peer review process, and care must be taken to ensure that formulary rules and treatment guidelines are not in conflict.

If medical necessity for a specific drug is established, the prescription should be allowed. If medical necessity for the specific drug is not substantiated, the prescriber would then be required to comply with the formulary. In cases where a delay in the start or continuation of a drug’s use could potentially create a medical emergency for the patient, an expedited dispute process should be available by which a rapid determination can be made. Jurisdictions should have an appeal process for a decision related to a formulary.

**STAKEHOLDER INPUT AND EDUCATION**

**Key:** Educate every stakeholder before, during, and after implementation.

Many state workers’ compensation agencies have advisory committees to discuss regulatory and legislative proposals. Advisory committee composition can include appointed members who represent various stakeholder interests including labor, management, claims administrators, and medical providers.

These bodies do not have binding authority to promulgate or adopt rules, but they do have significant influence on the regulatory process. If an advisory committee supports a proposal, it may be a predictor of support from the larger stakeholder community.
The administrative agency should be prepared to educate all stakeholders clearly and consistently. Clear, consistent, and preferably free education needs to be provided to all health care providers including pharmacists, attorneys, payers, supporting vendors, employers, and even injured workers as to how the formulary was constructed, how it will be implemented, and how best to comply. Education should be offered before, during, and after implementation.

Providing access to an online resource center may also be helpful in the education process. A resource center could provide key documents, key dates, frequently asked questions (FAQs), rules and statutes that define the formulary, and the complete formulary.

### Role of the Pharmacist and Pharmacy Benefit Manager (PBM)

**Key:** Pharmacists and PBMs are integral to formulary compliance and preauthorization approval.

Together, the pharmacist and PBM play a key role in the implementation of a formulary and in provider and claims administrator compliance. The pharmacist utilizes their software platform to communicate with the claim administrator, usually through the claim administrator’s PBM. The PBM has the claim administrator’s claim eligibility data as well as other clinical data that is needed to respond to the pharmacist’s request for approval to dispense a drug. The following is a list of common eligibility data provided to PBMs by the claims administrator:

- Claimant name, address, date of birth, social security number
- Employer name and address
- Claims administrator claim number
- Date of injury
- Benefit state or claim jurisdiction
- Claim status (open/closed)
- Compensability status (accepted/denied claim)
- Body part injured
- Diagnosis information

This eligibility data helps the pharmacist and PBM systems to identify when a state adopted formulary is applicable for the injured worker and the prescription presented at the pharmacy. PBMs program their systems to recognize which drugs require preauthorization for which states. This enables the PBM to send an automated message back to the pharmacy which either endorses the dispensing of the drug or flags the transaction for the claims administrator to review or approval based on state specific regulations.

If the drug requires additional authorization or review the PBM can instantaneously notify the pharmacist and the insurer that additional action is needed prior to dispensing. This notification prompts the insurer to initiate the jurisdictionally required steps to determine if a non-formulary drug should be approved or not. What happens next is dependent on the state specific regulations. Some states
require the physician to send the insurer a letter of medical necessity; other states require peer review or utilization review.

Whatever the workflow, the insurer must respond to the request; this is where there are some checks and balances to the process. If the insurer fails to respond in a timely manner, in most states the medication may automatically be deemed approved, and the pharmacist is authorized to dispense.

Both the pharmacist and the PBM help to speed up the approval process for any medication which requires additional review by the carrier. Without this type of automation built into the pharmacist and PBM systems, injured workers would be faced with long delays in gaining approval for medications to be dispensed.

**INTEGRATION WITH DISPENSING PROCESS**

Key: The drug formulary should be easy to use and integrate into the prescribing and dispensing process.

A drug formulary should be easy to use and integrate into the prescriber, pharmacy and PBM workflows and software systems. Each of these stakeholders has a role in the approval processes beginning with the prescriber. Figures 1 and 2 demonstrate the dispensing workflow.

**Figure 1: PBM Model Process – Non Formulary**
If the prescriber is aware of the formulary at the time of the office visit they can be prepared to quickly respond and prescribe accordingly to the jurisdictional requirements associated with approval for the prescribed drug. If the prescriber is not aware of the formulary, the pharmacist and the insurer, either directly or through the PBM, are integral to capturing and exchanging data which will help automate the approval process. The pharmacist transmits the prescription to the insurer through the PBM, who in turn will respond in real time with either an approval message or a preauthorization message back to the pharmacy and the insurer. This messaging usually initiates an insurer work flow including utilization review and requests for letters of medical necessity.
Drug Utilization Review (DUR)

Key: Pharmacists and PBM systems identify potential safety issues with automation

Drug Utilization Review (DUR), is defined as an authorized, structured, ongoing review of prescribing, dispensing and use of medication. DUR involves automating drug review against predetermined regulatory and/or business rules, which may result in changes to drug therapy when certain criteria are not met (END NOTE: Academy of Managed Care Pharmacy. Drug Utilization Review, 2009. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9296). DUR can be done prospectively, concurrent and retrospectively.

In Workers Compensation claims, prospective DUR is an inseparable part of the pharmacy and PBM workflow. Prospective DUR is an automated process driven by the pharmacist entry of a script into their system, sending it to the PBM, who then uses computerized algorithms to perform critical checks that incorporate drug specific clinical information, payer specific or state specific requirements. In prospective DUR this automation occurs in real time. The data in the patient’s profile will trigger a soft or hard “edit” which results in a message to the pharmacist. These messages contain standard language such as:

- Drug - drug interaction identified
- Therapeutic duplication (multiple similar medications for the same patient)
- Drug inappropriate for gender (Viagra prescribed for a female patient)
- Patient drug allergy alert
- Early refill request (potentially signaling overutilization)

“Soft” edits may be overridden by the pharmacist, like a generic substitution message, while a “hard” edit would require a prior authorization from the payer in order to dispense the medication. Using prospective DUR, PBMs can work with the prescribing physician and dispensing pharmacy to explore alternative drug therapies, including lower cost generics or less expensive brands.

Drug utilization review is not to be confused with Utilization Review (UR) as it is used in the workers’ compensation statues and regulations. Utilization review is the evaluation of the medical necessity and effectiveness of requested medical services and is usually performed by a nurse or a physician. Utilization Review is often used in workers’ compensation claims to determine if a requested medical service or procedure will be covered by the insurer.

Prospective DUR is a tool used to ensure patient safety, speed identification of patient risk factors and improve patient care. This instantaneous access to patient’s medical and/or pharmacy record and automated screening and analysis allows for speedy determination on the appropriateness of the drug therapy prescribed, and can prevent the dispensing of lethal combinations of medications.
STATE SNAPSHOTS

As a part of this resource, subcommittee members interviewed jurisdictional leaders to learn more about their experiences with implementation of a formulary in workers’ compensation. The following snapshots are intended to give insight and lessons learned on the design, implementation, maintenance, and evaluation of a formulary.

NORTH DAKOTA

Quick Facts: North Dakota was one of the first states to adopt a formulary in 2006. The motivation for adoption was to ensure drugs with questionable efficacy or safety were not used inappropriately in the treatment of injured workers. The North Dakota Workforce Safety and Insurance (WSI) formulary is proprietary and regularly maintained by a P&T committee.

Background

Prior to implementation of the formulary, there were no effective controls to regulate or restrict use of medications with questionable efficacy or safety. A mandate already existed in statute requiring managed care for the medical portion of care received by the injured workers, but pharmacy had not been included during implementation.

It was North Dakota’s intent to restrict the use of medications with questionable safety and/or efficacy and to restrict the use of medications to those indications which were either FDA approved or those that had sufficient clinical trials proving efficacy for off-label use.

WSI began working on a formulary in 2005 and took one year to develop the complete formulary. The formulary went into effect in mid-2006.

WSI has treatment guidelines, but they are not used for formulary management. The Pharmacy & Therapeutics Committee reviews all new medications or formulations, as well as any new critical information on existing medications and this information is used to make decisions regarding the makeup of the formulary.

Description of the Formulary

North Dakota’s formulary is a proprietary formulary. A Pharmacy and Therapeutics (P&T) Committee comprised of three physicians and three pharmacists reviews new and existing medications with recommendations for the inclusion or exclusion onto the existing formulary. Those recommendations are brought forward to the public during a fee schedule hearing before final inclusion onto the existing formulary. All medications are given one of three formulary statuses: (F)-Open formulary, available at the point of sale; (PA)- Requires prior authorization prior to being dispensed; (N/F)- Non-formulary, not covered by the agency.
Any new FDA approved drug is considered N/F until it is reviewed by the P&T Committee.

For example:

*Celecoxib cap 200 mg is labeled “PA” and “MDD”, which requires pre-authorization and has a maximum daily dose of 2x daily.*

*Diclofenac Sodium Solution 1.5% is labeled “N/F” and is a non-formulary drug.*

WSI’s PBM publishes the formulary, which can be downloaded at: [https://www.usscript.com/Media/Default/docs/FORMULARY-WSI.pdf](https://www.usscript.com/Media/Default/docs/FORMULARY-WSI.pdf)

The P&T Committee reviews a quarter of the formulary at each of their quarterly meetings. Updates are presented during the fee schedule meeting twice a year. Formulary updates are published following those meetings.

The state of North Dakota restricts all treatments, including medications, considered to be experimental. Off-label use of medications is reviewed through a prior authorization process using a national drug information database. In addition, a literature search for clinical trials either supporting or refuting the indication in question is conducted, if needed.

**Implementation**

The implementation process took place over the span of one year. One fourth of the formulary was evaluated at WSI’s quarterly Pharmacy & Therapeutics Committee meetings, and an initial formulary was presented during a fee schedule hearing. Once that process was completed, WSI worked with its pharmacy benefit management vendor to implement the specific recommendations for our formulary.

Information on implementation of the formulary was included in WSI’s provider newsletter. In addition, a fax blast was sent to all pharmacies contracted with the PBM.

**Prior-Authorization Process**

Typically the prior authorization is initiated by the pharmacy. A point-of-sale message is sent back to the pharmacy indicating that the medication does require prior authorization and to call Workforce Safety & Insurance (WSI). If the indication for use is one in which WSI has already determined is related to the work injury, then a prior authorization is entered into the claims system by the pharmacy department, which is sent twice daily to the WSI PBM.

If a liability determination has not been made, then a form is sent to the claims adjustor listing all of the approved indications (both on label and off-label) for that medication. The claims adjustor makes the decision whether the specific indication that the medication is being prescribed for is related to the work injury or not. Once that determination is made, then either a prior authorization approval or denial is entered into WSI’s claims system by the pharmacy department, and that information is sent to the PBM.

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10 WSI relies on their PBM to develop the document posted online. There are minor differences in the legend included in the publication and the status given to each drug by the WSI P&T Committee.
In addition, the pharmacy is notified of the status of the prior authorization request directly by the pharmacy department.

This process can also be initiated by the prescriber, either by a phone call or by completing a specific medication prior authorization form.

WSI has a utilization review process. Medication prior authorizations are generally not included in that process. The exceptions are requests for Prialt, Botox, and hyaluronic acid.

**Enforcement**

Enforcement is done by WSI’s PBM dependent upon the specific formulary status of the medication in question or by receipt of a prior authorization decision twice daily.

**New vs. Legacy Claims**

In general the process is the same for both new and legacy claims. Depending on circumstances, a grandfather provision has been used. An example was the implementation of step therapy for the proton pump inhibitors. Existing claims for these agents were grandfathered and only claims with an initial prescription for a proton pump inhibitor were subjected to the step therapy criteria.

**Dispute Resolution**

Any disputes are handled through binding dispute resolution. Either the prescriber or injured worker can initiate a request for reconsideration. Any additional information supplied by the provider is reviewed and the initial decision is either reversed or upheld. WSI has a binding dispute resolution office who consults with the Pharmacy Director, claims adjuster, and claims supervisor in making the determination. If upheld, there is no additional recourse to overturn the decision.

There is no expedited dispute resolution process in place.

**Outcomes**

Implementation of a formulary has allowed the state the ability to restrict medication use to those medications which have clinically demonstrated safety and efficacy while also demonstrating cost effectiveness. Use of a prior authorization process also allowed control over the use of medications only for FDA approved indications or for those indications in which there are good clinical trials to demonstrate effectiveness. This process has also allowed the initiation of step therapy protocols to ensure that less costly alternatives have been tried before more costly alternatives. WSI has also been able to establish daily dosage limits to ensure the safety of our injured workers.

**Recommendations**

*Lessons Learned*

- Look at existing enabling language that can be used to initiate a formulary. The formulary is considered a form of managed care and existing authority may exist.
Choose a PBM that is effective and has the infrastructure in place to implement the type of formulary that your jurisdiction chooses.

Hindsight

- We would have been more aggressive initially in restricting medications based on cost and not only on approved indications. This includes earlier adoption of step therapy protocols.
Ohio

Quick Facts: Ohio implemented a formulary in 2011, which is described in statute O.A.C 4123-6-21.3 and appendix. The rule-making timeline was 18 months for the initial formulary and revisions took 5-6 months. The political process involved stakeholders at the beginning including medical associations, plaintiffs’ bar, unions, and employer associations. From an educational perspective, there were numerous meetings with professional groups (e.g., plaintiffs’ bar and medical associations), mailings to prescribers and pharmacies, and articles in stakeholder publications.

Revisions in drug coverage have been made to the formulary since September 1, 2011. The most recent update took effect on December 1, 2015 and impacts 9 drugs in 4 different drug classes. There have been discussions around the feasibility and advantages of utilizing a modified version of the ODG list.

Background

The Ohio Bureau of Workers’ Compensation (BWC) drug formulary has been in place since September 1, 2011.

Prior to the formulary’s adoption, the prescription benefit for injured workers of State Fund employers was controlled through a Preferred Drug List, a Non-Preferred Drug List, and a Relatedness Drug List. These controls on prescription coverage were initiated in 2005. Due to a lack of full organizational support and administrative oversight, they were only marginally effective in improving drug utilization. The prescription processing system utilized by the Prescription Benefit Manager (PBM) electronically applied them at the point-of-sale. The relatedness edit looks for a link between the allowed conditions in a claim and the common indications for a drug. In the beginning, it was applied to 65 drug classes. As of August 2015, it is applied to 373 of the 405 drug classes in the formulary.

Before the implementation of the BWC formulary, all limitations on drug coverage were subject to a Prior Authorization (PA) process. This meant any drug requested on a PA form could be approved for use by a BWC claims staff member or physician reviewer. By Rule, only an independent physician peer reviewer could deny a PA drug request (or any other treatment). In practice, most requested drugs are approved by claims or clerical staff and not referred for independent physician peer review. Oversight and control of pharmacy related activities was disseminated across multiple areas of BWC. There was no pharmacy director or defined pharmacy department.

In mid-2009 a pharmacy program was established and staffed. In 2010, work began on the development of the tools necessary to properly oversee drug utilization. The Pharmacy & Therapeutics (P&T) Committee functioned as a sub-committee of a Quality Assurance Committee and had no defined authority or responsibilities. A rule was introduced into the Ohio Administrative Code (OAC 4123-6-21.2) giving structure, authority, and responsibility to the P&T Committee. Among other duties, it made the committee responsible for the development and maintenance of a drug formulary. The rule was adopted in January 2011.
With a committee administratively responsible for the development of a formulary, work began in earnest on creating the final document. Early in 2011, multiple stakeholders were engaged (i.e. medical organizations, health care organizations, and legal organizations), the formulary was given definition, and how it would be utilized was explained. It was determined the formulary would be driven by the clinical, not claims or fiscal, data.

By mid-2010, a decision was made that the BWC drug formulary should be written into the Administrative Code and should be “closed.” This meant any addition, deletion, or limitation to a drug must be accomplished through a Chapter 119 Hearing Process as it appears in the Ohio Revised Code. This provision in the Code requires two hearings before the BWC Board of Directors, a formal report on all stakeholder feedback, a Business Impact Analysis filed with and approved by the Lt. Governor’s office, a public hearing on the proposed rule or revision, and finally a hearing before the Joint Committee on Agency Rules Review of the legislature. Typically this process takes 5-6 months.

In the context of the number of drugs and drug classes that must be covered by a commercial insurance carrier, workers’ compensation plans utilize a relatively small number. The effect has been ongoing maintenance of the closed formulary has proven not to be an issue. In addition, the formulary rule contains language for emergency drug coverage. In unique clinical situations or for a new drug with significant therapeutic value, the BWC is permitted to cover a drug for six months while it is undergoing review by the P&T Committee. Since implementation of the formulary, this provision has only been used in five instances.

A very simple process was utilized to select the drugs included in the initial formulary. If a drug was covered during the preceding three years, it was included in the initial formulary. The only exception to this selection method was the skeletal muscle relaxant drug class, which was the first class of drugs where limitations were applied. All carisoprodol products were deleted from coverage and a 120-day duration of therapy was established for the remaining agents in the class. This limitation became effective for new prescriptions and new claims on September 1, 2011. For injured workers who were receiving a muscle relaxant before the implementation date, the restrictions were made effective in their claims on January 1, 2012.

Since implementation, there have been seven formulary revisions. These changes involve 14 different drug classes. The Rule appendix lists all drugs covered as well as any coverage restrictions.

**Description of Formulary**

The formulary began by including most of the drugs already covered. It stopped the use of new medication without P&T Committee action and formal rule revision. Likewise, it allows for a systematic review of drug classes for potential limitations going forward. If a drug is not listed in the appendix to the rule (OAC 4123-6-21.3) it can only be covered under two scenarios:

I. Pursuant to an administrative hearing, the Industrial Commission (IC) of Ohio orders the BWC cover a specific drug in a specific claim.

II. The rule (paragraphs F & G) allows for coverage of a non-formulary drug under specific clinical situations for a 6-month period while the drug is reviewed by the P&T Committee.
This exception is used to cover unique prescriptions (e.g. in organ transplant patients) or new pharmacological entities (Hepatitis-C treatment).

**Implementation**

Implementation was relatively anti-climactic. During the six months preceding implementation, significant efforts were expended to meet with medical associations, the plaintiffs’ bar, as well as specific opinion shapers within those groups. Steps were taken to ensure key members of the legislature were informed of the work and the reasoning behind the formulary. At each meeting the message from the BWC was consistent:

- The formulary is being implemented to improve injured workers’ care;
- Decisions are being driven by a committee of practicing physicians and pharmacists; and
- The focus is on proper utilization of medication, not choosing the least expensive drugs.

Since there have been no serious challenges or vocal criticisms from medical or legal organizations to the closed formulary, it appears the BWC’s strategy and efforts were successful.

**Prior-Authorization Process**

The pre-authorization process does not apply to a non-formulary drug. The only appeal process for a non-formulary medication is through the Industrial Commission Hearing process.

**Enforcement**

The formulary is enforced at the point-of-sale by edits in the PBM software.

**New vs. Legacy Claims**

There is no difference in coverage between a new claim and old claim. Coverage of any medication in all state fund claims is subject to the formulary rule. When revisions are made to the formulary, “legacy” claims are given time (typically 2-6 months) to move to another formulary drug. At implementation the only significant change for “legacy” claims was the removal of coverage for carisoprodol products. The BWC allowed three months for transition to different muscle relaxants.

**Dispute Resolution**

In Ohio, the Industrial Commission (IC) oversees the administrative decisions of the BWC. An injured worker can appeal the non-coverage of a medication to the IC and request coverage. This generally takes 4-6 weeks for a hearing. Hearings are formal, with both parties represented by counsel. At times, treating physicians provide live testimony or attend by conference call. If there is an emergency or a life sustaining issue (most appeals have not), there is an expedited process. Overall, the IC hearing officers believe the formulary is binding because it is in the administrative code and alternative medications are available in the formulary.
Outcomes

The initial focus of the formulary was on three drug classes – opioids, skeletal muscle relaxants, and anti-ulcer medications – because these were seen as the most frequently over-prescribed in workers’ compensation (Hanna, Ohio Bureau of Workers’ Compensation). Changes since adoption have been made, through the Rule Revision process, affecting the coverage of benzodiazepines, hypnotics, and anti-psychotics.

The following changes in utilization were documented for 2014 in comparison with 2010, the last full year of drug coverage before the formulary adoption:

Table 1: Ohio Formulary Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Number of Prescriptions</th>
<th>Total Doses</th>
<th># Scripts per injured worker</th>
<th>Total doses per injured worker</th>
<th>Total drug cost (%)</th>
<th>Total drug cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioids</td>
<td>-38%</td>
<td>-37%</td>
<td>-19%</td>
<td>-17%</td>
<td>-23%</td>
<td>-$19.9M</td>
</tr>
<tr>
<td>Anti-Ulcer</td>
<td>-83%</td>
<td>-80%</td>
<td>-19%</td>
<td>-8%</td>
<td>-95%</td>
<td>-$6.43M</td>
</tr>
<tr>
<td>Anti-Anxiety</td>
<td>-24%</td>
<td>-24%</td>
<td>+1%</td>
<td>+2%</td>
<td>-28%</td>
<td>-$254K</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>-11%</td>
<td>-14%</td>
<td>-8%</td>
<td>-11%</td>
<td>+23%</td>
<td>+$1.86M</td>
</tr>
<tr>
<td>Non-Barbiturate hypnotic</td>
<td>-25%</td>
<td>-41%</td>
<td>+2%</td>
<td>-20%</td>
<td>-51%</td>
<td>-$3.02M</td>
</tr>
<tr>
<td>Muscle relaxant</td>
<td>-72%</td>
<td>-73%</td>
<td>-47%</td>
<td>-49%</td>
<td>-78%</td>
<td>-$2.87M</td>
</tr>
<tr>
<td>Total Doses</td>
<td>-33%</td>
<td>N/A</td>
<td>-14%</td>
<td>-10%</td>
<td>-16%</td>
<td>-$20.7M</td>
</tr>
</tbody>
</table>

Recommendations

Lessons Learned

- It will take more time than you think.
- Anticipate injured workers and their attorneys will use the legislature and other leverage points to attempt to keep getting the medication they want or have historically received.
- Do not attempt to sell the concept based on a fiscal argument. There should always be a sound clinical argument for your decisions in this area.
- Communicate with your agency staff. Make sure everyone in your agency understands why a formulary is necessary and how it is being developed.
- The P&T Committee is crucial to success. Recruit the best members possible.

Would do Differently Given Hindsight

- Require an agency commitment of dedicated IT resources and data/research analysts in order to track trends and outcomes more quickly and effectively.
- Pay more attention to ensuring better and regular organized communications.
TENNESSEE

Quick Facts: Discussion began on a formulary in 2014 and it was adopted in January 2016. It is described in regulation 0800-02-25 Workers’ Compensation Medical Treatment Guidelines, which took effect on February 28, 2016. The process involved the Administrator identifying stakeholders at the beginning including medical associations, plaintiffs’ bar, unions, and employer associations for advice and input. From an educational perspective, there were numerous meetings with professional groups (e.g., plaintiffs’ bar and medical associations), mailings to prescribers and pharmacies, and articles in stakeholder publications.

Background

Tennessee chose to evaluate and implement a formulary to address several challenges with inappropriate use and increasing cost of prescription use. Discussion with system stakeholders identified the following goals for formulary adoption:

- Improve patient safety and limit potentially dangerous drug-drug interactions.
- Reduce expensive drug combinations and dosages that do not have extra benefits.
- Make weaning and tapering easier.
- Give claims administrators some leverage over extra medications; some patients used workers’ compensation to pay for other medications so they did not have to pay co-pays or deductibles.
- Prevent retrospective utilization review which is a significant problem for all and creates an overly complex set of appeals.

The formulary was adopted at the same time as a comprehensive set of treatment guidelines. Tennessee adopted and posted the current edition, and any future published updates, of the Work Loss Data Institute ODG Guidelines as published by the Work Loss Data Institute. In addition, the Bureau subscribes to the recommendations of the State of Tennessee, Department of Health, Chronic Pain Guidelines, the Bureau of Workers’ Compensation Pain Management/Opioid Guidelines Appendix, and any other related appendices to the above references guidelines adopted by the Administrator.

Description of Formulary

The Drug Formulary is found in Drug Appendix A published and updated by the Work Loss Data Institute. The rule incorporates future updates and will be updated monthly. Any drug identified with the status “N” in the current edition of the ODG Appendix A shall require prior approval. Prescription of “N” drugs should only be done when supported by documentation of evidence-based medicine. The rule specifically notes that compound medications and topical applications are “N” and require prior approval.

Implementation

The first step in implementation was adoption of enabling legislation, T.C.A. § 50-6-124, part of the Workers’ Compensation Reform Act of 2013. The formulary was vetted through the Bureau’s Medical
A DISCUSSION ON THE USE OF A FORMULARY IN WORKERS’ COMPENSATION

Advisory Committee (MAC) made up of providers, insurers, case managers, and employers. All meetings of the MAC were open to the public. Rules, reflecting modifications suggested in the public comment period, public hearing, and accepted by the Bureau, were approved by the Attorney General and the Government Operations Committee. The final rules became effective February 28, 2016.

Prior-Authorization Process

The prior-approval process is through the insurer and/or pharmacy benefit manager. The patient as well as the insurer and/or PBM will receive notification during point of sale at the pharmacy. At that point, drugs that do not require prior approval may be dispensed without delay. Drugs that require prior approval (“N” drugs) may be sent through utilization review.

Enforcement

The formulary is not mandatory. Notification of the insurer’s policies will start at the pharmacy point of sale. Drugs that are not approved may not be covered by the carrier if dispensed by the pharmacist.

New vs. Legacy Claims

The drug formulary went into effect on February 28, 2016. The formulary applies for all claims with a date of injury on or after January 1, 2016. New prescriptions written after January 1, 2016 are given six months after the effective date to be subject to the formulary. Refill prescriptions written before January 1, 2016 are given a year following the effective date.

Dispute Resolution

An appeal for a denied medication can be made to the Tennessee Bureau of Workers’ Compensation. The appeal is governed by the utilization review appeal process, described in the program rules, section 0800-02-06 and in T.C.A. § 50-6-102(20).

An expedited determination, for those denials that may pose an unreasonable risk of a medical emergency, may also be requested from the Bureau’s Medical Director.

Outcomes

The Tennessee’s formulary adoption is very recent, so there are no outcomes to share at this time.

Recommendations

Lessons Learned

- Gain the support of insurers and PBMs.
- Learn from the experiences of other states and use that learning in the development of your jurisdiction’s program.
- Explain the process clearly and as often as you can.
- Retrospective denials, the prior approval process, and utilization review should be integrated and consistent.
“First fill” timeframes should be clearly delineated.
Notification and educational efforts are time consuming, but vital.

**Would Do Differently**

- Be prepared for more questions.
Texas

Quick Facts: In 2005, the Texas Legislature directed the Commissioner to adopt both a closed formulary and evidence-based, scientifically valid, and outcome-focused treatment guidelines. The closed formulary was adopted in 2010 and went into effect on September 2011. Texas implemented the formulary in two phases, immediate adoption for claims with a date of injury (DOI) after the formulary effective date and delayed adoption for claims with a DOI before the effective date. The Division maintains a comprehensive history and multiple documents at: http://www.tdi.texas.gov/wc/pharmacy/index.html

Background

In 2005 the 79th Texas Legislature passed House Bill 7 (HB7), which amended Texas Labor Code §408.028 concerning Pharmaceutical Services. The pertinent provisions stated: "The commissioner by rule shall adopt a closed formulary under Section 413.011. Rules adopted by the commissioner shall allow an appeals process for claims in which a treating doctor determines and documents that a drug not included in the formulary is necessary to treat an injured employee's compensable injury." Further HB7 required the Commissioner of Workers' Compensation to adopt by rule treatment guidelines that are evidence-based, scientifically valid, outcome-focused, and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care. The purpose of the treatment guidelines is to ensure the quality of medical care and to achieve effective medical cost control.

The adoption of a formulary was part of a comprehensive reform package and thus preliminary activity for the closed formulary did not begin until 2008.

ODG Treatment in Workers’ Comp is the Texas treatment guideline and became applicable on May 1, 2007. Appendix A of ODG Treatment in Workers’ Comp is the basis for the Texas closed formulary. As a result treatment recommendations and the closed formulary are consistent with each other.

Description of the Formulary

The Texas closed formulary is defined in Texas Administrative Code §134.500, Definitions:

(3) Closed formulary—All available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, but excludes:

(A) drugs identified with a status of “N” in the current edition of the ODG Treatment in Workers’ Comp (ODG) / Appendix A, ODG Workers’ Compensation Drug Formulary, and any updates;

(B) any compound that contains a drug identified with a status of “N” in the current edition of the ODG Treatment in Workers’ Comp (ODG) / Appendix A, ODG Workers’ Compensation Drug Formulary, and any updates; and
A DISCUSSION ON THE USE OF A FORMULARY IN WORKERS’ COMPENSATION

(C) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care as defined in Labor Code §413.014(a).

Work Loss Data Institute maintains ODG Treatment in Workers’ Comp (ODG) / Appendix A, ODG Workers’ Compensation Drug Formulary with updates published monthly. A list of drugs excluded from the formulary is available on the Division of Workers’ Compensation website and is updated monthly to reflect changes in Appendix A.

There is no blanket policy regarding “off-label” use in the formulary. In some instances drugs that have been identified with common “off label” uses are individually addressed by the formulary. An example of this is Gabapentin (Anti-epileptic) – used for neuropathic pain

The following is an excerpt from the ODG Closed Formulary:

Recommended for some neuropathic pain conditions and fibromyalgia. (Wiffen-Cochrane, 2013) In treating diabetic neuropathy and postherpetic neuralgia compared with placebo, gabapentin is associated with a modest increase in the number of patients experiencing meaningful pain reduction. (Moore, 2014) Gabapentin is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Gabapentin listing for more information and references. See also Gralise (gabapentin enacarbil ER); Horizant (gabapentin enacarbil ER).

Implementation

Although the closed formulary was not applicable to any claims until September 1, 2011, the development of the closed formulary rules laid the groundwork for the education and communication activities necessary to successfully implement the closed formulary.

During rule development activities, the Division met numerous times with stakeholders individually and in groups to solicit input regarding the closed formulary. The Division posted informal working draft rules and solicited comments on the draft rules. Additionally, three stakeholder meetings were held to discuss the informal working draft rules. This led to a strong, collaborative working relationship between insurance carriers, health care providers, pharmacies, pharmacy benefit managers, and the Division. This process allowed time for stakeholders to participate in rule development and to understand the intent and impact of the rules.

After adoption of the rules, the Division had eight months to inform and educate system participant about the impending applicability of the closed formulary. The Division hosted over 30 events including seminars, webinars, education sessions, and group practice presentations throughout the state to help system participants prepare for the implementation of the closed formulary.
The Division also has detailed information concerning the development, implementation, and current operation of the closed formulary is posted on the pharmacy page of the Division’s website at http://www.tdi.texas.gov/wc/pharmacy/index.html

Additionally, the Division provides support through its annual education conference, seminars, field office educational sessions, and its ongoing provider outreach activities. The Division also engages stakeholders through quarterly meetings directed to insurance carrier and health care providers. The Comp Connection for Health Care Providers, 1-800-372-7713, provides one-on-one assistance to the health care provider community who serve injured employees.

After the initial implementation of the closed formulary the Division turned its focus to the transition of legacy claims to the closed formulary. The Division offered approximately 30 additional educational opportunities regarding the closed formulary and reminded insurance carriers and prescribing physicians of their responsibilities concerning legacy claims.

The Division provided communication tools for insurance carriers to use to initiate and facilitate discussions with prescribing physicians about transitioning legacy claims to the closed formulary. The Division monitored this activity through three insurance carrier data calls and meetings with medical directors and administrators of individual insurance carriers.

Prior-Authorization Process

Preauthorization requirements for the Texas workers’ compensation system are set out in Texas Administrative Code §134.600 Preauthorization, Concurrent Utilization Review, and Voluntary Certification of Health Care and Texas Administrative Code Chapter 19 Subchapter U relating to Utilization Reviews for Health Care Provided under Workers’ Compensation Insurance Coverage. In Texas, utilization review is considered the practice of medicine and all utilization review must be performed by an insurance carrier that is registered with, or a utilization review agent that is certified by, the Texas Department of Insurance to perform utilization review in accordance with Insurance Code, Chapter 4201 and Texas Administrative Code, Chapter 19, Agents’ Licensing.

The adopted treatment guidelines which include the formulary must be considered when a utilization review decision regarding medical necessity is made.

Enforcement

Pharmacies and pharmacy benefit managers have access to the list of drugs requiring preauthorization. For items excluded from the closed formulary, preauthorization is a requirement for reimbursement. If preauthorization is not approved prior to provision of the service, the bill will be denied for administrative reasons. There is not a second opportunity to retrospectively approve the prescription.

New vs. Legacy Claims

There was a bifurcated applicability process for the implementation of the closed formulary after the closed formulary rules were adopted in December of 2010. Beginning September 1, 2011, the closed formulary applied to claims with a date of injury (DOI) on or after September 1, 2011. Claims with a DOI prior to September 1, 2011 were designated as legacy claims. The closed formulary became applicable
to legacy claims on September 1, 2013. The closed formulary does not apply to “old law” claims (i.e., claims with a DOI prior to January 1, 1991).

Dispute Resolution

Medical necessity disputes may be pursued through Texas Administrative Code §133.308, MDR of Medical Necessity Disputes. Each independent review organization (IRO) performing independent review of health care provided in the workers' compensation system shall be certified pursuant to Insurance Code Chapter 4202 and Texas Administrative Code Chapter 12, Independent Review Organizations. The IRO decision must include an analysis of, and explanation for, the decision, including the findings and conclusions used to support the decision, a statement that clearly states whether or not medical necessity exists for each of the health care services in dispute, and if the IRO's decision is contrary to the division's policies or guidelines adopted under Labor Code §413.011, the IRO must indicate in the decision the specific basis for its divergence in the review of medical necessity of non-network health care.

A flow chart of the workers' compensation non-network independent review process can be found at: http://www.tdi.texas.gov/hmo/documents/wciroflowchart.pdf

If the dispute persists the parties may pursue a contested case hearing, review by the State Office of Administrative Hearings, and ultimately file suit in District court.

In an instance, when a drug excluded from the closed formulary has previously been prescribed and dispensed, preauthorization of the drug has been denied through the preauthorization process, and an unreasonable risk of medical emergency exists the prescribing physician or pharmacy may pursue a Medical Interlocutory Order (MIO) as described in Texas Administrative Code §134.550, Medical Interlocutory Order. This process shortens or eliminates some timeframes in the dispute process and allows for continued use of the drug through the duration of the dispute process. Since the initial implementation of the closed formulary, DWC has received 118 MIO requests. Sixty-two of the requests were approved, while the remainder were either withdrawn or the request was for a drug that did not require preauthorization.

Outcomes

Table 2: Texas Formulary Outcomes

<table>
<thead>
<tr>
<th>Type</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inured Employees receiving N-drugs</td>
<td>-65%</td>
</tr>
<tr>
<td>N-drug costs</td>
<td>-83%</td>
</tr>
<tr>
<td>N-drug costs as a percentage of all drug costs</td>
<td>-79%</td>
</tr>
<tr>
<td>Number of injured employees receiving other drugs</td>
<td>-1%</td>
</tr>
</tbody>
</table>
A DISCUSSION ON THE USE OF A FORMULARY IN WORKERS’ COMPENSATION

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>N-drug claims among all claims</td>
<td>-11%</td>
</tr>
<tr>
<td>Total number of prescriptions for N-drugs</td>
<td>-76%</td>
</tr>
<tr>
<td>Average number of N-drug prescriptions per claim</td>
<td>-31%</td>
</tr>
<tr>
<td>Generic substitution rate for N-drugs</td>
<td>13%</td>
</tr>
<tr>
<td>Number of N-drug prescriptions</td>
<td>-65%</td>
</tr>
<tr>
<td>Number of prescriptions for the ten most-prescribed N-drugs</td>
<td>-82%</td>
</tr>
</tbody>
</table>

Texas saw the following results for Legacy claims 12 months after applicability of the closed formulary:

- Legacy claims accounted for 38 percent of the claims and 57 % of the total pharmacy cost in September 2014.
- Legacy claims serviced in a month decreased from 35,604 in September 2011 to 12,215 in September 2014 (66 % decrease), mainly because there are no new claims added.
- The average pharmacy cost per legacy claim dropped by 18 percent in the first month they became subject to the pharmacy closed formulary (September 2013).
- Total cost of N-drugs decreased from $1.42 million in August 2013 to $607,000 in September 2013 (57 % decrease), and decreased to $290,000 in September 2014.
- For legacy claims, the share of N-drug cost in the total cost dropped from 18.5 % in August 2013 to 10.4 % in September 2013 (44 % decrease). N-drugs accounted for 6 % of the total cost in September 2014.

Recommendations

Lesson Learned

- Allow sufficient time to actively engage stakeholders prior to the adoption and implementation of the closed formulary.
- The adoption of a closed formulary is more easily explained if the focus is on medical necessity and appropriateness rather than cost.
- Transition to the closed formulary for individual claims works best when there are peer-to–peer discussions regarding treatment decisions.
- Other facets of the workers compensation system such as treatment guidelines, preauthorization, utilization review, and medical dispute resolution should be in place to support the effective implementation of the closed formulary.
Washington

State Snapshot: Quick Facts: Since 2004, Washington has been involved in an inter-agency effort to ensure safe and cost-effective use of prescription drugs. Washington Labor & Industries participates in the State’s Preferred Drug List (PDL) and also has an outpatient formulary. The PDL and formulary are used in conjunction with a pharmacy fee schedule to effectively manage prescription drug costs.

Background

In the early 2000s, prescription drug costs in Washington were one of the fastest growing components of healthcare spend. To address rising costs, Washington’s three largest healthcare purchasing agencies, Department of Social & Health Services for Medicaid, Health Care Authority, and Department of Labor & Industries, joined forces for pharmacy purchasing. Senate Bill 6088 (Chapter 29 Law of 2003) directed consolidated purchasing and called for the development of:

- Pharmacy & Therapeutics (P&T) Committee
- Evidence based PDL
- Endorsing Practitioner & Therapeutic Interchange Program (TIP)

A contractor reviewed evidence on effectiveness and safety of the 12 most costly and highly prescribed classes of drugs. These drug classes were then used to establish Washington’s PDL. The PDL was implemented by all three agencies on May 1, 2004. The number of included drug classes has since expanded to approximately 30 drug classes.

In addition to the PDL and Outpatient Formulary, L&I has treatment guidelines, including ones that address antiepileptic drugs for neuropathic pain and opioid guidelines for work-related injuries.

Description of the Formulary

L&I maintains an outpatient formulary, which is a list of drugs and therapeutic classes (or class codes) that can be used in an outpatient setting to treat a work-related injury or occupational disease. The outpatient formulary consists of a subset of the statewide PDL and a wrap-around formulary. It can be downloaded at: http://www.lni.wa.gov/ClaimsIns/Providers/TreatingPatients/Presc/default.asp.

The PDL

The PDL is an evidence-based list of drugs used by participating state agencies as the basis to purchase drugs within the state-purchased health care program. Drugs are given a status of:

- **Preferred drug:** A drug selected by state agencies as recommended by the P&T Committee or based on cost.
- **Non-preferred drug:** A drug that wasn’t selected due to inferior safety or efficacy or due to cost and may require prior authorization for coverage or placed on a higher cost copay tier.
Of the 30 PDL drug classes, L&I participates in 12 which are applicable to workers’ compensation (e.g. non-steroidal anti-inflammatory drugs, muscle relaxants, and antidepressants). The L&I PDL can be downloaded at: http://www.lni.wa.gov/ClaimsIns/Files/Providers/SelectedPDLforworkers.pdf.

Figure 3: The PDL Process

Washington participates in the Drug Effectiveness Review Project (DERP), conducted by Oregon Health and Science University, to access evidenced-based reports. They evaluate drug classes based on the following:

- Comparative effectiveness, safety, and special population of drugs within a class; and
- Quality of medical evidence including grading studies and rating the strength of the overall body of evidence.

The draft report is published by DERP for public comment. The final report is then reviewed by the P&T Committee which is made up of 10 actively practicing members in their area of clinical expertise from across Washington State. After evaluating the relative safety, efficacy, and effectiveness of drugs within a drug class they make a recommendation to the state on what drugs should be included in the PDL. The P&T Committee determines which drugs are equally safe and effective, or have advantages to special populations. Cost is not considered in their recommendation. The public has the opportunity to comment during this process.

A cost analysis is done on a separate basis. The state obtains bids for supplemental rebates from manufacturers prior to the P&T Committee meeting. Milliman then conducts an actuarial cost analysis of the drug classes which are being reviewed by the P&T Committee to determine which drugs result in the lowest net cost to the State.

The directors (designees) of each of the agencies makes the final decision as to which drugs will be included on the PDL. The State then notifies all stakeholders and implements PDL changes. Newly available drugs in PDL classes require prior authorization or are non-covered until reviewed by the P&T Committee.
Each drug class is re-reviewed on a yearly basis to summarize new evidence and identify new drugs and indications since the last review. The P&T Committee may request a single drug addendum which reviews drugs not included in the existing class. Another cost analysis is conducted with each review.

**Endorsing Practitioner & Therapeutic Interchange Program (TIP)**

A unique feature to the PDL is the therapeutic interchange program. TIP allows physicians and other prescribers to endorse the state’s PDL and requires pharmacists to automatically substitute the preferred drug for non-preferred drugs prescribed by these practitioners. However, if the prescription is a refill of an antipsychotic, antidepressant, chemotherapy, antiretroviral, immunosuppressive, or hepatitis C drug or the practitioner has indicated “dispense as written,” then the pharmacist shall dispense the prescribed non-preferred drug. If a drug is substituted, the pharmacist must notify the practitioner of the therapeutic interchange.

A non-preferred drug from a non-endorsed practitioner will not be paid unless the pharmacist or practitioner calls with medical justification.

**Wrap-around Formulary**

This term applies to drug classes which are covered under L&I’s benefits, but are not part of the PDL. For these drug classes, the department uses its rebate vendor’s national formulary for a base coverage. L&I also evaluates brand drugs for formulary consideration based on safety, efficacy, and cost relative to therapeutic alternatives.

**Prior Authorization for Non-preferred or Non-formulary Drugs**

The worker, pharmacist or provider has an opportunity to contact L&I’s PDL hotline to request authorization. If the request meets criteria for approval, hotline staff will authorize the drug. Otherwise, the request will be denied, and the caller will be referred to formulary alternatives. Requests for reconsideration will undergo a clinical review by either a nurse or pharmacist.

**Dispute Resolution**

Disputes can be resolved through a request for reconsideration. A provider has 60 days to protest a decision on a claim or a payment. L&I staff reviews the request and takes initial action within 14 days of receipt. L&I works to resolve all reconsiderations within 90 days. A provider can also appeal, either directly or subsequently, to the Board of Industrial Insurance Appeals.

**Outcomes**

The use of generics is very high in Washington. A 2011 WCRI Study showed only 6% of all prescriptions in Washington were brand name, compared to the 17-state median of 16% (WCRI Study). In the same study, the prescription cost per claim was among the lowest at just above $400 for claims with more than seven days of lost time. This was 40% lower than the median (Wang & Lui, 2011).
ADDITIONAL RESOURCES

Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines
- United States, 2012
Paulozzi, L., Mack, K., & Hockenberry, J.
CDC, Morbidity and Mortality Weekly Report, July 4, 2014
“Overprescribing of opioid pain relievers (OPR) can result in multiple adverse health outcomes, including fatal overdoses. Interstate variation in rates of prescribing OPR and other prescription drugs prone to abuse, such as benzodiazepines, might indicate areas where prescribing patterns need further evaluation.”
Download at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s_cid=mm6326a2_w

Decline in Drug Overdose Deaths After State Policy Changes - Florida, 2010-2012
Johnson, H., Paulozzi, L., Porucznik, C., Mack, K., & Herter, B.
CDC, Morbidity and Mortality Weekly Report, July 4, 2014
“During 2003–2009, the number of deaths caused by drug overdose in Florida increased 61.0%, from 1,804 to 2,905, with especially large increases in deaths caused by the opioid pain reliever oxycodone and the benzodiazepine alprazolam. In response, Florida implemented various laws and enforcement actions as part of a comprehensive effort to reverse the trend. This report describes changes in overdose deaths for prescription and illicit drugs and changes in the prescribing of drugs frequently associated with these deaths in Florida after these policy changes.”

“State policy makers might reduce the harms associated with abuse of prescription drugs by implementing changes that will make the prescribing of these drugs more cautious and more consistent with clinical recommendations.

The rates of use of pain relievers and benzodiazepine sedatives showed about three- to five-fold variation from the highest to lowest states. Variation was greater for the LA/ER and high-dose formulations of OPR. Higher OPR and benzodiazepine prescribing rates in the South presented in this report are similar to the findings of higher prescribing rates for other drugs in the South, including antibiotics (7), stimulants in children (8), and medications that are high-risk for the elderly (9). Previous studies have found that regional prescribing variation cannot be explained by variation in the prevalence of the conditions treated by these drugs (5,7). Other research indicates that wide variation in rates of surgery and hospitalization also cannot be explained by the underlying health status of the population (9,10). Wide variation in the use of medical technology, including pharmacotherapy, usually indicates a lack of consensus on the appropriateness of its use (9). Therefore, one possible explanation for the results of this study is the lack of consensus among health-care providers on whether and how to use OPR for chronic, noncancer pain.
Research on small-area variation in health care indicates that high rates of use of prescription drugs and medical procedures do not necessarily translate into better outcomes or greater patient satisfaction. In fact, high rates of use might produce worse outcomes (11,12). In this case, greater use of opioids and benzodiazepines might expose populations to greater risks for overdose and falls (2,3,13,14). Greater use is also associated with abuse (4), although such use might both cause and be caused by abuse."

Download at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a3.htm?s_cid=mm6326a3_w

**Higher Opioid Doses Predict Poorer Functional Outcome in Patients with Chronic Disabling Occupational Musculoskeletal Disorders**


“Opioids are frequently used for the postoperative treatment of chronic disabling occupational musculoskeletal disorders. In many such cases, long-term opioid use persists because of patient requests for ongoing pain relief. Little is known about the relationship between chronic opioid use and functional recovery in these patients.”

Download at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2665041/

**Natural History of Opioid Dosage Escalation Post-Injury: A Cohort Study of Injured Workers in the State of Louisina**

*Tao, X., Lavin, R., Yuspeth, L., & Bernacki, E.*

*Journal of Occupational and Environmental Medicine*, April 2012

“Closure rates and morphine-equivalent dose were analyzed over a 7-year period for 11,394 lost-time claims filed with the Louisiana Workers' Compensation Corporation. The percentage of claims in which opioids were ever prescribed increased from 43.3% in year 1 to 80.8% in year 7 post-injury. The percentage of claims in which individuals were prescribed long-acting (LA) opioids increased from 5.2% to 29.6%, and the percentage of claims in which individuals were prescribed only short-acting (SA) opioids increased from 38.1% to 51.2%. Morphine-equivalent dose increased from 10.0 mg/day (year 1) to 143.2 mg/day (year 7) for claims in which individuals were prescribed LA opioids. The average claim duration for claims in which individuals were prescribed no opioids, only SA opioids, and LA opioids was 415, 930, and 2025 days, respectively.”


**Early Opioid Prescription and Subsequent Disability Among Workers with Back Injuries: The Disability Risk Identification Study Cohort**

*Franklin, G., Stover, B., Turner, J., Fulton-Kehoe, D., & Wickizer, T.*

*Spine*, January 2008

“After adjustment for pain, function, injury severity, and other baseline covariates, receipt of opioids for more than 7 days (odds ratio = 2.2; 95% confidence interval, 1.5-3.1) and receipt of more than 1 opioid prescription were associated significantly with work disability at 1 year.”


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Relationship Between Early Opioid Prescribing for Acute Occupational Low Back Pain and Disability Duration, Medical Costs, Subsequent Surgery and Late Opioid Use
Webster, B., Verma, S., & Gatchel, R.
Spine, September 2007
“After controlling for the covariates, mean disability duration, mean medical costs, and risk of surgery and late opioid use increased monotonically with increasing MEA. Those who received more than 450 mg MEA were, on average, disabled 69 days longer than those who received no early opioids (95% confidence interval [CI], 49.2-88.9). Compared with the lowest MEA group (0 mg opioid), the risk for surgery was 3 times greater (95% CI, 2.4-4.0) and the risk of receiving late opioids was 6 times greater (95% CI, 4.9-7.7) in the highest MEA group. Low back injury severity was a strong predictor of all the outcomes.

Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States
Birnbaum, H., White, A., Schiller, B., Waldman, B., Cleveland, J., & Roland, C.
Pain Medicine, 2011
“As this study has shown, prescription opioid abuse concerns far more than those individuals directly affected by the condition. It is associated with a myriad of societal problems related to productivity losses and increasing criminal and legal justice costs that are rapidly becoming a major public health and economic concern. A multifaceted, coordinated response involving physicians, health care professionals, researchers (including the pharmaceutical industry), and the government is likely required to make substantial progress on this serious issue.”

Paulozzi, L., Mack, K., & Hockenberry, J.
CDC, Morbidity and Mortality Weekly Report, July 1, 2014
“The rate of drug overdose deaths increased 58.9% during 2003–2010. The number of drug overdose deaths decreased 16.7%, from 3,201 to 2,666, and the rate decreased 17.7% during 2010 and 2012 (Table 1, Figure 1). This change was largely attributable to the decrease in prescription drug-related deaths, which peaked at 2,722 in 2010 and decreased to 2,116 in 2012. The prescription drug overdose death rate decreased 23.2% to 11.1 per 100,000 persons, the lowest rate since 2007. Opioid analgesic overdose deaths declined from 2,560 to 1,892, with a corresponding rate decrease of 27.0%. Oxycodone, methadone, and hydrocodone rates decreased, whereas morphine and hydromorphone rates increased. Benzodiazepine overdose death rates decreased 28.4%, with alprazolam rates down 35.6%. The rate of carisoprodol-related deaths also declined, but not significantly. Prescribing declined for drugs whose overdose rate declined and increased for drugs whose overdose rate increased.”
Download at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s_cid=mm6326a2_w
Higher Opioid Doses Predict Poorer Functional Outcome in Patients with Chronic Disability Occupational Musculoskeletal Disorders
Kidner, C., Mayer, T., & Gatchel, R.
The Journal of Bone and Joint Surgery, April 2009
“Chronic opioid use beginning after a work-related injury is a predictor of less successful outcomes for patients whose final treatment intervention is an interdisciplinary functional restoration program. Higher dose levels are associated with progressively greater indemnity and medical costs for ongoing disability.”
Download at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2665041/

Reducing Inappropriate Opioid Use in Treatment of Injured Worker
IAIABC Policy Guide
Download at: www.iaiabc.org/resources

IAIABC Forum 2014 presentation - Opioids and Legacy Claims: Strategies for Success
REFERENCES


