Implementing a Drug Formulary for California's Workers' Compensation Program

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Preface

California Assembly Bill 1124 (Perea) required the state's Division of Workers' Compensation in the Department of Industrial Relations to establish a drug formulary for all workers' compensation payers in the state. Formularies in workers' compensation serve to reinforce safe and effective prescribing patterns for practitioners and payers. The objective of this report is to provide technical assistance to the division in establishing the formulary and developing related policies.

This research was undertaken for the Department of Industrial Relations under contract 15BS0355.

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The research reported here was conducted in the RAND Institute for Civil Justice (ICJ). ICJ is dedicated to improving the civil justice system by supplying policymakers and the public with rigorous and nonpartisan research. Its studies identify trends in litigation and inform policy choices about liability, compensation, regulation, risk management, and insurance. The institute builds on a long tradition of RAND Corporation research characterized by an interdisciplinary, empirical approach to public policy issues and rigorous standards of quality, objectivity, and independence. This research also draws from expertise in RAND Health.

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Questions or comments about this report should be sent to the project leader, Barbara Wynn (Barbara_Wynn@rand.org). For more information about the RAND Institute for Civil Justice, see www.rand.org/icj or contact the director at icjdirector@rand.org.

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Summary

Assembly Bill (AB) 1124 (Perea) requires the Division of Workers' Compensation (DWC) in California's Department of Industrial Relations to implement a drug formulary no later than July 1, 2017. The legislation intended that the formulary further "the goal of providing appropriate medications expeditiously while minimizing administrative burden and associated costs."

A carefully structured formulary can reinforce the Medical Treatment Utilization Schedule (MTUS) guidelines used to define medically appropriate care for California's injured workers, create incentives to encourage prescribing of medically appropriate drugs, and reduce the administrative burdens associated with utilization review (UR) and medical necessity appeals. Key strategies for achieving these outcomes are to eliminate prospective UR for first-line drug therapies and low-risk, low-cost drugs that are prescribed consistent with the MTUS and to require prospective review (PR) before other drugs are dispensed to an injured worker.

This report is the first in a series of three RAND Corporation reports on the drug formulary. Its objectives are to review existing formularies that DWC might consider and summarize their relative strengths and weaknesses, review the options for the related policies that are needed to implement and update the formulary, and make recommendations for the formulary implementation policies and updating process. The second report will provide an economic impact analysis of implementing the drug formulary. The third report will describe a monitoring framework for tracking the actual impacts of implementing the drug formulary.

Several assumptions regarding how DWC will design and implement the drug formulary underpin our methodological approach and policy analyses. First, we assume that DWC intends to adopt a formulary that is designed to maximize quality-of-care, health, and work-related outcomes. To accomplish these objectives, the formulary drug list and drug classification scheme should be evidence based and as consistent with the MTUS as possible. The formulary should also be integrated with the medical necessity determination process.

Second, we assume that controlling drug spending is an important but secondary objective. This suggests that any cost considerations incorporated into the formulary (such as restricting formulary drugs to the least costly therapeutic alternatives) should be determined through a separate process that occurs only after evidence-based drug therapies are identified consistent with the MTUS guidelines. Because the California Workers' Compensation (WC) program involves multiple payers and because there are no cost-sharing requirements, the available tools to control spending are likely to be more limited than those that might be considered by single-payer WC states or group health plans. The tools for encouraging cost effective drug use include (1) utilization management tools, such as PR for high-cost or high-risk drugs that are not first-line therapies to prevent inappropriate utilization and spending; (2) use of substitut-

able generics instead of brand-name drugs, except when there is a clinical rationale for prescribing the brand; (3) use of less costly therapeutic alternatives when the evidence suggests there is little or no difference in terms of effectiveness and safety; and (4) integration with the Official Medical Fee Schedule (OMFS) so that covered drugs have fee schedule prices.[1]

Third, we assume that the process and policies for determining how drugs are integrated into the formulary should be transparent. The time and resource constraints created by the requirement that the formulary be adopted by July 1, 2017, favor adapting an existing evidence-based formulary over developing a new formulary that is specific to the California WC program. However, because the MTUS draws on multiple sources for its treatment guidelines, some modifications may be required for consistency with the MTUS. Moreover, the policies and experiences of other programs inform potential implementation policies, but the policies that are implemented must be tailored to be consistent with AB 1124 requirements and California-specific policies, such as the MTUS, the medical dispute resolution process, and OMFS.

Formulary Structure

We reviewed five existing drug formularies:[2]

1. Washington State Department of Labor and Industries
2. The Reed Group's American College of Occupational and Environmental Medicine (ACOEM)
3. Work Loss Data Institute's ODG
4. Ohio Bureau of Workers' Compensation
5. California Department of Health Care Services (Medi-Cal, California's Medicaid program).

We compared each formulary across six criteria developed in consultation with California's DWC:

1. reliance on evidence-based criteria in determining the formulary drug list and recommendations for the formulary
2. compatibility with the MTUS
3. transparency in the decision process used to establish and maintain the formulary drug list and recommendations

[1] Each of these tools is already in place, but they are not used as effectively as they might. For example, UR is required for all drugs; PR waivers for first-line therapies can encourage physicians to prescribe these drugs before prescribing other drugs. If a brand-name drug is prescribed when a less costly generic equivalent is available, a pharmacist is required to dispense the generic unless the prescription notes "dispense as written." No criteria specify when the use of the "dispense as written" notation is appropriate. Not all drugs prescribed for injured workers have OMFS prices.

[2] In addition to the four WC formularies that we reviewed, North Dakota and Delaware have WC formularies. We did not review the North Dakota formulary because it was not derived from evidence-based treatment guidelines using a transparent process. Instead, the formulary policies were developed by US Script, a pharmacy benefit management company, and approved by Workforce Safety and Insurance's Pharmacy and Therapeutics Committee. The Delaware formulary is derived from Delaware's Medicaid formulary. Instead of reviewing this formulary, we chose to review the Medi-Cal formulary. DWC bases its pharmaceutical fee schedule on the Medi-Cal pharmaceutical fee schedule.

4. established process for regular updates to the formulary drugs and recommendations
5. accessibility and ease of use by treating physicians, payers, and injured workers
6. focus on drugs needed for injured worker conditions (for example, analgesics, such as opioids and nonsteroidal anti-inflammatory drugs, and muscle relaxants).

While each formulary has features that might be models for the California formulary, we concluded that DWC's options are limited by the need for the formulary to be consistent with the MTUS guideline drug recommendations. The current MTUS incorporates treatment guidelines from ACOEM for most conditions and from ODG for chronic pain and postsurgical physical medicine treatments. Both sets of guidelines have drug recommendations associated with treatment guidelines for common WC medical conditions. Establishing a single integrated formulary that is consistent with the MTUS requires one of two approaches: (1) Adopt both the formulary and guidelines of either ACOEM or ODG, or (2) develop a California-specific WC formulary (which we call the *MTUS formulary*) that is derived from the applicable ACOEM or ODG guidelines for different conditions and DWC's opioid guidelines. Adopting one of the other formularies that we examined (Washington State Department of Labor and Industries, Ohio Bureau of Workers' Compensation, or Medi-Cal) would raise major issues to make the formulary consistent with the MTUS.

Through the rulemaking process, California has adopted MTUS guidelines that it believes incorporate the best available evidence base for medical care provided to injured workers. However, these guidelines are outdated and need to be updated for most clinical topics. Therefore, the implementation of the formulary poses an opportunity to review the sources for the treatment guidelines and assure that they continue to be the most appropriate source for standards of care that meet the needs of California's injured workers and whether additional clinical topics should be added.[3] If the current MTUS multisource structure is retained, it would be important to implement updated guidelines before or coincident with the formulary implementation so that the updated guideline recommendations would be reflected in the formulary drug listing.

The decision on which formulary to implement involves significant trade-offs between ease of implementation and adherence to the current MTUS structure (Table S.1).

For several reasons, the ODG formulary would be easier to implement. It is already in use in several WC programs and incorporates PR recommendations. The formulary drug listing uses a simple yes-or-no structure to indicate whether PR is required for most drugs, which means that diagnostic information is not needed when processing most pharmacy bills. However, it also means that important nuances of condition-specific guideline recommendations are not reflected in the PR recommendations and that the prescriber must be familiar with the specific treatment guideline recommendations for the injured worker's condition. The drug listings are derived from evidence-based treatment recommendations that are updated regularly to incorporate new evidence. The ODG guidelines are more comprehensive than the ACOEM guidelines, but the methods used to develop them have been less rigorous

[3] ACOEM-based clinical topics that have not been incorporated into the MTUS, and their ACOEM effective dates include Interstitial Lung Disease (2015), Occupational Asthma (2014), and Hip and Groin (2011). ODG has chapters on pulmonary, hip and pelvis, and hernia conditions. ODG also has chapters on mental health and stress-related conditions and head conditions. ACOEM does not currently have guidelines on these topics, but guidelines for traumatic brain injury and behavioral health are under development.

Table S.1
Implementation Considerations in Determining Formulary Structure

	Adopt		
Considerations	**ODG Guidelines and Formulary**	**ACOEM Guidelines and Formulary**	**Updated MTUS Guidelines and Formulary**
Consistency with current MTUS	ODG-based MTUS guidelines cover chronic pain and postsurgical physical medicine.	ACOEM-based MTUS guidelines cover most clinical topics, but the MTUS uses the 2004 version of the guidelines, rather than most recent guidelines.	Depends on updating decisions. Revised ACOEM-based guidelines, and 2016 versions of ODG guidelines for chronic pain and DWC opioid guidelines would be the most consistent with current structure.
Adherence to evidence-based information in determining which drugs require PR	Yes-or-no rules on PR ignore condition-specific variation in some treatment guidelines.	Formulary rules do not include PR requirements; presumably, DWC would develop PR rules based on condition-specific drug therapy recommendations.	Assumes that PR rules would be based on specified criteria and that condition-specific PR rules would be established when needed.
Ease of implementation	Could be implemented off the shelf.	Requires developing PR rules based on specific criteria and clinical review.	Requires developing PR requirements based on specific criteria and clinical review and integrating the different guidelines into a single formulary.
Scope and currency of guidelines	Most comprehensive option for WC-related conditions with ongoing updating process .	Does not have mental health guidelines; guidelines for head disorders and behavioral health under development. Some clinical topics have not been updated since 2011, but revisions are in progress.	Does not have guidelines for pulmonary diseases or head disorders; ACOEM-based guidelines (including for stress-related conditions) have not been updated since implemented in 2004 and would need to be updated.

(Nuckols et al., 2014), and the methodology used to derive the PR requirements when there are condition-specific variations in the guideline recommendations is not transparent. Because only the MTUS chronic pain guidelines and postsurgical physical medicine guidelines are based on ODG, the adoption of the ODG guidelines would represent a major departure from the current MTUS guidelines.

Most MTUS guidelines are derived from ACOEM practice guidelines. The guidelines are developed through a process that is more rigorous, transparent, and evidence based than ODG's (Nuckols et al., 2014). Comprehensive reviews of existing guidelines occur about every five years, but the Reed Group plans to update its formulary quarterly. Implementing a formulary based on the ACOEM guidelines would require more initial investment than one based on ODG because the formulary's drug recommendations are organized by condition and do not include PR requirements. Adopting the ACOEM guidelines and formulary would require developing a formulary drug listing by active ingredient (rather than condition) and establishing PR requirements for drugs that are in the formulary listing. The PR requirements can be derived from the guideline recommendations relatively easily because the ACOEM formulary recommendations are maintained in an electronic format. While the ACOEM drug formulary recommendations are condition specific, the PR requirements need be only if clinical review determines there are sufficient differences in the condition-specific recommendations for a particular drug to warrant condition-specific PR rules. To the extent the PR requirements do vary

by condition, the ACOEM formulary would be more complex to operationalize but would also be more consistent with the treatment guidelines.

If the current MTUS structure is retained, updating the MTUS would involve adopting more-recent versions of the ACOEM-based MTUS guidelines and integrating them with the new DWC opioid treatment guidelines and the ODG-based chronic pain guidelines. Because the MTUS predominantly comprises ACOEM guidelines, the administrative burden of developing and maintaining a California-specific MTUS formulary should not be significantly more administratively burdensome than adopting the ACOEM formulary. In addition to the investment needed to operationalize the ACOEM drug recommendations into a formulary drug listing with PR recommendations, any conflicts between applicable ODG and ACOEM recommendations for individual drugs would need to be resolved so that it is clear which guideline has precedence.[4] However, the ongoing administrative burden is likely to be less if all guidelines draw from the same developer. The guidelines would already be internally consistent, so there would be no need to reconcile any differences in treatment recommendations and providers, and payers would only need to reference one guideline set. A hybrid approach would be to incorporate treatment guidelines from a single developer into the MTUS but to develop an MTUS formulary drug listing. The PR requirements would be derived from the MTUS guideline drug recommendations, but the drug listing would be tailored to the California WC context and maintained with the input of the Pharmacy and Therapeutics Committee. It would also allow DWC to incorporate other features into the drug listing, such as a first-fill policy and whether generic and over-the-counter versions of the drug are available that would enhance the accessibility and usability of the drug listing for patients, prescribers, pharmacists, and payers.

Recommendations

The MTUS guidelines should drive the decisions on the formulary structure so that both treatment guidelines and the formulary incorporate the evidence-based standards of care that best meet the needs of California's injured workers. Priority should be given to updating the MTUS guidelines. In doing so, the advantages and disadvantages of retaining the current multisource guideline structure should be weighed.

The formulary drug listing and PR requirements should be derived from the MTUS guidelines in effect as of the implementation date. Generally, PR should be waived for drugs that are first-line therapies or that are otherwise low-cost, low-risk drugs that are prescribed consistent with the MTUS guidelines. Condition-specific PR requirements should be imposed sparingly when there are significant differences in the drug recommendations.

[4] Treatment recommendations that are at variance with each other can occur when an injured worker's condition is addressed by two different guidelines. For example, the low-back clinical topic is derived from the ACOEM guidelines, while the chronic pain chapter is derived from ODG guidelines. Treatment recommendations from these sources could be at variance for an injured worker with chronic back pain. Under the July 2016 revision to the MTUS chronic pain guidelines, the chronic pain guidelines would have precedence if a treatment for a patient with chronic pain were addressed in both the chronic pain MTUS and the clinical topics (e.g., low-back) section of the MTUS.

Ancillary Implementation Policies

In addition to determining the formulary structure and ground rules, it will be important to establish, through rulemaking, ancillary policies governing how the formulary will be implemented and integrated with the medical necessity dispute-resolution process and the OMFS. Table S.2 summarizes the implementation policies that will need to be addressed in the formulary rules or through modifications in existing regulations.

Arguably, the most important formulary decisions pertain to deciding when PR will be required for a drug therapy. Currently, all drug therapies are subject to either prospective or retrospective UR. Waiving PR for first-line drug therapies and low-cost, low-risk drugs while strengthening the PR requirements for other drugs creates an incentive for providers to prescribe the first-line drug therapies before considering alternatives. As discussed earlier, these requirements should be derived from the MTUS guidelines and incorporated into the MTUS drug listing. In addition, consideration should be given to broader policies designed to encourage prescribing of medically appropriate drug therapies. The policies listed in Table S.3 summarize our recommendations regarding the circumstances under which PR should or should not be required for drug therapies.

Point-of-sale bill-processing screens should determine whether approval has been received for a nonpreferred drug before it is dispensed. Consistency with the MTUS and compliance with the PR requirements can be reinforced by continuing to allow retrospective review of the medical necessity of drugs that were dispensed without PR approval. If the review determines that the dispensed drugs are not medically necessary (i.e., inconsistent with the MTUS), the payer should not be obligated to pay for the drug.

In addition to PR policies to encourage prescribing and dispensing of medically appropriate drugs, other policies should be considered to meet the AB 1124 intent that DWC's formulary guidance "further the goal of providing appropriate medications expeditiously while minimizing administrative burden and associated costs." Table S.4 summarizes policies that DWC might consider in implementing the formulary that will facilitate achieving these objectives.

As amended, Labor Code §5307.29 requires that the formulary be updated no less often than quarterly. Ideally, updates in the formulary drug listings should be driven by updates in the treatment recommendations, but the two updates may not happen concurrently because the Labor Code requires a lengthier process for updating the treatment guidelines (rulemaking) than the formulary (posting changes on the DWC website without rulemaking). To keep the formulary and guidelines consistent with best available evidence concerning drug therapy recommendations, DWC needs statutory authority to post changes in the MTUS treatment guidelines for drug therapies simultaneously with changes in the formulary without rulemaking.

Table S.2
Summary of Major Policy Development Steps

Step	Description
Establish ancillary formulary policies	Define how the formulary applies by setting and drug type; describe PR policies; address policies for special types of drugs (over-the-counter, brand-name versus generic, etc.); and describe the update process and pharmacy and therapeutics committee rules.
Make conforming changes to UR and independent medical review (IMR) rules	Clarify how the formulary integrates with UR/IMR rules and the request-for-authorization process and consider policies that would reduce the UR/IMR time line for pharmaceuticals .
Make conforming changes to OMFS	Review policies for formulary drugs that do not have OMFS prices.

Table S.3
Summary of Recommended PR Requirements

Drug Classification	When is PR Required?
Preferred drug	Only when • The drug is prescribed in a dosage or duration that exceeds MTUS guidelines. • The drug is not indicated in the MTUS guideline for the injured worker's compensable condition. • The drug is for a brand name affected by the generic drug policy.
Nonpreferred drug	Always unless • First-fill policy is applicable. • Waived by payer under prior authorization rules.
Nonlisted drug	Always unless waived by payer under prior authorization rules.
Other potential policies	• Non–FDA approved drugs – Compounded drugs – Investigational or experimental – Over-the-counter combination drugs – Non–FDA intrathecal drugs • Certain physician-dispensed drugs.

Table S.4
Summary of Other Recommended Ancillary Policies

Topic	Recommended Policy
First-fill policy	Adopt a first-fill policy that waives PR for drugs prescribed immediately following injury, including a short course of opioid therapy for severe pain.
Physician dispensing	Curtail physician dispensing by requiring PR for all drugs dispensed after the first-fill period.
Generic versus brand name	Require PR if a brand name is prescribed when a generic equivalent is available at lower cost.
Therapeutic interchange of less costly drug with similar therapeutic effects	Incorporate cost considerations into the drug formulary over time through pharmacy and therapeutic committee review during the update process.
UR/IMR policies	Integrate drug medical necessity determinations into the existing dispute resolution process so that adverse UR decisions can be appealed for IMR.

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Abbreviations

AB	Assembly Bill
ACOEM	American College of Occupational and Environmental Medicine
BWC	Ohio Bureau of Workers' Compensation
CMS	Centers for Medicare and Medicaid Services
DERP	Drug Effectiveness Review Project
DFR	Doctor's First Report of Occupational Illness or Injury (Form 5021)
DWC	Division of Workers' Compensation (part of the California Department of Industrial Relations)
FDA	Food and Drug Administration
FUL	Federal Upper Limit
GI	gastrointestinal
IDDS	implantable drug-delivery systems
IMR	independent medical review
L&I	Washington State Department of Labor and Industries
MCDAC	Medi-Cal Contract Drug Advisory Committee
MPN	medical provider network
MTUS	Medical Treatment Utilization Schedule
NDC	National Drug Code
NSAID	nonsteroidal anti-inflammatory drug
ODG	Official Disability Guidelines
OIG	Office of the Inspector General
OMFS	Official Medical Fee Schedule
OTC	over-the-counter
P&T	pharmacy and therapeutics

PBM	pharmaceutical benefits manager
PDF	Portable Document Format
PR	prospective review
RFA	request for authorization
SB	senate bill
TAR	treatment request authorization
UR	utilization review
WC	workers' compensation
WCIS	Workers' Compensation Information System
WCRI	Workers' Compensation Research Institute
WLDI	Work Loss Data Institute

Glossary

brand-name drug	Also known as an *originator drug*, a brand-name drug is one marketed by a manufacturer under a brand name (rather than its generic name). Brand-name drugs are often single-source drugs following their initial Food and Drug Administration (FDA) approval because of patent protection and FDA-granted regulatory exclusivity. Later, generic versions of some brand-name drugs enter the market and compete with the brand-name drug on price.
compounded drug	A drug formulation that combines two or more active drug ingredients to meet the needs of specific patients for drugs that are not otherwise available commercially is a compounded drug. These drug products are not approved by the FDA, although their constituent ingredients are.
drug	In this report, this term encompasses all classes of pharmaceuticals that are covered under the workers' compensation (WC) program, including prescription drugs, over-the-counter drugs, and compounded drugs.
first-fill	In the WC context, this is the initial fill of a prescription within a short period following the date of injury, often before a determination has been made regarding whether the claim is compensable.
formulary	In the WC context, this is a listing of drugs that will be covered when medically appropriate for an injured worker's compensable condition. The list may also incorporate additional information on utilization management tools and other information for prescribers and patients.
generic drug	This is a drug approved by the FDA by referencing an originator brand-name drug's initial application. Generic drugs can enter the market after the reference product's regulatory exclusivity has expired and after its patents have either expired or been successfully challenged in court. Many generics are assigned an "A" therapeutic equivalence rating by the FDA, which signifies that they can be substituted by pharmacies to the extent permitted by state law.

independent medical review	This is the process used to review a claims administrator's utilization review decision that modified or denied a medical treatment. An independent peer reviewer conducts the review.
medical provider network	This is a group of providers, including physicians and ancillary providers, that provides medical treatment for work-related injuries and illnesses. There must be a written agreement between the employer and provider, and the provider must agree to provide care consistent with the MTUS.
off-label use	The use of a prescription drug for a purpose not indicated on the FDA-approved drug label is considered off label.
over-the-counter drug	This is a drug that can ordinarily be purchased or dispensed without a prescription. In WC, these drugs are typically prescribed for the injured worker so that he or she is not charged, and the pharmacy bills the payer (or PBM) for the cost of the drug.
pharmaceutical benefits manager	A PBM is an organization that processes and pays drug claims, administers drug benefits and formularies, negotiates with drug manufacturers on price, and provides other services to payers.
pharmacy network	This is group of preferred pharmacies for a payer (insurer or self-insured employer) or PBM.
prospective review	In California's WC program, this is the process through which a physician seeks approval for medical treatment, including proposed drug therapy, before it is prescribed and dispensed. The term *prior authorization* is more common in the pharmacy benefit and formulary context to describe this process. A payer may require PR—usually based on medical necessity criteria—to cover a drug.
therapeutic alternative	Also known as *therapeutic substitutes*, therapeutic alternatives constitute a set of different drugs with similar effects from which a prescriber chooses when writing a prescription. For example, statin drugs are therapeutic alternatives (different active drug ingredients) to reduce cholesterol. Therapeutic alternatives may have important differences in terms of effectiveness and safety for specific subgroups and individual patients.
therapeutic class	This is a categorization of drugs into groups based on shared characteristics. The many different therapeutic classification schemes include those based on pharmacological properties and clinical use. Drugs assigned to the same therapeutic class are often therapeutic alternatives.

therapeutic equivalent	We use this term to refer to FDA-designated "AB"-substitutable versions of the same active ingredient, i.e., drugs that can be freely exchanged by pharmacists or other providers, unless otherwise noted. The most typical case is an "AB"-substitutable generic version of a brand-name drug. "AB"-substitutable drugs can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.
utilization review	This is the process used in California for claims administrators to review the medical necessity of prescribed treatment. UR for pharmaceuticals may occur prospectively or retrospectively.

CHAPTER ONE

Introduction

California's Workers' Compensation Program

California's workers' compensation (WC) program provides medical care and wage replacement benefits to workers suffering on-the-job injuries and illnesses. It is a mandatory "no-fault" system in which benefits are paid by the employer without the need to determine whether employer or employee negligence caused the injury. In 2014, an estimated 17 million workers in California were covered by WC insurance, and 534,000 claims were filed for workplace-related injuries and benefits, ranging from minor medical treatment cases to catastrophic traumatic brain injuries and spinal cord injuries (Division of Workers' Compensation [DWC] Workers' Compensation Information System (WCIS) 2014 data file at DWC, 2016b). Employers provide WC coverage through several mechanisms, including purchasing WC insurance from commercial insurance companies or from the California State Compensation Insurance Fund (a public nonprofit carrier) or by setting up a self-insured employer fund. DWC, within the Department of Industrial Relations, is responsible for administering the program.

In California, an injured worker is entitled to receive all medical care reasonably required to cure or relieve the effects of their injury with no deductibles or cost sharing. Since 2004, a set of evidence-based guidelines, the Medical Treatment Utilization Schedule (MTUS), has defined the scope and duration of care that is reasonably required to cure or relieve the effects of the injury.[1] Claims administrators (insurers, self-insured employers, or third-party administrators) are required to have a utilization review (UR) process to determine whether medical care is medically appropriate, which means whether the medical care is consistent with the MTUS guidelines. If care is denied as medically unnecessary, the injured worker is entitled to appeal the denial, with an independent medical review (IMR) organization conducting a peer review of the medical appropriateness of the care.

As is the case with other therapies, an injured worker is entitled to pharmaceutical services that are indicated for the workers' injuries and prescribed and dispensed consistent with the MTUS guidelines. However, there have been concerns over both the rising cost per claim for pharmaceuticals and the extensive use of opioids within the WC system. A Workers' Compensation Research Institute (WCRI) study found that 68 percent of the claims with pain medication prescriptions received narcotics. For nonsurgical cases, the morphine equivalent

[1] The guidelines are presumptively correct but are rebuttable by a preponderance of scientific evidence establishing that a variance from the guidelines is reasonably required. For injuries not covered by the designated guidelines, treatment is to be in accordance with other evidence-based medical-treatment guidelines generally recognized by the community and scientifically based (California Labor Code §4604.5). Regulations at Title 8, California Code of Regulations §§9792.21.1 and 9792.25.1, set forth the Medical Evidence Search Sequence and the Methodology for Evaluating Medical Evidence.

amount of narcotics received by the average injured worker in California was 17 percent higher than the typical amount of the 25 study states in the study (Thumula, Wang, and Liu, 2014).

These concerns have been reinforced by the experience under the medical necessity dispute-resolution process. Drug treatments deemed medically unnecessary during UR account for nearly half of all IMR appeals. IMR decisions uphold 93 percent of the UR denials for medically unnecessary drug therapies, raising additional concerns about the administrative burden imposed by current prescribing practices on the UR/IMR medical necessity dispute-resolution process (RAND Corporation analysis of 2014 IMR decisions).

In response to the concerns over the medical appropriateness of opioid and other drug therapies and the administrative burden of assuring medically appropriate drug treatments, Assembly Bill (AB) 1124 (Perea) requires that DWC implement a drug formulary by July 1, 2017.

WC formularies are one tool to encourage the efforts of practitioners to prescribe effective, safe, and high-value drugs. A formulary is a list of drugs indicating which drugs a payer will cover and under what conditions.[2] Formularies are often linked to other aspects of pharmacy benefit management to confirm medical necessity and encourage appropriate use.[3] Insurers often conduct drug UR to monitor prescription activity relative to the formulary. When implemented in conjunction with medical treatment guidelines, a carefully structured formulary can reinforce the treatment guidelines, create incentives through PR requirements to encourage prescribing of preferred drugs, and reduce the administrative burden for UR and IMR appeals.

Other State Experiences with WC Formularies

In recent years, several states have implemented drug formularies for their WC programs. Washington and Texas are two well-publicized examples of evidence-based WC formularies, with very different approaches to formulary development and maintenance. Washington State implemented a formulary in 2002 as part of a broader push within the state to pool purchasing power for drugs across several agencies, including Medicaid and the state's Department of Labor and Industries (L&I). L&I then supplements the Washington State formulary with a "wraparound" formulary that considers drugs specifically for WC-related medical conditions that are not addressed in the state formulary. Taking a different approach in 2011, Texas established a WC drug formulary by adopting an existing formulary, the ODG formulary from the Work Loss Data Institute (WLDI).

Also in 2011, Ohio adopted its own WC formulary based on recommendations of a pharmacy and therapeutics (P&T) committee, while Oklahoma (in 2014) and Tennessee (in

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[2] In principle, formularies are either "open" or "closed," depending on whether the default assumption is that drugs not explicitly listed on the formulary are or are not covered. However, the terms "open" and "closed" are used inconsistently with respect to formularies; in practice, neither open nor closed formularies prevent injured workers from receiving medically appropriate drugs. As a result, we avoid using these terms in this report.

[3] One example of a pharmacy benefit management tool is prospective review (PR), which is used in California's WC UR policies to describe the process a physician uses to seek approval for a proposed drug therapy before prescribing and dispensing it. We use *PR* throughout this report to describe the comparable policies in other states, although, in other contexts, *preauthorization* and *prior authorization* are common terms for this process. In California, the term *prior authorization* more specifically means therapies that a claims administrator (or a UR entity it has contracted with) preapproves without requiring UR.

2016) implemented formularies derived from the ODG guidelines. North Dakota (in 2006), Delaware (in 2013), and Nevada (in 2016) have also adopted WC formularies.

The impact of implementing a formulary in the individual states has been pronounced. A 2011 WCRI comparative study found that Washington's drug costs per indemnity claim were 40 percent below the median of the 17 states included in the study; in contrast, California's per claim costs were 80 percent higher than the 17-state median (Wang and Liu, 2011). In Texas, prescribers rapidly shifted their prescribing practices to focus on drugs that did not require PR. Between 2011 (before the formulary was implemented) and 2014, the number of injured workers prescribed drugs that required PR dropped 83 percent, while the costs associated with these drug prescriptions fell 80 percent (Texas Department of Insurance, 2016). Ohio estimates that opioid prescriptions dropped 40 percent from fiscal year 2011 to 2015, and muscle relaxant prescriptions decreased 72 percent during the same period (Ohio Bureau of Workers' Compensation [BWC], 2015).

A California Workers' Compensation Institute study comparing the Texas and Washington formularies found that the Washington formulary is more restrictive than the Texas formulary. When the authors applied the formularies to California WC drug data, they estimated that the potential average savings in WC drug payments would be 12 percent under the Texas formulary, compared to 41 percent under the Washington formulary (Swedlow, Hayes, and David, 2014).

California Labor Code Requirements for a Drug Formulary

Against the backdrop of concerns over drug costs per claim, opioid usage, and medical necessity disputes and informed by the experience of other states, AB 1124 (Perea) was enacted in September 2015. As amended by AB 1124, Labor Code §5307.27 requires that the DWC administrative director implement an evidence-based drug formulary by July 1, 2017, as part of the MTUS. Implementation is to be phased in for workers injured before July 1, 2017, to ensure that they safely transition to the medications included in the formulary.

The formulary will be applicable to all prescribers and dispensers of outpatient drugs provided to injured workers. Drugs prescribed consistent with the formulary must be available regardless of whether the pharmacy services are provided inside or outside a pharmacy network. The drug formulary and standards adopted by the administrative director are applicable to drugs provided by a network pharmacy under contract with a payer (or a pharmaceutical benefits manager [PBM] under contract with the payer).

The formulary is to be established through a transparent process that includes consultation with stakeholders and publication of at least two interim reports that describe the status of the formulary's development. The administrative director is to update the formulary at least quarterly and, in doing so, consult with an independent six-member P&T committee. These updates are exempt from rulemaking and may be implemented through orders posted on the DWC website.

In addition to the Labor Code revisions, AB 1124 expresses legislative intent that the formulary include guidance addressing access to evidence-based medically necessary use of specific types of drugs: pain management prescription drug therapies, drugs used for other than Food and Drug Administration (FDA)–approved indications (off-label prescribing), generic drugs, and cost-effective brand-name drugs. Finally, guidance on the formulary use is "to fur-

ther the goal of providing appropriate medications expeditiously while minimizing administrative burden and associated costs."

Purpose of This Report

DWC asked the RAND Corporation to provide technical assistance in the design and implementation of the formulary and related policies and in estimating the economic impact of the formulary. The key questions this research addresses include the following:

- How should the drug formulary be structured? What are the advantages and disadvantages of existing formularies that the California WC program might consider?
- What implementation policies should be considered to address the AB 1124 requirements and promote the provision of appropriate pharmaceuticals expeditiously while minimizing the administrative burden?
- How is implementing the formulary likely to affect drug utilization patterns and spending? What are the costs and benefits of implementing an evidence-based formulary consistent with the AB 1124 requirements for injured workers, providers, employers, and society?
- What key indicators and measures should be used to monitor implementation of the formulary?

This report is the first in a series of three reports on the drug formulary. The objective of this report is to review existing formularies that DWC might consider, summarize their relative strengths and weaknesses, review the options for the related policies that are needed to implement and update the formulary, and make recommendations for the formulary implementation policies and updating process. The second report will provide an economic impact analysis of implementing the drug formulary. The third report will describe a monitoring framework for tracking the actual impacts of implementing the drug formulary.

Guiding Assumptions

Several assumptions about how DWC will design and implement the drug formulary underpin our methodological approach and policy analyses.[4] First, we assume that DWC intends to adopt a formulary that is designed to maximize quality-of-care, health, and work-related outcomes. To accomplish these objectives, the formulary drug list and drug classification scheme should be evidence-based and as consistent with the MTUS as possible. The formulary should also be integrated with the medical necessity determination and dispute-resolution processes. Targeted UR will reinforce consistency between the proposed treatment and the MTUS. The medical necessity dispute-resolution process (which provides for an IMR of adverse UR decisions) will provide an appeals process for obtaining medically necessary drugs that are not addressed by the MTUS but are supported by other evidence demonstrating medical appropriateness (for example, more-recent evidence-based guidelines than the MTUS).

[4] Our assumptions were informed by a DWC presentation at a September 8, 2015, public hearing and developed in consultation with DWC (California Department of Industrial Relations, 2015).

Second, we assume that controlling drug spending is an important but secondary objective. This suggests that any cost considerations incorporated into the formulary (such as restricting formulary drugs to least costly therapeutic alternatives) should be determined through a separate process that occurs only after evidence-based drug therapies are identified consistent with the MTUS guidelines. Because the California WC program involves multiple payers and because there are no cost-sharing requirements, the available tools to control spending are likely to be more limited than those that might be considered by single-payer WC or other government programs. The tools for encouraging cost-effective drug use include (1) use of substitutable generics instead of brand-name drugs, except when there is a clinical rationale for prescribing the brand; (2) use of less costly therapeutic alternatives when the evidence suggests little or no difference in terms of effectiveness and safety; (3) utilization management tools, such as PR for high-cost or high-risk drugs that are not first-line therapies to prevent inappropriate utilization and spending; and (4) integration with the Official Medical Fee Schedule (OMFS) so that covered drugs have fee schedule prices.

Third, we assume that the process and policies for determining how drugs are integrated into the formulary should be transparent. The time and resource constraints created by the requirement that the formulary be implemented by July 1, 2017, favor adapting an existing evidence-based formulary over developing a new formulary that is specific to the California WC program. However, because the MTUS draws on multiple sources for its treatment guidelines, some modifications may be required for consistency with the MTUS. Moreover, the policies and experiences of other programs may inform potential implementation policies, but the policies that are implemented must be tailored to be consistent with AB 1124 requirements and California-specific policies, such as the MTUS, the medical dispute-resolution process, and OMFS.

Overview of Methods and Approach

In our research design, we distinguished between the structure of an evidence-based formulary and the ancillary policies that address how the formulary is to be used.

Formulary Structure

In total, we identified six existing WC formularies (four state-specific and two national). We selected four of the WC evidenced-based formularies for in-depth review and added the Medi-Cal drug formulary. The formularies that we reviewed are

1. Washington L&I
2. The Reed Group's American College of Occupational and Environmental Medicine (ACOEM)
3. WLDI's ODG
4. BWC
5. California Department of Health Care Services (Medi-Cal, California's Medicaid program).

The ODG and ACOEM WC formularies are both national formularies that have been derived from evidence-based treatment guidelines that are already used to differing degrees

in California's MTUS. Both Washington L&I and Ohio have large single-payer WC programs that have used very different approaches in implementing and updating state-specific formularies. North Dakota is another single-payer state that has developed its own formulary. Since the other two states have more characteristics in common with California, we chose not to review North Dakota's formulary. Another determining factor was that the evidence base for the North Dakota formulary is less transparent than those for the other two formularies.[5] Delaware also maintains its own WC formulary, which is derived from its Medicaid program's formulary. We chose not to review this formulary and instead reviewed the Medi-Cal formulary. We added the Medi-Cal formulary to our list because it is already in use in California and because California's WC pharmacy fee schedule is based on Medi-Cal's.

We reviewed the publicly available documentation on how each formulary was developed and is maintained. We supplemented our document review with interviews with and supplemental materials from the formulary maintainers. The proprietary formulary maintainers (ODG and ACOEM) provided us with access to their online formularies; the other maintainers provide online access to their formularies at no cost. We compared the formularies across a set of criteria established in consultation with DWC and presented for discussion at a DWC public hearing held February 17, 2016, to discuss formulary design and implementation issues. The criteria reflect the Labor Code requirements for the formulary and operational requirements for successfully implementing a formulary consistent with the MTUS. The following summarizes the criteria we used:

- reliance on evidence-based criteria in determining the formulary drug list and recommendations for the formulary
- compatibility with the MTUS
- transparency in the decision process used to establish and maintain the formulary drug list and recommendations
- an established process for regular updates to the formulary drugs and recommendations
- accessibility and ease of use by treating physicians, payers, pharmacies, and injured workers
- focus on drugs needed for injured worker conditions (for example, analgesics, such as opioids and nonsteroidal anti-inflammatory drugs [NSAIDs], and muscle relaxants).

Chapter Three discusses these criteria in greater depth.

We also obtained detailed files of the lists of drugs discussed in the formularies that allowed us to compare how the formularies handle selected high-volume WC drug ingredients for specific conditions. We also compared the high-volume WC prescriptions to the selected formularies to understand the extent to which the formulary drug listings address current drug treatments and the proportion of prescriptions that would require PR under each formulary's rules. Chapter Four discusses the methods we used and our findings.

[5] Specifically, a North Dakota Workforce Safety and Insurance P&T committee approves the formulary drug listing, which is not derived from evidence-based medical treatment guidelines. A public hearing is held as part of the pharmacy fee schedule update, but there is no formal rulemaking pertaining either to the P&T committee process or its recommendations, which are implemented by a PBM under contract with the state.

Implementation Policies

To obtain information on the range of policies that need to be addressed in implementing a drug formulary, we first reviewed the rulemaking and other documentation that the states that have implemented WC formularies have produced. Ohio and Washington have developed their own WC formularies, while Texas, Tennessee, and Oklahoma have adopted the ODG formulary. We followed our review of state drug formulary policies with interviews with state officials. In addition, we obtained input on the strengths and weaknesses of different formulary design and implementation policies through semistructured interviews with experts representing different stakeholder perspectives (provider, payer, applicant's attorney, PBM, and pharmacy) and comments made at the DWC public hearing held on February 17, 2016. Specifically, the following questions were posed to the participants at the public hearing:

- What types of drugs should be included in the formulary?
- When should PR be required? What criteria should be used to classify drugs as requiring PR? Should the classification apply across the board to the drug or differentiate by condition?
- Should there be a first-fill policy for new injuries?
- Should different policies apply to physician-dispensed drugs than for pharmacy-dispensed drugs?
- What policies should apply to the use of generic versus brand names? Off-label usage? Compounded drugs? Investigational or experimental drugs?
- How should formulary policies integrate with medical treatment guidelines and the medical necessity review and dispute-resolution process? If PR is not required, under what circumstances should there be retrospective review? What occurs if the drug is subsequently determined not to be medically necessary (e.g., not consistent with the MTUS guidelines)?
- With regard to both pharmacy-dispensed and physician-dispensed drugs, how should the formulary policies be enforced at the point of sale? How should the policies differ for network versus nonnetwork pharmacies?
- How frequently should the formulary be updated and what is the process for doing so?
- What special policies are needed, if any, for claims with dates of injury occurring before July 1, 2017, or for injured workers receiving drugs who are affected by a formulary update?

Organization of This Report

The remainder of this report is organized as follows:

- Chapter Two provides background information on California utilization and spending trends for drugs; highlights current policies affecting drug utilization and payment; and describes how drug prescriptions currently flow through bill-processing and the medical necessity determination and dispute-resolution process.
- Chapter Three compares the attributes of the five formularies selected for review. We begin with an overview of each formulary and then evaluate each formulary's perfor-

mance based on our evaluation criteria for gauging the strengths and weakness of a formulary.

- Chapter Four compares the sets of ground rules used across the five formularies. These rules, which may affect usability, determine whether generics are always preferred over brand-name drugs, whether there are preferences for particular drug formulations or dosage strengths, and whether certain drugs may be substitutable. We then examine how the differences in ground rules affect the percentage of WCIS payments for prescriptions and the percentage of drugs that would require PR. This analysis is focused on drugs in three therapeutic classes: opioids, NSAIDs, and muscle relaxants.
- Chapter Five discusses policy options for key formulary implementation based on a review of current California policies and the policies other states with WC formularies have adopted. The topics include the types of drugs and care settings the formulary addresses, utilization management tools (PR, point-of-sale processing, retrospective review), the medical necessity dispute-resolution process, first-fill policies following an injury, and cost-saving policies (restrictions on physician dispensing, use of generic versus brand-name drugs, therapeutic interchange). We focus on the policies of five states with WC formularies: Ohio, Oklahoma, Tennessee, Texas, and Washington.
- Chapter Six outlines options for updating the list of formulary drugs, including the role of the P&T committee. We focus on P&T committee rules, including conflict-of-interest rules and transparency of decisionmaking, applicable to the committees involved in the Washington, Ohio, and Medi-Cal formularies.
- Chapter Seven synthesizes our findings and recommendations into a preliminary implementation plan and discusses next steps. The plan is preliminary because there are still aspects of the drug formulary that require further analysis before a final implementation plan can be developed. The plan first addresses the structure of the drug formulary and what would be needed to implement a formulary that is based on the MTUS. It then discusses the ancillary policies that affect how pharmacy prescriptions would flow through the bill-processing and medical necessity determination processes.

CHAPTER TWO

An Overview of Outpatient Drugs Furnished to Injured Workers

Purpose

This chapter provides background information on outpatient drugs furnished under California's WC program. First, we provide information on drug utilization and spending trends. Next, we describe how drug prescriptions currently flow through the bill-processing and medical necessity dispute-resolution processes.

Data and Methods

We used a mix of methods to develop the information presented in this chapter. We used the WCIS database (DWC, 2016a) as the primary data source for our analysis of the trends in drug use and spending from 2007 through 2013. The WCIS uses electronic data interchange to collect comprehensive information from claims administrators to help the Department of Industrial Relations oversee the state's WC system.[1] Medical data are transmitted to DWC within 90 calendar days of the date the bill is paid or a final determination is made to deny the billed medical services. By law, claims administrators with at least 150 total claims for injured workers per year are required to report medical data for all services provided on or after September 22, 2006. In earlier studies using this database, we found that there is underreporting but that the reported data are generally representative.

We flagged pharmacy claim lines and all medical claim lines with a reported National Drug Code (NDC) for our analyses. We excluded physician-administered drugs (so-called "J-codes") from our analyses. These drugs account for a small share of prescription drug volume and payments in California WC. We merged these data to the TRUVEN Health Analytics RED BOOK database by NDC to assign NDCs to therapeutic classes and to flag NDCs as "brand" or "generic," over-the-counter (OTC), bulk, and repackaged. If we restricted the data in a particular analysis by, for example, excluding compounded drugs, we expressly noted this.

We assigned all drugs with an opioid active ingredient, including synthetic opioids, to a class for opioids. We then used the RED BOOK therapeutic classes for the remaining drugs.

We supplemented our WCIS analyses with an environmental scan for relevant literature.

Our discussion of the current flow of drug bills was informed by interviews we conducted with individuals (or groups of individuals) representing different stakeholder perspectives: physician, pharmacy, PBM, UR organization, and payer. Several interviewees also provided flow charts that depicted their understanding of the bill-processing system.

[1] A *claims administrator* is an insurer; a self-insured, self-administered employer; or a third-party administrator.

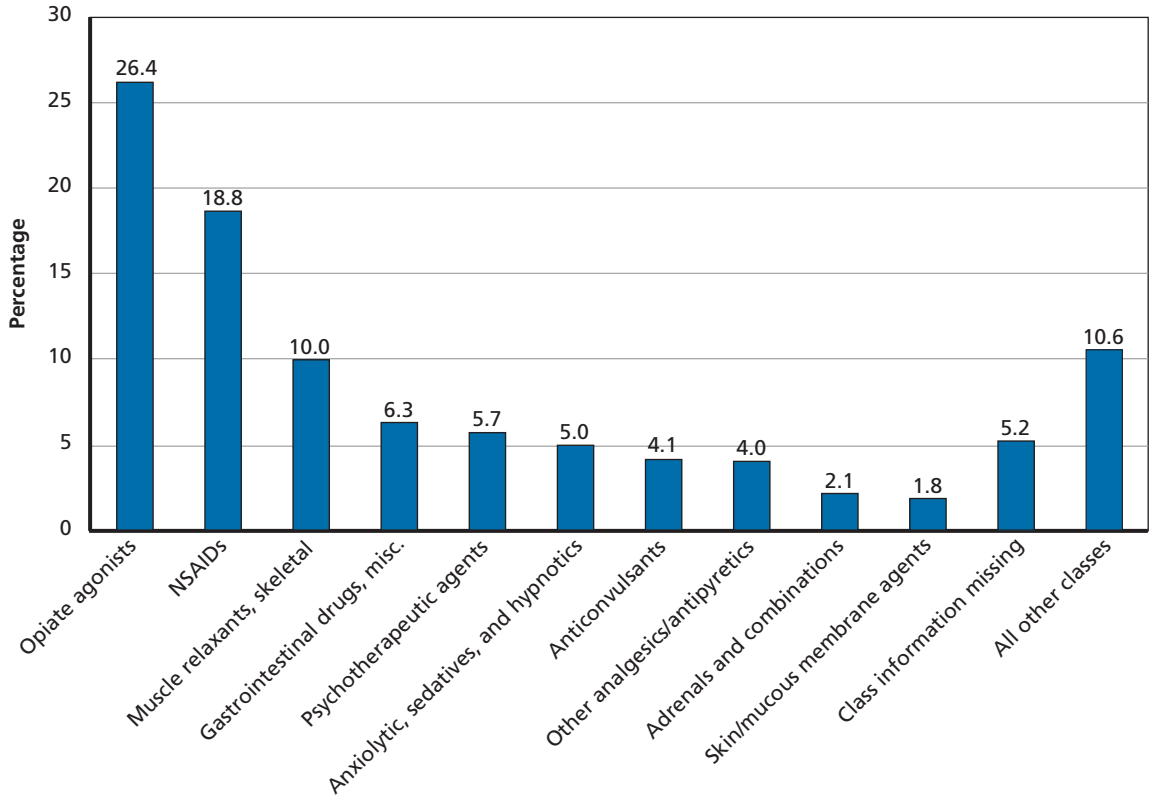
Trends in Outpatient Drugs Furnished to Injured Workers in California

In 2014, systemwide, the WC system paid an estimated $627 million for outpatient drugs, which represents 8.3 percent of its total spending for medical care.[2] Figure 2.1 shows the highest-volume therapeutic classes of drugs the system paid for in 2013.

Utilization and Spending

Overall, the distribution of utilization (Figure 2.2) and payments (Figure 2.3) across drug therapeutic classes was relatively stable over the seven-year study period. While opioid analgesics remain the top-prescribed drug class in WC, the share of opioid bill lines decreased from 29 percent in 2010 to 26 percent in 2013. This change roughly coincides with changes in

Figure 2.1
Drug Classes by Share of Volume in WCIS, 2013



SOURCE: RAND analysis of WCIS pharmacy and medical claims for outpatient drugs exclusive of physician-administered drugs.
NOTES: Volume is measured in terms of billed lines. The bulk of claims in "Gastrointestinal drugs, misc." are for antiulcerants, e.g., omeprazole. NDCs without a level 2 or 3 RED BOOK class are in "Class information missing." Classes in "All other classes" with more than a 1-percent share of volume include cardiac drugs; antipruritics or local anesthetics for skin and mucus membranes; miscellaneous central nervous system agents; antibiotics; and cathartics and laxatives.
RAND *RR1560-2.1*

[2] The Workers' Compensation Insurance Rating Bureau of California collects and reports medical expenditures by insurers (Workers' Compensation Insurance Rating Bureau, 2016). We converted the bureau's estimate of pharmaceutical expenditures by insurers into a systemwide estimate based on the insured market share of claims reported to WCIS (DWC, 2016a).

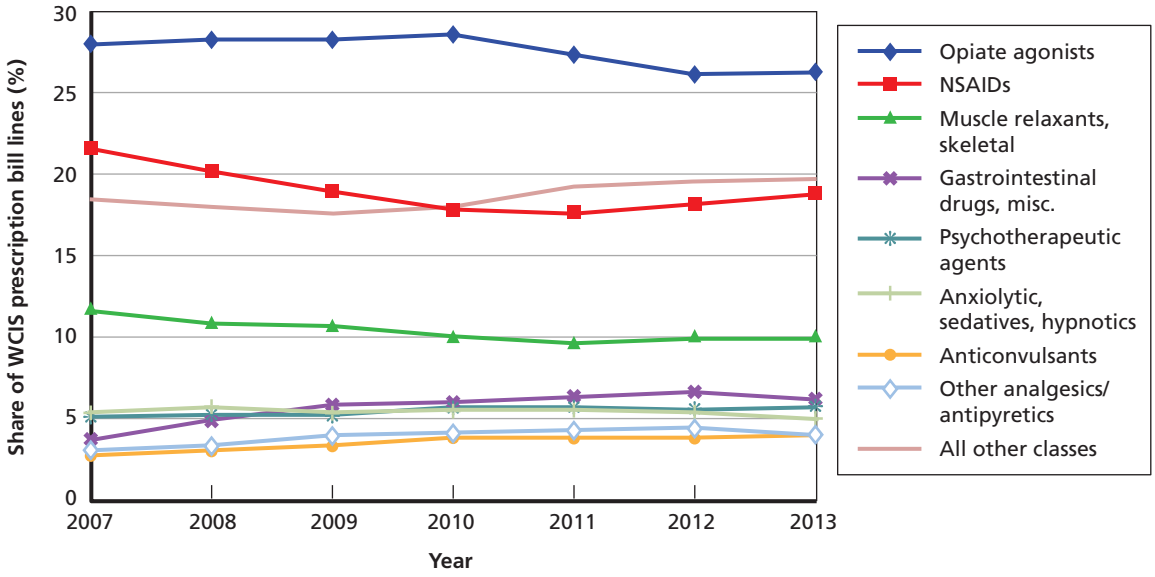
MTUS chronic pain guidelines issued in late 2009. It also corresponds with modest growth in the share of prescriptions for NSAIDs (by 5 percent over the same period), an alternative treatment option for pain.

We found a marked increase in prescribing and payments for antiulcerants (e.g., omeprazole), which account for the bulk of prescriptions in the "gastrointestinal drugs, misc." category in Figures 2.2 and 2.3. These drugs accounted for 11 percent of payments and 6 percent of volume in 2013, compared to 7 percent of payments and 4 percent of volume in 2007. They are typically prescribed in conjunction with NSAIDs to reduce gastrointestinal complications.

The average paid amount per billed line increased for some drug classes more than others (Figure 2.4). For example, the average paid amount per line for opiate agonists and for psychotherapeutic agents increased by nearly 40 percent from 2007 to 2013, while the price for NSAIDs—a class with many generic products and robust price competition—remained relatively flat. The payment per line for other analgesics—including topical analgesics—increased by over 800 percent from 2007 to 2013. Topical analgesics (RED BOOK's "Analgesic S/M" category) alone experienced a doubling in bill line volume and a 40-fold increase in payments from 2007 to 2013, or a roughly 20-fold increase in payments per bill line.

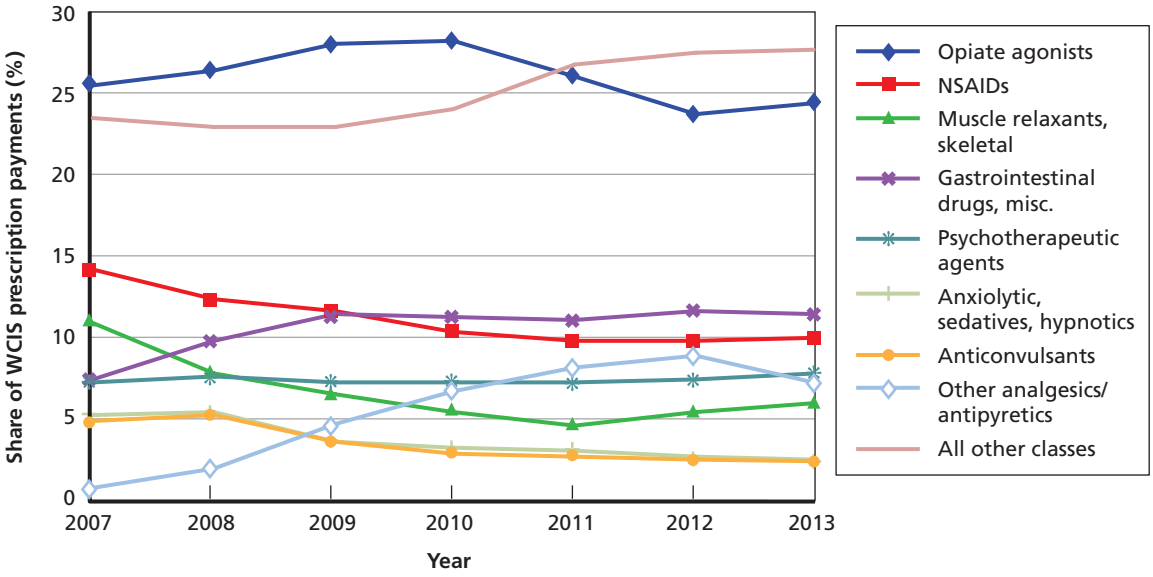
To describe overall utilization patterns, we calculated the change over time in the average number of drug line items and payments for injured workers with at least some paid medical bills in each calendar year. We found a 43-percent increase in the average number of drug line items per injured worker (Figure 2.5) and a 100-percent increase in drug payments per injured worker (Figure 2.6) from 2007 to 2013.

Figure 2.2
Trends in Therapeutic Class Share of Volume in WCIS, 2007–2013



SOURCE: RAND analysis of WCIS prescription and medical claims.
NOTES: Volume is measured in terms of billed lines. The bulk of claims in the "Gastrointestinal, misc." class are for antiulcerants, e.g., omeprazole.
RAND *RR1560-2.2*

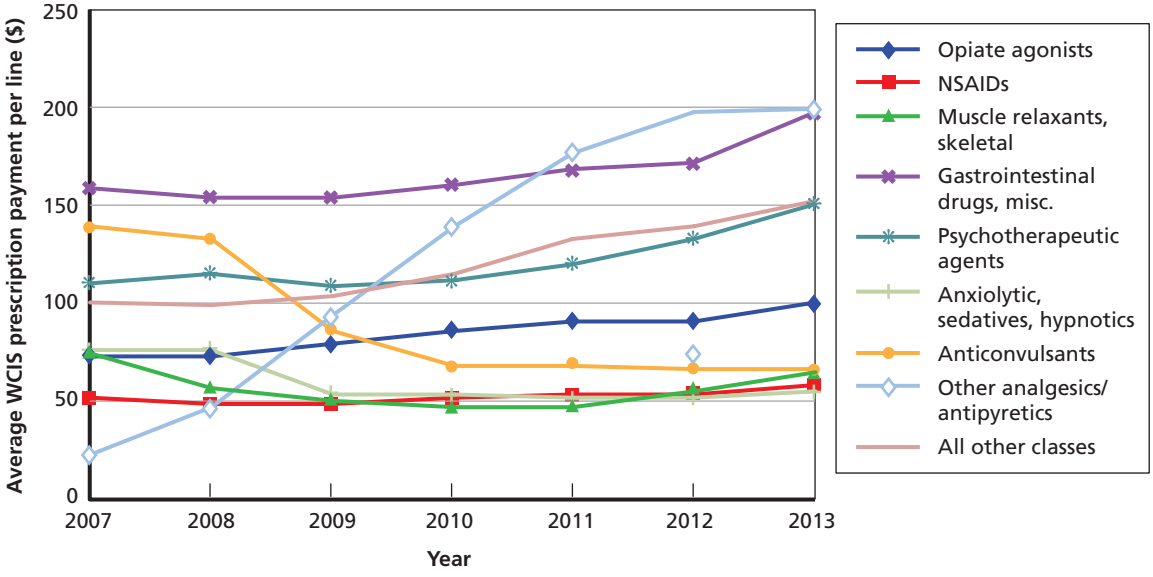
Figure 2.3
Trends in Therapeutic Class Share of Payments in WCIS, 2007–2013



SOURCE: RAND analysis of WCIS prescription and medical claims.
NOTES: Volume is measured in terms of billed lines. The bulk of claims in the "Gastrointestinal drugs, misc." class are for antiulcerants, e.g., omeprazole.

RAND *RR1560-2.3*

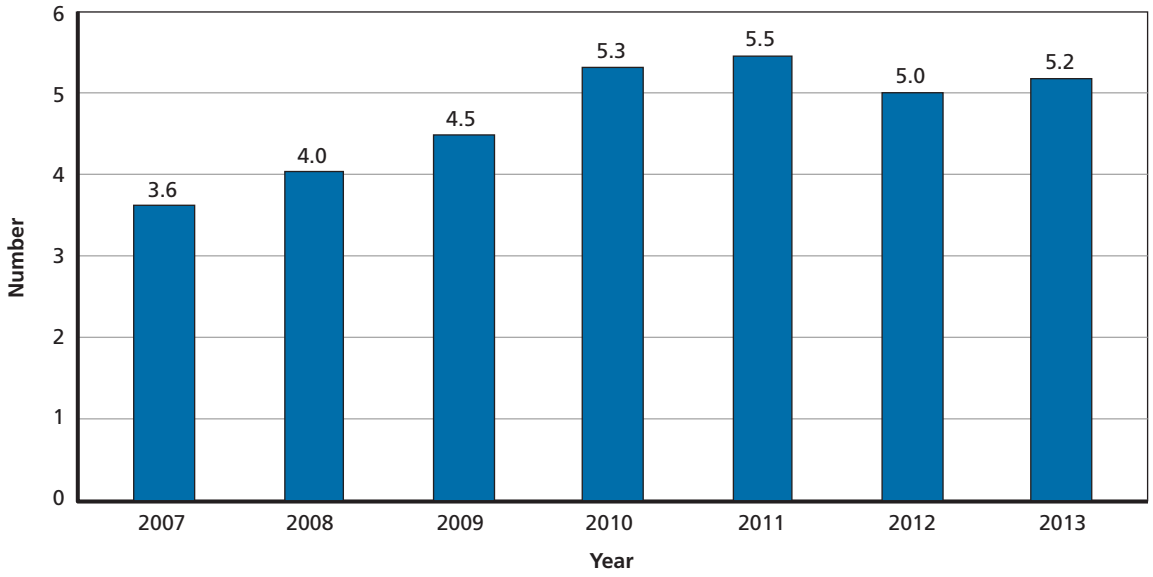
Figure 2.4
Trends in Average Payment per Drug Line in WCIS, 2007–2013



SOURCE: RAND analysis of WCIS prescription and medical claims.
NOTES: Volume is measured in terms of billed lines. The bulk of claims in the "Gastrointestinal drugs, misc." class are for antiulcerants, e.g., omeprazole.

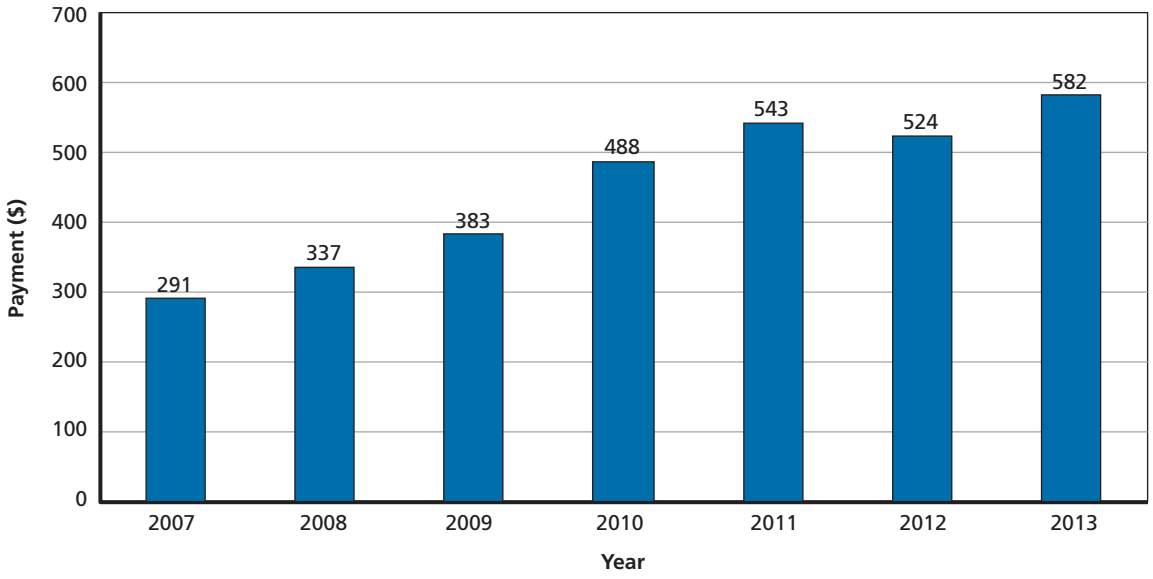
RAND *RR1560-2.4*

Figure 2.5
Average Outpatient Drug Line Items per Injured Worker in WCIS, 2007–2013



SOURCE: RAND analysis of WCIS prescription and medical bills.
NOTES: Each ingredient in a compounded drug is billed as a separate line item. The denominator includes all injured workers with nonzero medical claims in the given calendar year.
RAND *RR1560-2.5*

Figure 2.6
Average Payment per WC Claim in WCIS, 2007–2013



SOURCE: RAND analysis of WCIS prescription and medical bills.
NOTES: Each ingredient in a compounded drug is billed as a separate line item. The denominator includes all injured workers with nonzero medical claims in the given calendar year.
RAND *RR1560-2.6*

Generic Versus Brand-Name Drugs

The FDA can approve a generic drug after the brand-name drug's patents and periods of market exclusivity expire. Under the FDA definition, a *generic drug product* is a therapeutic equivalent to a reference drug product (often a brand-name drug) in active ingredient, dosage form, strength, route of administration, quality, performance characteristics (absorbed by the body at the same rate), and intended use. The FDA's "Orange Book" lists generic drugs that the FDA has assigned an "A" substitutable designation, which signifies that the reference drug and generic are substitutable (FDA, 2016a).[3]

Over time, price competition often drives generic prices down significantly below what they were before the generics entered the market. Because generic drugs are therapeutically equivalent to reference drugs and often less expensive, payers often encourage the use of generics to control costs. California Labor Code §4600.1 requires dispensing FDA-approved substitutable generics unless a generic is not available or the prescribing physician specifically provides, in writing, that a nongeneric (brand-name) drug must be dispensed (AB 1124 sunsets this provision of the Labor Code, so the formulary rules will need to address dispensing of brand-name drugs when generics are available). The share of WC paid prescriptions for brand-name drugs when an approved generic substitute is available has been relatively constant over time, at about 5 percent (Figures 2.7 and 2.8). In 2013, an estimated 5.4 percent of prescriptions and 10.2 percent of drug spending was for brand-name drugs for which one or more generic equivalents were available (compared to 4.8 and 8.3 percent, respectively, in 2007). In general, more common brand-name drugs have generic equivalents in 2013 compared to 2007. This may be one driver of the growing proportion of generic bill lines and shrinking proportion of brand bill lines without available generics from 2007 to 2013.

Physician Dispensing

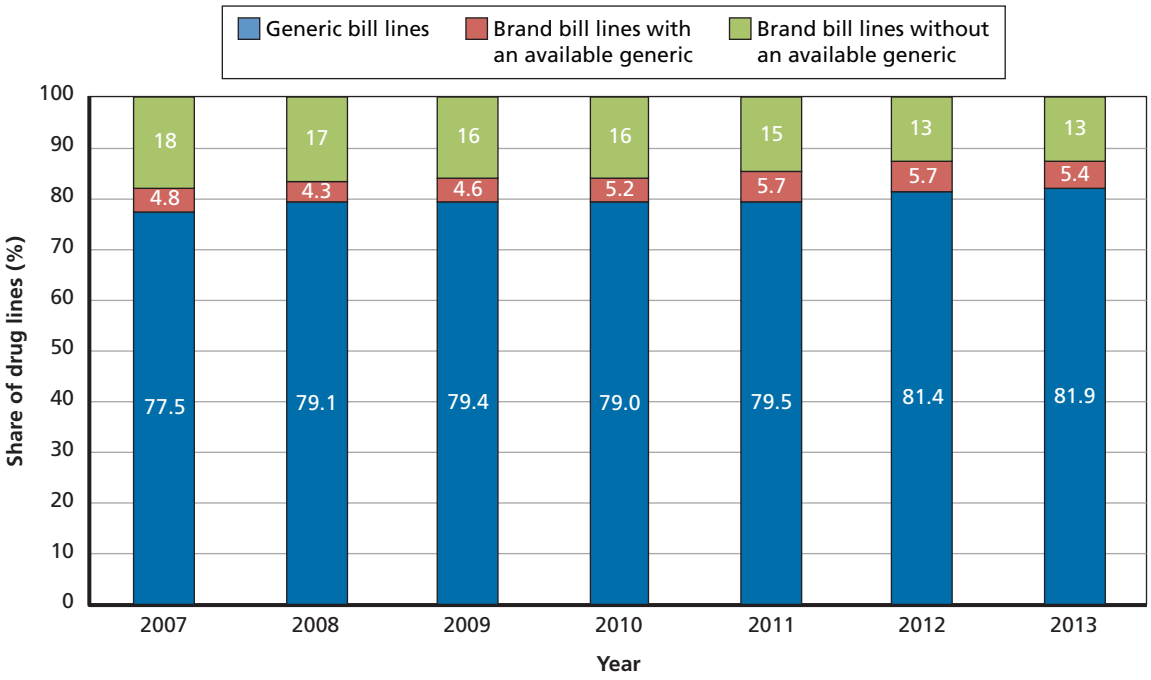
Section 4024(b) of the California Business and Professions Code allows physicians and other practitioners acting within the scope of their practices to dispense drugs to patients within their offices.[4] The Labor Code implicitly recognizes physician in-office dispensing in §4600.1 (dealing with generic drugs) and §5307.1 (dealing with the OMFS). AB 1124 did not address physician dispensing.

Physician dispensing is facilitated by FDA-approved "repackagers" who purchase drugs in bulk and repackage them into individual prescription sizes for sale by physician offices. Thus far, California has tried to address physician dispensing through its OMFS rules. Since 2004, the OMFS for pharmaceuticals has been based on the Medi-Cal fee schedule. Because Medi-Cal does not cover physician-dispensed drugs, the fee schedule did not have a Medi-Cal price for repackaged drugs. DWC addressed this loophole in 2007 by requiring that the allowance for each drug ingredient be based on the original manufacturer's NDC allowance. A significant portion of WC prescription drugs are still dispensed by physicians (Figures 2.9 and 2.10). In 2013, 54 percent of prescription drug lines and 48 percent of drug payments were for physician-dispensed drugs, exclusive of compounded drugs. Overall, there are important

[3] California's Business and Professions Code §4073 allows a pharmacist to substitute another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form and of the same generic drug name.

[4] The rules governing in-office dispensing are found in §4170-4175 of the California Business and Professions Code. They include a requirement that the prescriber inform the patient that he or she may elect to obtain the drug from the prescriber or from a pharmacy.

Figure 2.7
Relative Share of Outpatient Drug Claim Lines by Brand and Generic Category in WCIS, 2007–2013



NOTES: Totals exclude claim lines for bulk ingredients and OTC products. Drugs in "Brand bill lines with an available generic" were flagged using TRUVEN's RED BOOK data. Specifically, these bill lines are for NDCs flagged as brand names with at least one NDC flagged as generic within the same active ingredient, dosage strength, formulation, and route of administration. We required that generic NDCs meeting these criteria were first marketed (i.e., added to the RED BOOK database) prior to the calendar year of the brand-name drug's bill line. The denominator for this chart includes only generic and brand billed drug lines.

RAND *RR1560-2.7*

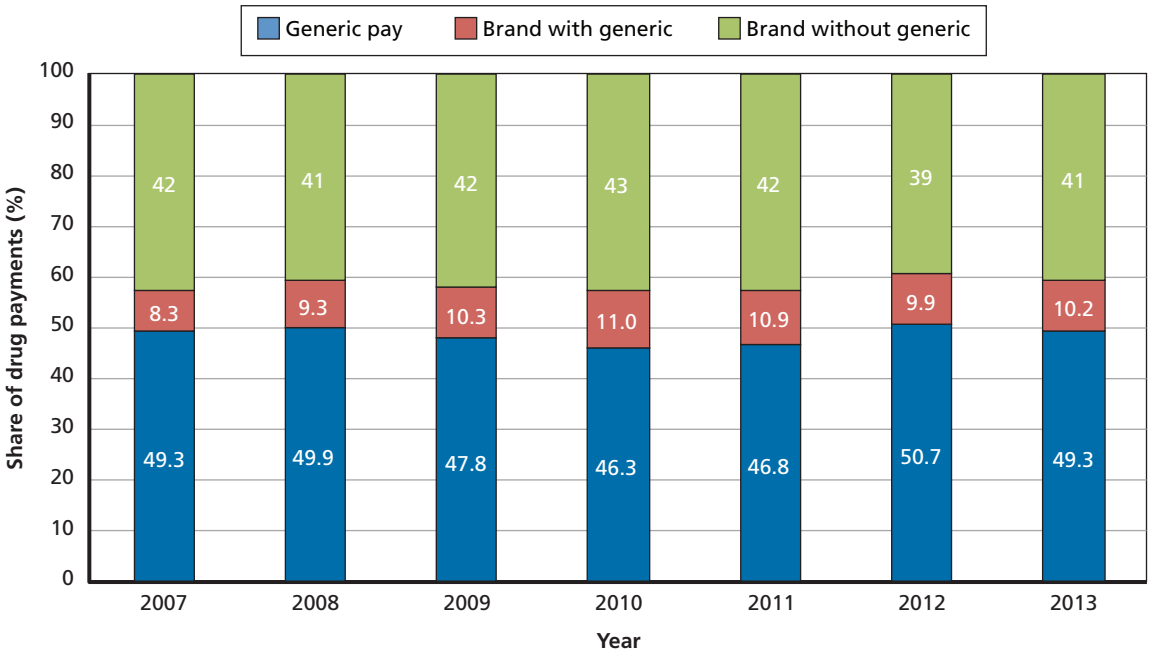
differences in the mix and type of drugs dispensed by physicians rather than by pharmacies. Physicians are less likely to dispense brand-name drugs. OTC drugs and some analgesics—especially tramadol hydrochloride—were frequently physician dispensed.[5] The larger shares of prescription volume (in Figure 2.9) than prescription payments (in Figure 2.10) for brand-name drugs with generic equivalents and opioids suggest that physician-dispensed prescriptions cost less on average than pharmacy-dispensed prescriptions, either because the unit prices were lower or because the quantities dispensed were smaller.[6] Likewise, larger payment shares compared to volume shares for physician-dispensed drugs in "Other analgesics/antipyretics," including topical analgesics, suggest that physician-dispensed prescriptions in these categories had a higher average cost than pharmacy-dispensed prescriptions.

There are issues regarding the impact of physician dispensing on quality, utilization, cost, and patient satisfaction. Proponents of physician dispensing argue that in-office dispensing is convenient for patients, provides more confidentiality, and increases patient compliance in filling and refilling prescriptions. Opponents argue that allowing physicians to profit from dis-

[5] More than one-half (55 percent) of tramadol billed lines are medical rather than pharmacy lines.

[6] Prior WCRI and the California Workers' Compensation Institute work suggests that unit prices for physician-dispensed drugs are higher than unit prices for pharmacy-dispensed drugs. As a result, our finding may be driven more by the smaller quantities dispensed.

Figure 2.8
Relative Share of Outpatient Drug Claim Line Payments by Brand and Generic Category in WCIS, 2007–2013



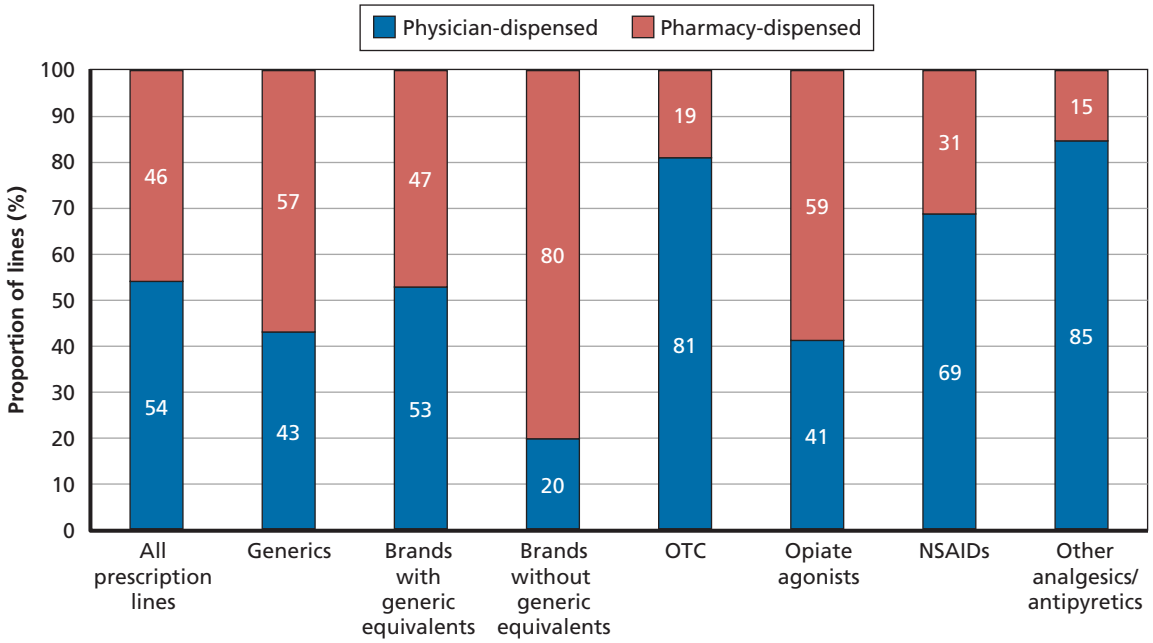
NOTES: Totals exclude claim lines for bulk ingredients and OTC products. Drugs in "Brand with generic" were flagged using TRUVEN's RED BOOK data. Specifically, these bill lines are for NDCs flagged as brand names with at least one NDC flagged as generic within the same active ingredient, dosage strength, formulation, and route of administration. We required that generic NDCs meeting these criteria were first marketed (i.e., added to the RED BOOK database) prior to the calendar year of the brand-name drug's bill line. The denominator for this chart includes only generic and brand billed lines.

RAND *RR1560-2.8*

pensing medications could inappropriately influence prescribing practices and encourage the provision of medically unnecessary drug therapies (Vivian, 2002). High-quality care is also potentially jeopardized because physician-dispensed prescriptions often bypass both a pharmacist's review of prescriptions for errors and drug interactions and a payer's prospective UR process to ensure the proposed treatment therapies are medically appropriate; instead, UR occurs retrospectively, after the drug has already been dispensed to the injured worker. A California Workers' Compensation Institute study found that physician-dispensing is associated with 17-percent-higher average paid medical benefits per claim, 13-percent-higher average indemnity benefits per claim, and 9 percent more temporary disability days (Swedlow, Gardner, and Ireland, 2013). Similarly, a study examining the effect of physician-dispensing on Illinois WC outcomes found that claims with physician-dispensed medications were associated with higher pharmaceutical, medical, and indemnity costs and more lost-time days than claims associated with pharmacy-dispensed medications (White et al., 2014). This study found that the effect for physician-dispensed opioids was nearly double that for pharmacy-dispensed opioids.

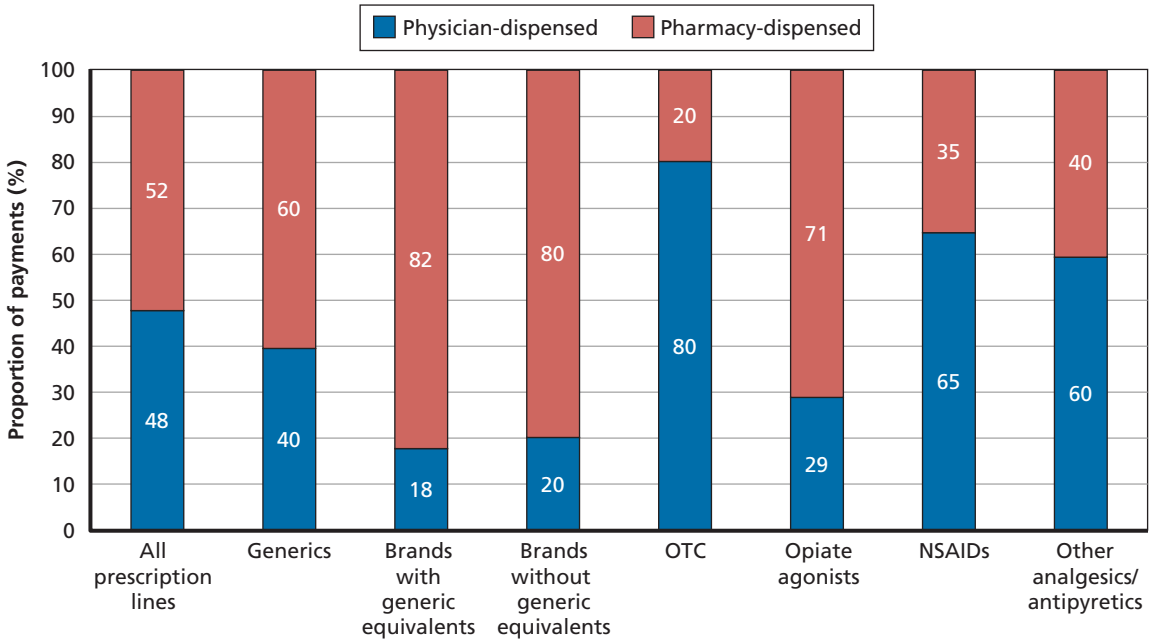
Physician dispensing of opioids is particularly concerning. Studies have identified opioid use as a significant driver of medical and indemnity costs (Bernacki et al., 2012; Tao et al., 2015; White et al., 2012). The experience in Florida following its prohibition of physician dispensing of Schedule II and Schedule III opioids suggests that there may be overprescribing of physician-dispensed opioid drugs. After the prohibition was implemented, the number

Figure 2.9
Relative Share of Physician-Dispensed and Pharmacy Outpatient Drug Lines, 2013



RAND *RR1560-2.9*

Figure 2.10
Relative Share of Physician-Dispensed and Pharmacy Outpatient Drug Payments, 2013



RAND *RR1560-2.10*

of prescriptions for stronger opioids decreased but was offset by a corresponding increase in physician-dispensed weaker opioids (Schedule IV) and NSAIDs, with no change in the number of prescriptions for the stronger opioid prescriptions dispensed by pharmacies (Thumula, 2013).

Other Concerning Prescribing Practices

Tightening OMFS rules for physician dispensing of repackaged drugs in 2007 (discussed above) led to an increase in prescriptions for compounded drugs and medical foods and copacks (Ireland and Swedlow, 2010).[7] Compounding has traditionally involved combining two or more drug ingredients to meet the needs of specific patients for medications that are not otherwise commercially available. They should not be confused with FDA-approved combination drugs that include more than one drug ingredient, such as hydrocodone-acetaminophen. While traditional compounded drugs are customized for individuals, some OTC products are precompounded and marketed in California for physician dispensing.

Compounded drugs are exempt from FDA approval if they meet the conditions of the Drug Quality and Security Act (enacted in 2013). The act requires a compounder engaged in compounding sterile drugs to register with the FDA; become an "outsourcing facility"; and not compounded drugs that are essentially copies of approved drugs, including OTC drugs with final FDA monographs.[8] Outsourcing facilities are also subject to licensure by the state pharmacy board. In addition, California's Business and Professions Code §4052(a)(1) limits physician dispensing of compounded drugs to a 72-hour supply. The most commonly prescribed compounded drugs for WC patients are topical analgesic creams and lotions.

In 2012, AB 378 (Solorio) made changes in the OMFS to address the rising cost of compound drugs, medical foods, and copacks by limiting maximum allowances based on ingredient costs. In the first six months following implementation, the volume of compounded drugs fell, but the average payment per prescription increased significantly because of increases in both ingredient unit prices and the number of ingredients (Swedlow and Auen, 2013). More-recent analyses indicate that changes resulted in a reduction in payments for physician-dispensed compounded drugs but an increase in payments for pharmacy-dispensed compounded drugs (Wilson et al., 2015). Relative to 2011, there has been a 44-percent increase in the number of prescriptions for compounded drugs, and the average paid amount per prescription has more than doubled.

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[7] A *medical food* is specially formulated and processed for a patient who is seriously ill or requires the food as a treatment modality. It is not a drug. *Copacks* are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription (Wynn, 2011). This report does not address either type of product, but the MTUS chronic care guidelines do address them.

[8] The Drug Quality and Security Act (enacted in 2013) allows a compounder engaged in compounding sterile drugs to register with the FDA and become an "outsourcing facility." An *outsourcing facility* is subject to the FDA's current good manufacturing requirements, is inspected by the FDA, and must report any adverse events related to its products. A drug product compounded by an outsourcing facility is exempt from FDA approval only if it is not "essentially a copy of one or more approved drug products." Under draft guidance for the industry issued in July 2016, the FDA proposes to determine that a compounded drug product that contains a bulk drug substance that is also a component of an FDA-approved drug is "essentially a copy of one or more approved drug products" unless the prescribing practitioner has determined and documented that there is a clinical difference between the compounded drug and the comparable approved drug. A compounded drug product is essentially a copy of a covered OTC drug if it contains a bulk drug substance that is also a component of a covered OTC drug. A covered OTC drug product is one for which the FDA has published a monograph specifying the conditions under which the OTC drug is generally recognized as safe and effective (FDA, 2016c). Most compounded drugs dispensed for injured workers are topical creams and ointments that would not be compounded by an outsourcing facility.

A recent WCRI report highlights a new concern with physician dispensing. The report indicates that the OMFS is now being undermined by physician dispensing of "specialty" drugs (FDA-approved drugs with unique dosages or formulations). These products, which were introduced when the AB 378 provisions were being implemented, have unit costs that are much higher than those for the commonly prescribed strengths of the same drug ingredient and appear to be prescribed for financial, rather than medical, reasons (Wang, Thumula, and Liu, 2016). For example, the researchers found that 55 percent of physician-dispensed cyclobenzaprine HCL (Flexeril) in the first quarter of 2014 was for 7.5 mg, at an average unit price of $3.01, compared to unit prices of $0.38 and $0.39 for the more common 5-mg and 10-mg dosage strengths. In comparison, only 2 percent of the pharmacy-dispensed prescriptions were for the 7.5 mg strength, at an average unit price of $1.52 (Wang, Thumula, and Liu, 2016).[9]

Prescribing of Medically Inappropriate Drug Therapies

As noted earlier, California's medical necessity dispute-resolution process has two components: (1) A payer determines the medical appropriateness of medical treatment through UR, and (2) an employee may appeal a UR decision to modify or deny care by requesting IMR. Nearly 50 percent of IMR requests are for pharmaceuticals, even though these services represent only 6.2 percent of individual treatments (billed line items). Nearly one-third of prescription drug IMR appeal decisions were for opioid analgesics, and more than one-half were for opioids, muscle relaxants, or NSAIDs (Figure 2.11). Overall, 8.6 percent of IMR appeal decisions for specific prescription drug treatments were overturned (that is, the requested treatment was determined to be medically appropriate) and ultimately furnished to injured workers, while the vast majority—91.4 percent—were upheld as medically inappropriate. The proportion of these decisions that were overturned varied significantly across drug classes, from greater than 20 percent for gastrointestinal agents, impotence agents, and antidepressants to under about 3 percent for sedatives, muscle relaxants, and topical compounds (Figure 2.12). Opioid analgesics had about the average overturn rate, 9.5 percent.

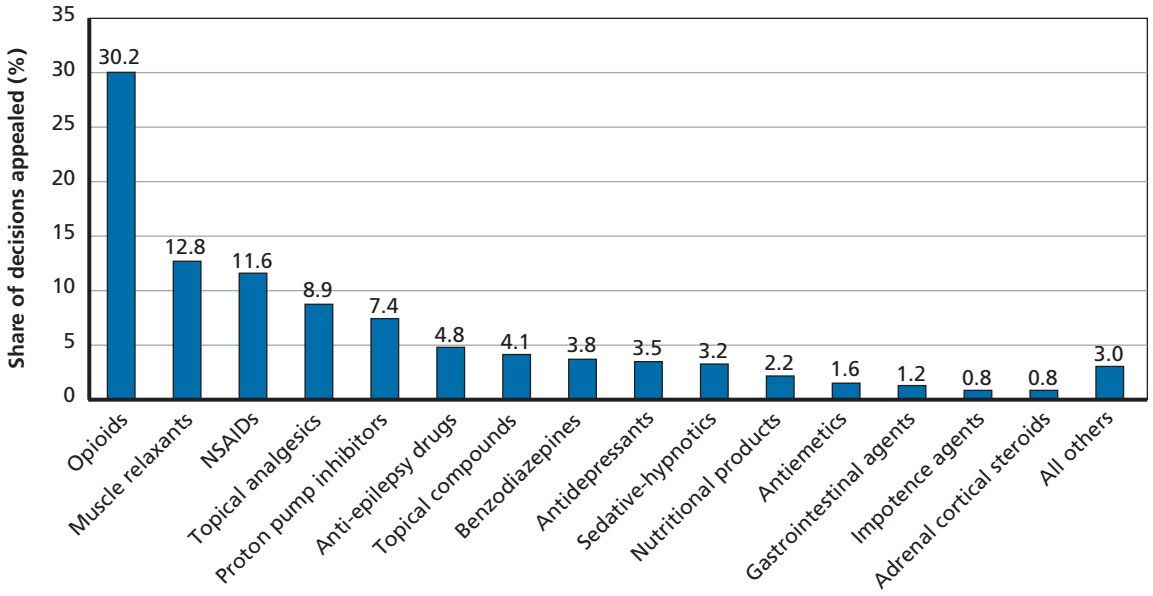
Prescribing Drugs Not Covered by the Medi-Cal Fee Schedule

The OMFS establishes the maximum allowable amount that is payable for a covered medical service unless the payer and provider negotiate a different payment amount. For pharmaceuticals, the OMFS is based on the Medi-Cal fee schedule for outpatient pharmacy services. The allowance is determined using a unit price (per metric decimal) based on the lowest cost for the ingredient or, if "no substitutions" is indicated on the prescription, a "no substitution" cost for the brand name:

- For simple prescriptions, the Medi-Cal price is the applicable unit price times the number of units plus a dispensing fee of $7.25 for patients who are not in a nursing home. Most unit prices are based on 83 percent of the average wholesale price for a drug. The average wholesale price is the manufacturer's suggested "sticker price" for wholesalers to charge pharmacies. The average wholesale price is compiled by commercial publishers of drug pricing data, such as First Databank (undated) and TRUVEN Health Analytics' RED

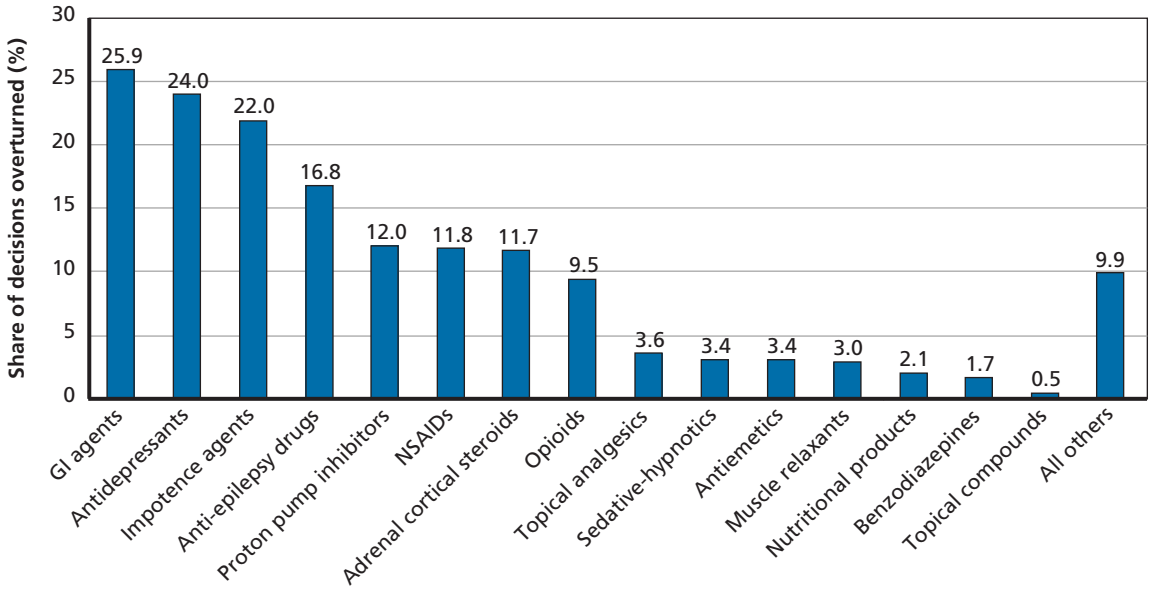
[9] Wang, Thumula, and Liu (2016) identified two other new-strength drug products: 2.5/325 mg hydrocodone-acetaminophen and 150 mg tramadol HCL extended release. Higher proportions of both drug products are physician dispensed.

Figure 2.11
Share of Prescription Drug IMR Appeal Decisions, by Issue, 2014



SOURCE: RAND analysis of IMR data provided by Maximus, the California IMR organization for WC.
RAND *RR1560-2.11*

Figure 2.12
Share of Outpatient Drug IMR Appeal Decisions Overturned, by Class, 2014



SOURCE: RAND analysis of IMR data provided by Maximus, the California IMR organization for WC.
RAND *RR1560-2.12*

BOOK (2016) and does not reflect actual pharmacy acquisition costs for drugs. Lower unit prices apply to certain multisource (generic) drugs.
- For prescription compounded drugs, Medi-Cal determines the price for each ingredient separately (based on the applicable unit price and quantity) and adds a compounding fee based on the dosage form and route of administration and, if applicable, a sterility fee to the professional services fee. Labor Code §5307.1(e) limits the allowance for a compounded drug product dispensed by a physician to 300 percent of documented paid costs, but in no case more than $20 above documented paid costs.
- The allowance for OTC drugs (which require a prescription before they are covered) is determined using the same formula as the prescription drug.

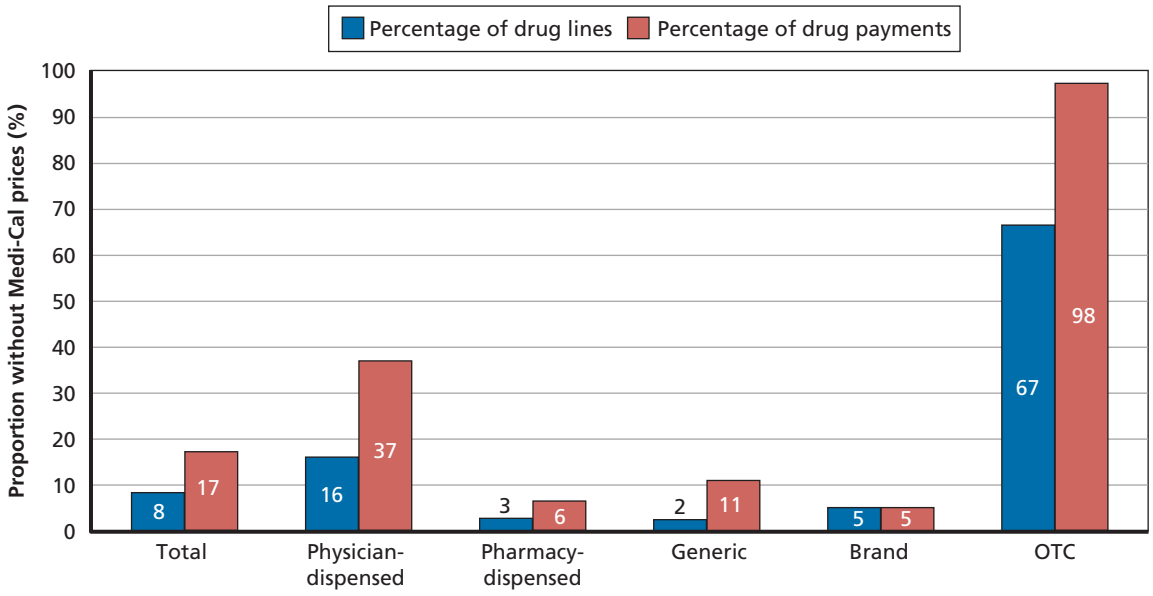
The Medi-Cal fee schedule is limited to covered drugs provided by drug manufacturers that participate in the federal Medicaid drug rebate program; as a result, not all drugs provided to WC patients appear in the Medi-Cal fee schedule.[10] If a drug product is dispensed that does not have a Medi-Cal unit price (e.g., a repackaged drug), OMFS rule §9789.40(b) provides that the unit price for the underlying drug product from the original labeler will apply; if there is no price for the underlying drug product, the OMFS allowance is based on 83 percent of the average wholesale price of the lowest priced therapeutically equivalent drug.

A significant share of prescriptions—8 percent of all prescription lines—do not have a Medi-Cal price (Figure 2.13). These prescriptions account for 17 percent of prescription payments. Physician-dispensed drugs, many of which are categorized as OTC drugs in the RED BOOK data, are significantly less likely to have Medi-Cal prices than other drugs. AB 378 amended Labor Code §5307.1(e) to establish an additional limit on physician-dispensed drugs. The maximum allowance is limited to the lowest of the OMFS fee schedule amount, 120 percent of the documented paid cost to the physician, or 100 percent of the documented paid cost to the physician plus $250. This provision has not been codified in regulations. While it should be self-implementing, obtaining information from the dispensing physician regarding the costs of the medication may not be cost-effective on a bill-by-bill basis.

A relatively small set of drugs accounts for the majority of prescription lines and payments without Medi-Cal prices. The top 20 drugs, ranked by total payments for NDCs without Medi-Cal prices, account for 80 percent of total payments for such drugs in the 2013 WCIS data (Table 2.1). Several topical analgesics—for example, combinations of capsaicin, lidocaine, and menthol—are listed in the top 20 drugs. Tramadol hydrochloride, a synthetic opioid used to treat pain, accounts for 16 percent of drug lines and 24 percent of drug payments for NDCs without Medi-Cal prices. The majority of tramadol drugs without Medi-Cal prices are for extended release capsules in an unusual 150 mg strength and suspension formulations without Medi-Cal prices. The drug lines that do not have Medi-Cal prices for ranitidine hydrochloride and diphenhydramine hydrochloride are for atypical suspensions. For example, the Medi-Cal fee schedule has prices for a 15 mg/ml solution of ranitidine hydrochloride but not for the commonly prescribed 16.8 mg/ml suspension, 93 percent of which is physician dispensed.

[10] The *contract drug list* is a listing of drugs that do not require PR. It is limited to manufacturers that also participate in the state's supplemental rebate program. The Medi-Cal fee schedule includes these manufacturers, as well as those that participate only in the federal rebate program.

Figure 2.13
Share of Outpatient Drug Lines and Payments Without Medi-Cal Prices, 2013



SOURCE: RAND Analysis of 2013 WCIS data. Bills for drugs used in compounding and discontinued drugs were excluded from the totals and percentages in the table.

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Pharmacy Networks

In California's WC system, the Labor Code permits two types of network pharmacies: those that are part of a PBM's pharmacy network and those that are part of an employer's medical provider network (MPN). Labor Code §4600.2 allows a payer to contract with a pharmacy, group of pharmacies, or pharmacy benefit network to provide medically appropriate medicines and medical supplies. The provision stipulates that drugs and supplies will be provided to injured workers consistent with the terms of the contract. DWC has not issued rules setting standards for pharmacy benefit networks. In the absence of rules, the only guidance specific to pharmacy benefit networks is found in the Labor Code. In *Jose Brambila v Vons Inc.*, 2010, a WC Appeals Board panel affirmed that the payer was not liable for medications provided outside the pharmacy network.

MPNs are another important tool currently available to manage pharmaceutical benefits. Under Labor Code §4616, an employer has the right to establish an MPN and control care provided to injured workers throughout the course of the claim. The network may include physicians and ancillary services, including pharmaceuticals. Care provided within the MPN must be consistent with the MTUS. Implementing rules include access standards and other requirements that must be met for physician services, but these standards do not apply to pharmacies and other ancillary providers. The employer is not liable for care provided outside the network. The expedited hearing process is used to determine whether medically necessary care is not available through the network.

To some extent, the two provisions appear redundant, and the intended purpose of both provisions is to provide medically appropriate pharmaceuticals. Indeed, some MPN contracts

Table 2.1
Top 20 Active Ingredients Ranked by Total Payments Without Medi-Cal Fee Schedule Prices

	Percentage of				
Ingredient(s)	All Drug Lines	Ingredient Drug Lines	Drug Lines Without OMFS Prices	All Drug Payments	Payments for Drugs Without Medi-Cal Prices
Capsaicin/menthol/methyl salicylate	1.3	100.0	15.3	5.1	29.6
Tramadol hydrochloride	1.3	26.2	15.8	4.1	23.9
Capsaicin/lidocaine/menthol/methyl salicylate	0.3	100.0	3.6	1.2	6.8
Lidocaine and menthol	0.2	100.0	2.3	1.1	6.4
Capsaicin and menthol	0.4	100.0	4.9	1.0	5.7
Menthol and methyl salicylate	0.5	100.0	6.6	0.5	3.0
Gabapentin	0.1	3.5	1.5	0.4	2.4
Ranitidine hydrochloride	0.1	35.4	1.2	0.4	2.2
Cyclobenzaprine hydrochloride	0.1	4.2	1.7	0.4	2.1
Diphenhydramine hydrochloride	0.1	53.9	1.2	0.4	2.1
Acetaminophen and hydrocodone bitartrate	0.3	3.4	3.9	0.4	2.1
Sildenafil citrate	0.1	98.1	1.1	0.3	1.5
Tadalafil	0.1	91.7	0.9	0.2	1.3
Menthol	1.2	100.0	14.6	0.2	1.3
Hydroxytryptophan/magnesium/melatonin/pyridoxine/tryptophan	0.1	100.0	0.7	0.1	0.8
Docusate sodium	0.2	25.8	2.5	0.1	0.7
Hyaluronate sodium	0.0	29.1	0.3	0.1	0.5
Chondroitin sulfate/dimethyl sulfone/glucosamine sulfate	0.1	100.0	0.8	0.1	0.5
Modafinil	0.0	8.2	0.1	0.1	0.4
Docusate sodium and sennosides A and B	0.1	100.0	1.3	0.1	0.4
All other ingredients without Medi-Cal prices	1.6	2.3	19.8	0.1	6.3
All drugs without Medi-Cal prices	8.3		100.0	17.2	100.0

include pharmacy network contracts, while others expand a PBM's pharmacy network to include occupational medicine clinics and selected physician dispensers. Having both provisions means that an employer may decide whether to contract with an MPN that furnishes both physician and pharmaceutical services or to have separate contracts with a physician network and a pharmacy benefit network.

Regardless of the Labor Code applicable to network pharmacies, PBMs manage most WC drug benefits in California that are pharmacy dispensed. They operate under contract with payers to manage pharmacy claims by establishing formularies, authorizing benefits, and negotiating prices with network pharmacies. They either contract with the pharmacies to provide pharmaceutical services or own and operate pharmacies (or mail order services). Under most arrangements, the PBM retains the difference between what it pays for drugs to its network pharmacies and the contracted amount (typically a discount off the OMFS allowance).

Current Flow of Drug Prescriptions

This section describes two basic pathways for WC drug prescriptions under the current system once a compensability determination has been made on an injured worker's claim. It does not discuss the typical pathway for drugs that are prescribed and dispensed before this determination has been made. The compensability determination must be made within 90 days after an employer is notified of the injury and reflects both the payer's assessment of the compensability of the claim and the nature of the compensable injuries and affected body parts. In this interim period before the compensability determination is made, an employer is liable for the first $10,000 in medically appropriate medical services. However, contracts between the payer and PBM may transfer liability from the employer to the PBM. Although the details vary, payer contracts with PBMs often require the PBM to assume the cost for a drug that is dispensed before the compensability determination if the claim is subsequently denied or if UR determines the drug to be medically inappropriate for the worker's compensable injuries.

An injured worker is typically provided with a drug card that indicates where prescriptions should be filled. Once the compensability determination is made, the basic pathways are different when drugs are dispensed (1) by a network retail pharmacy or (2) by the prescribing physician or a nonnetwork pharmacy. In the network pharmacy situation, the contractual arrangements between the payer, PBM, and network pharmacies affect the type of communication exchanges and the respective roles of each party in processing pharmacy bills and making medical necessity determinations.

Prescriber

The prescriber determines the medications that he or she believes are most appropriate for treating the injured worker's condition. In doing so, the prescriber may consult the MTUS to determine the recommended treatments. The prescriber may submit a request for authorization (RFA) to the claims administrator and defer prescribing the medication until authorization is received from the payer. Alternatively, the prescriber may either dispense the drug or provide the prescription to the injured worker to take to a pharmacy (or submit the prescription electronically) without filing a request for authorization or if one is filed, waiting for completion of the PR.

Pharmacy

When a *network* pharmacy receives the prescription, it contacts the PBM electronically to confirm WC eligibility and authorization to dispense the drug. Depending on its arrangements with the PBM, the pharmacy may have direct access to information on the claimant through the PBM and may be delegated certain functions, e.g., generic substitution or contacting the

prescriber about a potential therapeutic substitution. Unless its contract with the PBM requires all pharmacy bills to be dispensed through the PBM, a pharmacy may decide to go "out of network" and file a paper bill with the payer when a pharmacy prescription is problematic, e.g., a compounded drug (Wynn, 2011).

A *nonnetwork* pharmacy may use a pharmacy services biller to bill the payer electronically for the drugs; in that case, there may be contact with the claims administrator to confirm WC eligibility and authorization to dispense the drug. Alternatively, a nonnetwork pharmacy may dispense the drug and submit a paper bill to the payer or redirect the injured worker to a network pharmacy.

If a pharmacy dispenses the medication without obtaining authorization, the payer is not liable for the drug cost if subsequently determined medically unnecessary; however, the PBM may assume liability and pay a network pharmacy for the drug. If the employer limits its coverage to pharmacy network providers, a nonnetwork pharmacy may file a lien to recover its charge for the prescription.

Claims Administrator or PBM

The roles the claims administrator and PBM play in adjudicating a prescription depend on how the responsibilities for processing network pharmacy bills are allocated between the two. Typically, information on the injury is not shared until the compensability determination is made, and the level of detail provided on the claimant (e.g., nature of injury and body part, diagnosis) depends on the arrangements between the claims administrator and the PBM. The PBM most often screens and pays the network pharmacies at discounted rates and bills the payer at the OMFS rates. The bill-processing screens determine which prescriptions may be approved at the point of sale and which require further claims administrator review and whether there has been a PR decision. The screens identify situations involving premature refills, drugs that are not indicated for the worker's condition, brand-name prescriptions for which generic versions are available, and high-cost or high-risk drugs that require the approval of the claims administrator (or a UR organization under contract to the claims administrator). The PBM may approve drugs when delegated authority to do so, but the PBM should not modify or deny a prescription unless the claims administrator or its designated UR organization has made an adverse UR determination. If the prescription passes the PBM's bill-processing screens, the pharmacy is notified, and the drug is dispensed. If a drug does not pass prepayment screens and if there is no PR decision on the record, the prescription should be referred to the claims administrator for authorization. While some requests can be handled quickly (e.g., the claims adjustor has authority to approve the prescription), others require clinical review, and a decision may not be forthcoming for several days. The PBM notifies the pharmacy that the drug cannot be dispensed until it is reviewed.

If a drug is dispensed without PR approval, the claims administrator may review the drug therapy retrospectively to determine whether it is consistent with the MTUS. If it is not, an adverse UR decision is issued. The injured worker may file a request for IMR review of the UR decision.

In addition to the bill review and processing function described above, the claims administrator or PBM have responsibilities for a postpayment drug UR program to identify inappropriate prescribing patterns.

Summary

This chapter provided an environmental scan of outpatient drugs provided to California's injured workers. Most trends in utilization and spending for outpatient drugs furnished to injured workers from 2007 to 2013 are matters of concern:

- We found a 43-percent increase in the average number of drug line items per WC claim and a 100-percent increase in average drug payments per injured worker from 2007 to 2013.
- While opioid analgesics remain the top-prescribed drug class in WC, the share of opioid billed lines remained high, at 24 percent, in 2013.
- Utilization and payments for antiulcerants and topical analgesics, both of which are disproportionately physician-dispensed, increased significantly. In particular, topical analgesics were prescribed twice as often at 20 times higher cost per prescription in 2013 than 2007.
- The percentage of lines for generic drugs increased from 78 percent to 82 percent, but the percentage of total payments that were for brand-name drugs for which a generic version was available grew from 8.3 percent in 2007 to 10.2 percent in 2013.

Other indicators are also concerning. In 2013, physician-dispensing accounted for 54 percent of drug lines with disproportionately high shares of drugs without Medi-Cal prices, including high-cost OTC topical ointments and unique dosage strengths and formulations of FDA-approved drugs. Nearly 50 percent of IMR appeals were for drugs that were denied during UR as medically unnecessary; IMR upheld 91 percent of these decisions.

The findings highlight the issues underlying legislative intent that the WC formulary further "the goal of providing appropriate medications expeditiously while minimizing administrative burden and associated costs." DWC has the option of addressing these issues either by implementing an existing formulary and a set of operating procedures or by developing its own from the MTUS guidelines. In Chapter Three, we turn to examining the strengths and weaknesses of several existing WC formularies and associated processes.

CHAPTER THREE

Comparison of Existing Drug Formularies

This chapter summarizes the key formularies evaluated in this report. We compare each formulary across six criteria developed in consultation with California's DWC and using stakeholder input gathered at a public meeting in February 2016:

1. reliance on evidence-based criteria in determining the formulary drug list and recommendations
2. compatibility with the MTUS (California's evidence-based WC medical treatment guidelines)
3. transparency in the decision process used to establish and maintain the formulary drug list and recommendations
4. established process for regular updates to the formulary drug list and recommendations
5. accessibility and ease of use by treating physicians, payers, pharmacies, and injured workers
6. focus on drugs needed for injured worker conditions.

The first section of this chapter describes each criterion in more detail; the second summarizes how each formulary operates; and the third discusses how each formulary compares on each criterion. When information was not publicly available, we did attempt to contact the formulary developers for more information on particular policies. Evaluation of the quality of the treatment guidelines and drug recommendations was beyond the scope of this study.

Evaluation Criteria

The first criterion is the extent to which the formulary uses evidence to determine which drugs are included. Evidence on drug effectiveness ideally comes from peer-reviewed clinical trials, comparative effectiveness, meta-analyses, and other studies. Many evidence-based medicine and technology assessment organizations rank studies by type and study design. For example, meta-analyses combining the results of multiple trials may provide stronger evidence than several small randomized controlled trials (GRADE Working Group, 2004). Each formulary should have an established process outlining how evidence is identified, assessed, and incorporated into formulary decisions.

The second criterion is that the formulary should be compatible with the MTUS. Concordance between formularies and the MTUS is important because the formulary recommendations should be consistent with the guidelines. California has drawn on both ACOEM

and ODG guidelines in developing the MTUS and has developed its own opioid guidelines. One issue with adopting an existing formulary that is not derived specifically from the MTUS is whether it will be consistent with the MTUS treatment guidelines and recommendations. Any disagreement between the formularies and the MTUS will need to be resolved before the formulary can be implemented. The extent of differences between the MTUS and a given formulary will affect the ease of implementation. Issues related to operationalizing the formulary, such as defining the PR criteria, are discussed in greater detail in Chapter Four.

The third criterion addresses the fact that formulary decisions are important to patients, providers, payers, and manufacturers, so the decisionmaking process, the inputs and information used in decisionmaking, and the rationale for specific decisions should be transparent. For each formulary, there should be methods for incorporating public comment. There should also be a process for determining how the public is notified of changes, either through agency rulemaking or other mechanisms.

To meet the fourth criterion, each formulary maintainer should have a clearly defined process for updating the formulary to take into account new drugs that come onto the market, new evidence as it becomes available, and other changes in drug markets. For most commercial insurers, the regular updating process is conducted through a P&T committee or reliance on a third party (such as a PBM, often with its own P&T committee). Any updating decisions should also incorporate methods for dealing with legacy claims,[1] particularly for drugs being removed from a formulary.

The fifth criterion specifies the resulting formulary be easily accessible to the end users, such as patients, physicians, pharmacists, and payers. This criterion has several aspects: whether the formulary is available to the public; whether the drug listing is constructed in a way that makes it easy to locate active drug ingredients and related coverage rules; and whether the coverage rules, such as PR requirements, are easily operationalized. Ideally, the formulary should be publicly available and searchable by drug, and the conditions under which drugs are approved should be clearly indicated.

The final criterion states that the formulary should address the therapeutic classes that are commonly used to treat injured workers. For example, a formulary designed for traditional group health insurance may have many unnecessary therapeutic classes but may also be missing some classes or drugs within a class that are of particular importance to injured workers.

Summary of Formulary Operations

Table 3.1 summarizes key features of each drug formulary, and the following subsections describe each formulary. The next section compares the features related to our evaluation criteria in more detail, while Chapter Four compares how each formulary handles specific drugs.

Washington

Washington State created a common drug formulary and pooled purchasing decisions across three state agencies in 2002: Medicaid (Department of Social and Health Services), public employees (Health Care Authority), and WC (L&I; Washington Senate Bill [SB] 6088-29). L&I supplements the Washington State formulary to create a formulary better focused on

[1] *Legacy claims* are those with a date of injury occurring prior to a change in policy to the benefit structure.

Table 3.1
Overview of Formulary Operations

Formulary	Type of Formulary	Formulary Decisionmaking Process	Type of Drug Listing
Washington	State multiagency formulary with wraparound formulary for other common WC drugs	*State:* P&T committee makes evidence-based formulary recommendations to agencies; agencies use separate process to limit recommended drugs to the least costly drugs with similar therapeutic effects. *Wraparound:* PBM makes recommendations to L&I.	Categorizes drugs as preferred (no PR), PR required, or noncovered.
ACOEM	Proprietary formulary focused on WC drugs	Formulary recommendations are derived from evidence-based treatment guidelines; cost does not affect drug recommendations.	Lists drugs by condition, describes each as recommended or not recommended, and indicates the strength of the evidence. Does not have PR requirements.
ODG	Proprietary formulary focused on WC drugs	Formulary recommendations are derived from evidence-based treatment guidelines; cost does not affect drug recommendations.	Lists drugs by therapeutic class, states whether PR is required and indicates whether generic versions are available.
BWC	Single-payer state WC formulary focused on WC drugs	P&T committee makes recommendations to BWC, including on therapeutic interchange, that are implemented through rulemaking.	Lists drugs according to therapeutic classes that relate to compensable conditions; listings include any limitations on drug dosages and/or duration. Nonlisted drugs are covered by exception through PR.
Medi-Cal	Formulary used by California's Medicaid program	Medi-Cal pharmacist evaluates evidence-based recommendations of the Medicare Contract Drug Advisory Committee and negotiates prices with manufacturers.	Lists drugs whose manufacturers have contracted with the state and that do not require PR.

WC patient needs. Washington L&I draws on the state formulary for a subset of the drugs that are relevant to WC claims, such as NSAIDs and muscle relaxants, and takes advantage of the pooled agency purchasing power for these drugs. In selecting the subset of state formulary drugs, L&I excludes drugs that are not relevant to WC (e.g., those commonly used for maternal and child health but not for treatment of work-related injuries and illnesses) or that require WC-specific rules to be consistent with WC treatment guidelines (e.g., long-acting opioids). L&I supplements the subset of state formulary drugs with a wraparound formulary that is tailored to WC conditions. This formulary includes the drugs subject to WC-specific treatment rules and other drugs the state formulary does not address. We henceforth refer to the L&I wraparound formulary as the *L&I formulary*, to distinguish it from the Washington State drug formulary. The dual formulary structure allows L&I to implement a formulary that is tailored to the needs of the WC population while taking advantage of features of the Washington State formulary, such as evidence-based drug recommendations, negotiated rebates, and a therapeutic interchange program (which we describe later). According to L&I staff, roughly 40 percent of the WC drugs dispensed are on the Washington L&I formulary.

Washington L&I uses separate processes for including drugs on the two formularies. Drugs on the Washington State formulary are selected for inclusion based on thorough evidence reviews with a transparent selection process in which public comment is accepted at every point. The state uses the Drug Effectiveness Review Project (DERP) at the Oregon Health and Science University. The project conducts systematic reviews of evidence on drug effectiveness and safety (Oregon Health and Science University, 2016). The public is allowed to comment on draft reports, and pharmaceutical companies can also submit materials. Washington State's P&T committee then makes recommendations for inclusion on the formulary. The P&T committee considers the drug without regard to its cost. However, drug costs are a factor for the final decisions on which drugs will be listed in the Washington State formulary as preferred drugs. After the P&T committee has made an evidence-based recommendation, Washington State contracts with Milliman (an actuarial consulting firm) for cost review of the drug, assessing which drugs have the lowest net cost after taking into account rebate offers and the prices the agencies report for the drugs. The agency heads make the final decisions on which drugs should be listed as preferred drugs in the Washington State formulary.

The drugs in the L&I formulary do not undergo the same transparent, evidence-based, public decisionmaking process. Drugs that are under consideration for inclusion in the L&I formulary are evaluated through a separate, nonpublic process. Washington L&I contracts with a health insurer, ModaHealth, to administer parts of the process. Moda contracts with a PBM, MedImpact, to conduct evidence reviews and assess cost impacts for inclusion in the L&I formulary through MedImpact's national formulary. MedImpact also processes claims and rebates, while Moda administers the mail-order services.

Pharmacists are allowed to substitute a therapeutically equivalent (generic) drug, unless the physician has indicated the drug be dispensed as written (Washington Administrative Code 182-530-4150, 2015). L&I also encourages generic utilization by requiring PR for brand-name drugs. Beyond promoting generics, the Washington State drug formulary goes a step further and also considers therapeutic interchange. The Washington State formulary's P&T committee makes recommendations on whether drugs within the same drug class have similar therapeutic effects that, together with the cost considerations, are taken into account in determining the final Washington State formulary. The state encourages therapeutic interchange through its Endorsing Practitioner Therapeutic Interchange Program for the Washington State formulary. This program allows a pharmacist to substitute a preferred drug, but one with a mechanism of action similar to that of the requested drug, when a nonpreferred drug is prescribed by an endorsing practitioner (Washington Administrative Code 182-50-200). The program does not allow therapeutic interchange for antipsychotics, antidepressants, chemotherapy, antiretrovirals, immunosuppressants, or certain refills for immunomodulator or antiviral treatment for hepatitis C. Substitution occurs only for practitioners who have endorsed the therapeutic interchange program. If the endorsing practitioner indicates the nonpreferred drug should be dispensed as written, it is dispensed without PR. In contrast, PR is required if a nonendorsing practitioner prescribes a nonpreferred drug.

American College of Occupational and Environmental Medicine

ACOEM develops treatment guidelines for specific WC conditions. Drug recommendations are developed as part of the treatment guidelines, using several key criteria (the Reed Group, 2013). The first requires the selected treatments to be the most effective, according to evidence, for the condition, and the supporting evidence should be of high quality. Conservative treat-

ments should precede any invasive treatments. The treatment should not increase disability or dependence. Treatment decisions should be made in partnership with the patient. Finally, when two treatments are equivalent in terms of effectiveness, the more cost-effective one should be preferred. The evidence-based review process is rigorous and was recently revised to conform with advances in methods for developing quality guidelines (ACOEM, 2016).

The ACOEM formulary is a new product that is derived from ACOEM treatment guidelines. It is managed by the Reed Group. An external review team consisting of representatives from WC insurers, ACOEM, and academics reviews updates to the list of treatment recommendations (The Reed Group, undated). The Reed Group enlists a PBM, Healthesystems, to build the drug recommendations from the treatment guidelines and add in any necessary detail, in consultation with pharmacists, physicians, and the editors of the ACOEM guidelines. The resulting drug recommendations are a proprietary product.

While the Reed Group markets its final product as a drug formulary, it is not a formulary in the traditional sense. A traditional formulary is a list of covered drugs with rules on how the drugs may be accessed and under which conditions. In contrast, ACOEM provides drug treatment recommendations for a particular condition based on the strength of the clinical evidence. The recommendations are organized by clinical condition. Turning ACOEM's list of guideline recommendations into a traditional formulary would require developing a drug listing and ground rules, such as which drugs require PR. We discuss these ground rules further in Chapter Four. For the purposes of this chapter, we assume that either the Reed Group or DWC would take the necessary steps to translate the guidelines into a drug list if an ACOEM-based formulary were adopted.

Official Disability Guidelines

WLDI develops treatment guidelines and a drug formulary for WC: the ODG. Similar to ACOEM, ODG is proprietary, and the complete treatment guidelines and recommendations are provided through a paid subscription service. In addition, the ODG formulary drug list is available publicly to states adopting this set of drug recommendations. Until recently, an abridged version of the ODG guidelines was also available to the public on the National Guideline Clearinghouse website. WLDI withdrew these guidelines in June 2016 amid concerns from the National Guideline Clearinghouse that it was unable to verify that each ODG treatment guideline topic met new criteria for systematic evidence review. WLDI has issued an updated statement of methodology that should address transparency issues in the future (WLDI, 2016). ODG also issued an explanation that it withdrew from the National Guideline Clearinghouse because the clearinghouse is not suited to ODG's ongoing updating process and the needs of its users. The Reed Group does not list its guidelines with the clearinghouse (Farrell, 2016).

WLDI uses an evidence-based process to develop the ODG treatment recommendations, including recommendations on drug therapies. The WLDI evidence incorporation process involves updating the guidelines with new evidence as it becomes available, and the literature searches are repeated at least every six months. The updates are ongoing, and there is no regularly scheduled comprehensive review and update of a guideline chapter. WLDI staff ranks evidence on a scale (high, medium, and low quality) prioritizing evidence from systematic reviews with large sample sizes. "Chapter leads"—the ODG Editorial Advisory Board contributors who are physicians charged with updating the guidelines for a given injury—approve the updates, and stakeholder groups regularly review the updates (ODG, 2016). The ODG

development process incorporates feedback from stakeholders on a regular basis through the ODG Helpdesk.

WLDI derives its drug recommendations from the treatment guidelines. The ODG formulary Appendix A is a list of drugs showing which require PR, similar to a traditional formulary. The ODG drug listing is searchable by drug or therapeutic class. Each active ingredient is assigned a "Y" if the drug is approved without PR or an "N" if the drug requires PR. The PR requirement is based on whether the guidelines recommend the drug as a first-line therapy, but the process for making this determination is not transparent. Most PR requirements apply across all conditions; only a few drug classes vary by condition (for example, some antidepressants require PR for pain but not for mental health conditions). The actual practice guideline recommendations are more condition specific.[2] A secondary step would be required if any other nuanced rules for the conditions under which drugs may be accessed were to be incorporated into the formulary. Therefore, we assume that WLDI or DWC would take the step to translate the drug list into a formulary consistent with the MTUS.

Ohio Bureau of Workers' Compensation

BWC implemented a drug formulary in 2011. The formulary initially focused on opioids, skeletal muscle relaxants, and antiulcer medications and later was extended to cover benzodiazepines, hypnotics, and antipsychotics. Changes in the formulary are based on recommendations from a P&T committee. The rules state that the P&T committee will base its evaluations and recommendations on "current medical literature and generally accepted best clinical practices." The P&T committee establishes its own bylaws and operating rules subject to BWC approval. Rulemaking is used to add or remove drugs on the formulary based on P&T committee recommendations. The process begins with two initial hearings before the BWC Board of Directors. Two reports—a stakeholder and a business impact report—are filed with the lieutenant governor's office. There is an additional public hearing and then a final hearing before the Legislature's Joint Committee on Agency Rules Review.

Ohio is a single-payer state that outsources pharmacy benefits management to OptumRX, a PBM that adjudicates the PR requests for formulary drugs that are not typically used to treat work-related conditions and other drugs that are not on the formulary (BWC, 2015). Requests for nonformulary drugs are handled through a separate appeals process. There is no coverage for compounded drugs except through the appeals process.

Ohio handles generics slightly differently from other states. If the physician writes "dispense as written" on the prescription, the injured worker will have to pay the difference in the

[2] For example, the ODG guidelines recommend antiepilepsy drugs for neuropathic pain but not for pain generated by damaged tissues or acute pain. The ODG PR recommendation is "Y" without distinguishing among types of pain for four out of 13 listed drugs. The most recent Cochrane review (Wiffen et al., 2013) on using antiepilepsy drugs for pain found evidence that gabapentin and pregabalin worked for neuropathic pain associated with diabetes and shingles. Pregabalin also was effective for central neuropathic pain (after a stroke) and fibromyalgia. Both drugs are listed as "Y" drugs. The gabapentin extended release is listed as "N" but is not discussed in the treatment recommendations. The ODG formulary also lists carbamazepine and oxcarbazepine as "Y" drugs. Because the treatment recommendations do not define these two as first-line drugs and discuss potential adverse effects, the rationale for listing them as "Y" drugs is not readily apparent. The ODG recommendations for these two drugs do not appear to have been updated to reflect the findings from the recent Cochrane review and more-recent studies. The review authors concluded that, for other drugs, there was no evidence, insufficient evidence, or evidence of a lack of effect, including for carbamazepine, and that oxcarbazepine raised potentially serious adverse effects.

maximum allowable cost between the brand and the generic version unless one of two exceptions for medically necessary brand-name dispensing applies.

Medi-Cal

The Medi-Cal contract drug list is the formulary for California's fee-for-service Medicaid beneficiaries. The listed drugs do not require PR (Maiuro, Coronado, and Edwards, 2009). Medi-Cal uses the list to leverage significant rebates from drug manufacturers and minimize drug costs.

Manufacturers, physicians, pharmacists, or the department itself may initiate a review of potential changes to the list. There is not a regular updating time frame. The Medi-Cal Contract Drug Advisory Committee (MCDAC) makes advisory recommendations for additions and deletions based on five criteria (Department of Health Care Services, 2011) defined in §51313.6 of Title 22, California Code of Regulations. The first is whether the drug is considered safe, and the second is whether the drug is considered effective. The third is whether the drug fills an essential need, to ensure access to lifesaving treatments. The fourth evaluates whether the drug has the potential for misuse and, if so, whether it should be included. The final criterion is cost, which can be the determining factor when the other criteria do not distinguish one drug from another.

After receiving the MCDAC's recommendations, a pharmacist within the department works primarily with manufacturers throughout the review and negotiation process for inclusion of the drug on the formulary based on therapeutic (evidence-based) information and the manufacturer's business proposal and an evaluation of the five criteria. Any single criterion can be accorded overriding emphasis for approving or denying a drug addition to the contract drug list. Public input is not an established part of the process but is not precluded (Department of Health Care Services, 2011).

Formulary Comparison on Evaluation Criteria

Summary of Comparison

Table 3.2 summarizes how the formularies compare against each criterion. Each formulary has strengths and weaknesses, so no single formulary exceeded the criteria in all areas. For example, ODG, ACOEM, and the Washington State formulary have more clearly defined processes for incorporating evidence, but the Ohio and Medi-Cal drug lists have more publicly available and easy-to-interpret formularies for end users. The remainder of this section discusses each of our criteria and how formularies compare with it.

Reliance on Evidence-Based Criteria

As described at the beginning of this chapter, Washington State uses the DERP at the Oregon Health Science University, and its panel of experts, to evaluate evidence from both manufacturers and the peer-reviewed literature. A P&T committee serving the joint purchasing program in Washington State then weighs the evidence review and makes recommendations. Public comment is accepted at multiple points in the process. However, this process applies to only a portion of drug classes used in WC. L&I contracts with a PBM to develop the L&I formulary drugs, including opioids, in a process that is not transparent, and the public cannot formally comment on these changes before they are adopted.

Table 3.2
Summary of Formulary Comparison on Evaluation Criteria

Criteria	ODG	ACOEM	Washington	Ohio	Medi-Cal
Reliance on evidence-based criteria	Incorporates peer-reviewed literature, evaluated with ranking system and editorial committee for decisionmaking.	Incorporates evidence through a committee, ranking the evidence for each drug used for each medical condition.	Uses an evidence-based practice center to develop the evidence base the P&T committee uses to make final recommendations for drugs. L&I wraparound formulary drugs are approved through a PBM.	Uses a P&T committee but does not have specific descriptions of how and what types of evidence should be weighed.	Uses the MCDAC. Several criteria for determining whether a drug should be added to the preferred drug list are related to medical appropriateness evidence.
Compatibility with the MTUS guidelines	California has adopted modified ODG chronic pain and postsurgical physical medicine treatments.	California adopted the 2004 version of the ACOEM clinical guidelines but has not updated them to include revisions and additional topics.	Formulary is designed to be compatible with Washington treatment guidelines.	Formulary is not derived from treatment guidelines.	Formulary is not designed to be compatible with MTUS.
Transparency of formulary decisions	The process for developing drug recommendations is defined, but the criteria used to determine whether a recommended drug is a first-line therapy are not clear. Stakeholder comment on guideline revisions is a formal part of the update process.	The process for developing drug recommendations is clearly defined. Stakeholder comment on guideline revisions is a formal part of the update process. The PBM's role in maintaining the formulary is not clear.	In the Washington State formulary decision-making process, the state issues public notices on particular drugs, and public comment is allowed at several steps. There is no public input for L&I formulary decisions.	The P&T committee holds regular public meetings. Changes are implemented through a rulemaking process.	There is little established process for public input. Final decisions, but not the process, are made available to the public.
Clearly defined updating process	Guidelines are updated on an ongoing basis, at least every six months. Formulary updates occur as frequently as monthly based on guideline revisions. Formulary updates are clearly marked for subscribers.	Guideline revisions occur every 3–5 years. The formulary drug list will be updated quarterly based on guideline revisions. The formulary changes are clearly marked for subscribers.	Washington State formulary updates occur yearly and follow a clearly defined process. The update process for the L&I formulary is not clearly defined, and updates occur as needed.	The updating process is clearly defined. The P&T committee meets at least three times per year.	The updating process is clearly defined when a staff member, manufacturer, or member of the public requests review. Updates occur as needed.

Table 3.2—Continued

Criteria	ODG	ACOEM	Washington	Ohio	Medi-Cal
Accessibility and ease of use	The drug list is publicly available through the websites of subscribing states, but guidelines require subscription. Drugs requiring PR are clearly marked.	The formulary is proprietary and currently not searchable by drug.	The formulary is publicly available and has a drug lookup tool. Restrictions are clearly marked.	The formulary is publicly available. Restrictions are clearly marked.	The drug list is fully available on the website,. Restrictions are clearly marked.
Focus on drugs needed for injured worker conditions	Formulary development is driven by treatment guidelines for injured workers.	Formulary development is driven by treatment guidelines for injured workers.	Formulary development is driven by injured worker conditions.	Formulary originally driven by drugs that had been prescribed in previous three years of formulary creation.	Formulary covers a much broader patient population and not a specific focus on WC drugs.

The ACOEM treatment guidelines utilize systematic reviews of published evidence, evidence-based multidisciplinary practice panels, stakeholder input, external review, and pilot testing to assess treatments for particular conditions (Harris et al., 2008; ACOEM, 2016). Particular drugs are rated based on the strength of the evidence for the given condition. Drugs may be recommended based on strong or even limited evidence for a given condition. ODG also uses an evidence-driven process to rank new evidence from the literature and incorporate it into the treatment recommendations. ODG's editorial committee makes each recommendation, and external reviewers from stakeholder groups review it. Until ODG issued its new methodology, its evidence-based review process was less transparent than the ACOEM process and was not available to the public. For example, the inclusion or exclusion terms for interventions were not articulated, and the process for reaching consensus on treatment recommendations was not described. When researchers evaluated ACOEM and ODG guidelines for use of opioids for chronic pain as of July 2013 (reflecting the methods in place until recently) using the Appraisal of Guidelines for Research and Evaluation instrument, the overall mean quality score for ODG was 3.50 compared to 4.75 for ACOEM, based on publicly available information about the development methods (Nuckols et al., 2014).[3] Because the same guideline development process applies to all clinical topics, the assessment will be equally applicable to other clinical topics until there has been a comprehensive update using the processes adopted in 2016. The researchers also used A Measurement Tool to Assess Systematic Reviews to examine the methodological quality of the developers' systematic reviews of the evidence. Here, the overall rating for ODG was higher (fair to good) than for ACOEM (fair). Ohio and Medi-Cal use P&T committees to provide drug recommendations, but the process used to weigh the medical evidence is not transparent.[4]

Compatibility with the Medical Treatment Utilization Schedule Guidelines

The overall relationships between each formulary and the MTUS guidelines serve as indicators of whether the formulary drug recommendations are likely to be consistent with the MTUS guidelines and recommendations. Another important question is whether there are significant differences in how specific drugs are classified in the formulary relative to the treatment guidelines. Arguably, formularies derived from evidence-based medicine should be fairly similar in their recommendations for specific drug therapies. However, there may also be differences based on other factors, including which drugs are addressed in the formulary (discussed in the last subsection) and the extent to which therapeutic interchange is taken into account. In Chapter Four, we investigate this correspondence for the drugs used by California workers with low-back, knee, or shoulder injuries.

Washington L&I is focused on WC conditions but is designed for a different context from California's and has its own treatment guidelines.

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[3] The Institute of Medicine (2011) states in its guideline development standards that the process for developing and funding a guideline "should be explicitly detailed and publicly accessible." The researchers did not have access to the ODG guidelines to evaluate clarity of the guideline presentation. On the other Appraisal of Guidelines for Research and Evaluation domains, ODG rated higher on stakeholder involvement (59 versus 55) but lower on other dimensions, including rigor of the development process (49 versus 60) and editorial independence (50 versus 75).

[4] P&T committees provide important expertise and clinical judgment when making decisions on incorporating new evidence for existing drugs, weighing the evidence for including a new drug, and setting up restrictions for access to certain medications such as narcotics. The P&T process is discussed in greater detail in Chapter Six.

ACOEM treatment guidelines serve as the basis for most MTUS guidelines, i.e., the chapters on such body parts as the lower back and shoulders. As a result, the ACOEM formulary should be more closely aligned with the MTUS than with the other formularies. However, the MTUS ACOEM-based guidelines predate the versions of the treatment guidelines from which the ACOEM formulary recommendations are derived. Specifically, the MTUS is based on the 2004 edition of the ACOEM guidelines (with a 2007 revision to the guidelines for elbow disorders) and does not reflect changes to the guidelines since a comprehensive revision in 2011, which was followed by further revisions to six body-part chapters in 2013–2016. Thus, even the ACOEM formulary for the body-part clinical topics likely poses some compatibility issues unless the MTUS guidelines are updated to the most recent ACOEM guidelines.

The MTUS chronic pain chapter is a modification of ODG chronic pain guidelines. While the ODG formulary drug recommendations for chronic pain should align with the MTUS, there are potential compatibility issues. Specifically, the ODG treatment guidelines and formulary are updated more frequently than the MTUS guidelines,[5] and the MTUS chronic pain guidelines are modifications to the ODG treatment guidelines. In particular, the MTUS update of the chronic pain guidelines effective July 2016 does not include the ODG chronic pain recommendations for opioid usage. Also, the ODG formulary recommendations for clinical topics other than chronic pain may not be consistent with the MTUS ACOEM-based guidelines.

Ohio uses ODG treatment guidelines, but the BWC formulary is not derived directly from the treatment guidelines. Rather, it was established by the P&T committee using the commonly prescribed drugs for WC conditions at the time of enactment.

Finally, the Medi-Cal formulary is designed for a broader set of medical conditions, given its population of enrollees, and is also not consistent with MTUS.

Transparency in the Decision Process

Transparency of decisions to end users of the formularies, such as prescribers, pharmacists, payers, and injured workers, is a key criterion. The transparency of the decision process varies across the formularies reviewed, largely due to PBM involvement at various stages. The operations of PBMs, in terms of incorporating and evaluating evidence and in the ability to incorporate stakeholder input, are not transparent. While PBMs have P&T committees that handle these functions, the actual decision process is not available to the public and may vary by PBM. The process for developing the Washington State formulary is the most transparent in terms of making the public aware of decisions and accepting public comment at multiple stages in the process. However, the drugs in the L&I formulary are included through a PBM and are not transparent.

ACOEM's process for developing drug therapy recommendations is transparent and provides opportunities for stakeholder comment and input. A PBM helps translate the recommendations into the formulary by including, for example, notes to prescribers or reviewers on particular drug ingredients.

ODG documents do not outline a role for a PBM in developing their formulary drug recommendations. ODG incorporates stakeholder feedback by reviewing treatment recommendations before they are final and by accepting feedback through the ODG website. The

[5] For example, the MTUS chronic pain guidelines adopted in July 2016 replaced guidelines adopted in 2009 and are based on the April 6, 2015, version of the ODG.

process for determining PR requirements (i.e., which recommended drugs are first-line treatment options not requiring PR) is not transparent.

The Ohio P&T committee must hold public meetings on drug recommendations at least three times per year. The public is allowed to comment, and changes to the formulary occur through rulemaking. Medi-Cal does not have a formal process for including public input.

Clearly Defined Process for Regular Updates

Not all the formularies reviewed have a transparent and established method for updating the drug formulary. The Washington State formulary is updated yearly, but there is no clearly defined process for the L&I formulary.

ACOEM's formulary is derived from treatment guidelines that are periodically updated. ACOEM's stated policy is that comprehensive updates, which involve evidence-based multidisciplinary practice panels, will occur at least every three to five years but that focused updates may occur more frequently for major changes in the literature (ACOEM, 2016). The updating process is time consuming, and several chapters from ACOEM's third edition, issued in 2011, have yet to be updated. However, the Reed Group advised us that several guideline chapters are currently being updated and should be available later in 2016 or in 2017. Because the ACOEM formulary is new, the updating cycle is less certain than those for the more established formularies. The Reed Group also advised us that ACOEM's drug recommendations will be updated quarterly beginning this year. Any major new evidence requiring an immediate change to an existing recommendation (e.g., an FDA black-box warning) would be included as it arises, and significant changes in drug recommendations would be considered independent of the periodic chapter review process.[6]

ODG conducts ongoing reviews of the medical evidence and updates the guidelines as needed. A guideline change may or may not prompt a change in the drug formulary. Changes in the formulary are issued as needed but no more than monthly. In 2015, actual changes to the formulary drug listing and recommendations were made four times, affecting the listings for eight drug ingredients.[7]

Ohio's rules require that the P&T committee review the formulary annually and publish changes through a rulemaking process that makes the updating process more cumbersome than those of other formularies (BWC, 2014).

Medi-Cal does not have a regularly scheduled updating process; rather, reviews of the contract drug list can be initiated at any time by staff, manufacturers, or the public.

Ease of Use and Accessibility to the End Users

A drug formulary should be accessible and easy for prescribers, pharmacists, PBMs, and payers to use.

Washington L&I's formulary is publicly available as a Portable Document Format (PDF) file and as a drug lookup tool.[8] The PDF file varies between listing whole therapeutic classes as

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[6] The Reed Group issued revisions to the ACOEM guidelines and formulary on June 18, 2016, that incorporated updated guidelines for low-back pain.

[7] WLDI maintains a log of guideline changes. Our review of the log for 2010–2013 changes indicates that most added new material and/or cross-references. It does not appear the updating process includes ongoing deletion of outdated material.

[8] A *drug lookup tool* is a web-based search portal allowing users to search by drug name (Washington State Department of Labor and Industries, undated).

preferred and listing individual drugs as preferred. A user trying to look up a particular drug must then go to the drug lookup tool to find more-specific information.

ACOEM's formulary is proprietary and requires a subscription to the treatment guidelines. There is no publicly available version. Furthermore, the formulary is organized by condition only, so users cannot look up a particular drug to see if it is recommended. The Reed Group has indicated that they could create a tool to allow users to search by drug. The ACOEM formulary poses the most implementation challenges. First, there are no PR recommendations, so DWC would need to develop them. Second, because the recommendation for a particular drug can vary by condition, a PBM or payer may need to know the injured worker's diagnosis before applying any PR rules that are derived from the guidelines. In Chapter Four, we explore the extent to which the recommendations vary across conditions.

The ODG formulary is also proprietary, but the drug listing is posted and available to the public for states using this formulary for their WC programs. The listing is searchable by drug, and users can easily identify which active ingredients require PR. However, examining which drugs are associated with particular conditions requires a subscription to the treatment guidelines. Because the PR requirements for most active ingredients are uniform across conditions, the PR rules are straightforward for PBMs or payers to apply. The PR requirements for some mental health drugs differ according to whether the prescription is for a mental health or a pain condition.

Ohio's formulary is publicly available and is organized by drug name. The Ohio formulary specifies the covered form, whether PR is required, and any limitations on dosage strengths or duration. By adding the drug limitations to the drug listing, the Ohio formulary is most accessible and easy to use. In the other formularies, the prescriber needs to access both the formulary drug listing to determine whether PR is required and the treatment guidelines to determine whether there are any limitations on treatment and the conditions for which the drug is recommended.

Medi-Cal's contract drug list is publicly available and is searchable by drug name with clearly marked restriction criteria.[9] Some of these restrictions are diagnosis based.

Chapter Four discusses in greater detail the differences in how the various formularies present drugs.

Focus on Drugs Needed for Injured Worker Conditions

The formularies we reviewed have different approaches to covering drugs related to WC injuries. However, despite the differences in focus on injured worker conditions, all the formularies contain high-volume WC drugs, such as opioids, NSAIDs, and muscle relaxants. In Chapter Four, we compare California's existing WC drug utilization (in WCIS) to the drugs listed in each of the formularies. We find that, with the exception of topical analgesics, each formulary lists all top 20 active ingredients in total WCIS payments.

Washington L&I has crafted its formulary around conditions commonly occurring in injured workers, which was the reason for creating the L&I formulary. ACOEM and ODG derive their drug lists from treatment guidelines developed specifically for WC injuries and illnesses. The Ohio formulary contains a wide variety of classes, originally developed using the high-volume drugs in Ohio's WC system. Medi-Cal is not focused on WC conditions

[9] California Department of Health Care Services, undated.

because its formulary was intended for a different population with more conventional health care needs, such as chronic illness, pregnancy and childbirth, and drugs for children.

Conclusions

This chapter has described the strengths and weaknesses of several existing formularies on which California may want to model its WC formulary. We used the following criteria to compare the formularies:

- *Reliance on evidence-based criteria*. We found that several formularies, including Washington State's, ACOEM, and ODG, have strong processes for incorporating evidence when evaluating drug decisions.
- *Compatibility with the MTUS.* On the surface, the ACOEM guidelines should be most compatible with the MTUS. However, because the other formularies are also evidence based, their drug recommendations may also be compatible with the MTUS. We investigate this issue further in Chapter Four by examining by the differences in the drug listings and PR recommendations.
- *Transparency in the decisionmaking process.* We found that some parts of the processes for all the formularies are transparent to the public or users of the guidelines, but often not the whole process.
- *Clearly defined process for regular updates.* Regular updates occur annually for the Ohio formulary, and the ODG formulary is updated as frequently as monthly on an as-needed basis. Because it is relatively new, the ACEOM formulary has not established a track record.
- *Ease of use and accessibility.* We found variation in accessibility and ease of use across formularies for the end users, such as prescribers, pharmacists, and payers. The Ohio formulary is arguably the most accessible. It is publicly available and integrates the drug listing with limitations on drug dosages and duration.

CHAPTER FOUR

Comparison of Formulary Ground Rules

This chapter compares the sets of ground rules used across formularies. These rules tell end users whether generics are always preferred over brand-name drugs and whether oral versions are preferred over injectable versions and can even delve into such issues as which drugs might be substitutable within a drug class.

Differences on these dimensions may affect usability. We begin by first describing several key ground rules necessary for any formulary and comparing how and whether each formulary deals with each ground rule. We then compare how the ground rules affect the differences in drugs listed on each formulary and the number of listed drugs that would be preferred. Non-preferred drugs would require PR.

ACOEM's drug listing is derived from condition-specific recommendations. Due to the resulting high level of nuance in the ACOEM recommendations, we also compare how the ACOEM guidelines handle drugs in the anti-inflammatory class across knee, shoulder, and low-back injuries. Condition-specific PR rules are more complex to handle in a pharmacy claims processing system but can be used to better match evidence-based treatment to specific patient and clinical contexts.

Ground Rules for Formulary Development

At its most basic form, a formulary is a list of drugs for which an insurer will pay. Formulary rules can steer patients to medically appropriate treatments and treatments of greater value, such as a generic drug over its brand-name equivalent. To implement a formulary, developers must establish a set of ground rules for how drugs will be covered and which drugs may have coverage priority (preferred drugs). These rules should be readily available to patients, prescribers, pharmacists, and payers.

The formulary should contain a list of active ingredients that are prescribed and whether they are covered under what conditions. An active ingredient is the molecule with therapeutic value in a particular drug. An active ingredient, such as acetaminophen, underlies a variety of different drug products. For example, acetaminophen comes in a variety of strengths (the amount of the active ingredient), forms (tablet, capsule, syrup), and generic store brands or name brands (such as Tylenol).

Formulary developers often organize the listing of active ingredients into therapeutic classes. For example, the NSAID class contains multiple drug ingredients—naproxen sodium (Aleve), naproxen (Naprosyn), ibuprofen (Motrin), and others. Organizing active ingredients by therapeutic class facilitates the selection of a medically appropriate preferred drug that does not require PR and a comparison of average costs across drug ingredients.

The FDA assigns NDCs to all drug products manufactured, prepared, compounded, or processed for commercial distribution. The NDC indicates each product's unique combination of manufacturer or labeler, product (including active ingredient, strength, and form), and package size. Prescription drug bills are processed and priced at the NDC level. However, formularies typically list drugs at the less-granular active-ingredient level, rather than at the NDC level. This means that the formulary listing is potentially applicable to different formulations of the drug, dosage strengths, and package sizes and to both generic and brand-name drugs. As a result, payers need a set of ground rules concerning what the listing for an active ingredient in a formulary implies.

Language Regarding Listed Active Ingredients

Comparing the treatment of various active ingredients across the WC formularies we examined is difficult because not all formularies list the same active ingredients, and of the ingredients listed, not all formularies indicate whether a drug is preferred the same way. The key ground rules related to this point are (1) whether a listed drug is preferred (does not require PR) and (2) what PR or other policies apply to drugs that are not listed in the formulary.

The formularies take different approaches to how they list whether a given active ingredient is preferred. Washington L&I subdivides approved active ingredients into preferred drugs, which are approved without PR, and nonpreferred drugs, which require PR before the prescription is dispensed. For example, the proton pump inhibitor therapeutic class is approved. Within that class, only the generic versions of omeprazole, omeprazole magnesium, and pantoprazole are approved. The brand-name versions of these drugs would be nonpreferred and require PR. There are no preferred drugs within the therapeutic classes categorized as requiring PR, and any drug prescribed in these classes requires PR before being dispensed. L&I lists therapeutic classes that include drug ingredients that are rarely indicated for a worker's compensable injury as "denied" (or, essentially, not covered). An exception may be requested through PR if a non–work-related condition directly slows the patient's recovery from the work-related condition.

ACOEM lists whether the active ingredient is recommended and indicates the level of evidence associated with the recommendation. ACOEM's recommendations are based on its WC treatment guidelines and so do not address drugs for non-WC conditions. As ACOEM has not developed PR criteria for individual drugs, adopters of this formulary would have to establish their own rules regarding which listed drugs are preferred and do not require PR and how unlisted drugs should be handled.

ODG lists active ingredients as "Y" (yes, the drug is preferred and may be prescribed without PR) or "N" (needs PR before prescribing). ODG lists only therapeutic classes that are commonly prescribed in the WC population. The guidance notes that the drug recommendations do not provide direction for other therapeutic classes but recommends PR for these unless emergency use is required. The guidance does not indicate how unlisted drug ingredients within a listed therapeutic class should be treated; however, the WLDI advised us that any unlisted active ingredients (including combinations of active ingredients) should be considered "N" drugs.

Ohio uses a drug list with specific requirements listed for which drugs require PR and any other restrictions. The state uses step therapy (usually trying lower-cost therapies in a class first), limits quantities for some drugs, and restricts some drugs to certain conditions. Unlisted drugs are considered not covered. There are appeal mechanisms for obtaining coverage for

recently approved drugs on a time-limited basis, until the P&T committee has an opportunity to review a new-drug request.

Technically, Medi-Cal's contract drug list is not a preferred drug list. However, it serves a similar purpose because most drugs on this list do not require PR for the Medicaid program. PR is specified for certain circumstances, e.g., when the drug is used for a condition different from the one indicated on the listing or if a drug having specific dosage forms or strengths listed is used with a different method of administration or strength. This list restricts some manufacturers from coverage because they do not participate in the state's supplemental rebate program.

Drug Formulations

An active ingredient can come in multiple formulations, such as capsule, tablet, injectable, or infusible versions. In practice, formulary ground rules should address dosage strength and formulation, in addition to active ingredient, to avoid confusion for the end user of the formulary.

Formularies can differ widely in the level of detail they use to differentiate the various forms of an active ingredient.[1] Formularies may specify the name of the active ingredient, without further elaboration on whether all forms of this active ingredient are included in the listing. Washington L&I's preferred drug listing includes oral forms only, broadly defined to include oral, solid, and liquid formulations. In contrast, the Reed Group advised us that an ACOEM recommendation includes all forms of a drug ingredient. We were unable to find formulation discussed in the ODG formulary ground rules, but WLDI advised us that the rule is that, unless another form is specifically listed, ODG listings refer only to the oral (tablet, capsule) forms. Ohio and Medi-Cal specifically list the forms covered with and without PR.

Generic Versus Brand-Name Drugs

Beyond form, an additional ground rule is whether PR applies differently to brand-name and generic versions of an active ingredient. Many formularies use this important distinction to drive utilization toward lower-cost drugs.

Washington L&I distinguishes between generic and brand-name formulations in its listings, stating, in general, that only the generic formulations are preferred. ACOEM and ODG do not distinguish between generic or brand names in their drug listings. Both of these formularies do provide average drug cost information alongside the guidelines to guide prescribers to more cost-effective options, and the ODG formulary lists whether generic versions are available for the drug ingredient. Ohio does not pay for the brand-name version if a generic is available. Medi-Cal largely restricts coverage to generic versions when these are available.

Therapeutic Class

A final ground rule is the establishment of a therapeutic classification scheme to group individual NDC codes into broader classes used to treat diseases. NDCs are constantly being updated as new products come onto the market and as manufacturers cease making old formulations. Over time, several companies have evolved selling services that map NDCs into therapeutic classes and update these classifications regularly. The classification scheme is important in guiding a P&T committee in evaluating which drugs might be substitutable for a particular

[1] We use both *active ingredient* and *drug* in this chapter. *Drug* usually applies to the individual active ingredient, form, dose, and manufacturer (NDC-level), while *active ingredient* will encompass all drugs with the same active ingredient.

condition when considering therapeutic interchange. It is also important to pharmacists who need to be able to discuss with a physician who has prescribed a nonpreferred drug what alternative might be preferred.

We found differences in which drugs were considered part of a given therapeutic class across the various formularies because each formulary uses a different classification scheme. Washington L&I and Medi-Cal use First Databank; ACOEM and Ohio BWC use Medispan; and ODG develops its own classifications based on how the drugs are used for WC purposes. For the analyses in this chapter, we used the high-volume active ingredients for the prescriptions in the WCIS as the starting place to compare how active ingredients are handled across the formularies, regardless of the therapeutic classification used in each formulary.

Impact of Ground Rules

The detail of each formulary's ground rules can create differences in the comprehensiveness of active ingredients addressed in the drug listing. To compare the percentage of payments for a given active ingredient that each formulary addresses explicitly, we used electronic files provided by each formulary developer and matched the NDCs in WCIS to the NDCs associated with the formulary drug listings (Appendix A provides details on how NDC codes were assigned to formularies with no NDC-level list in the electronic file). A formulary "addressed" a drug product reported in the WCIS if the NDC for the drug product was listed in the electronic formulary file. We summed the payments for the drug products by drug ingredient. For each drug ingredient, we report in Table 4.1 the percentage of WCIS payments that matched to NDCs for drug products listed in the formulary. An important caveat of this approach is that a formulary developer may intend for all NDCs of an active ingredient to be addressed in its formulary, but NDC codes in the particular lists may be old or incorrectly written. In Table 4.1, we highlight differences across the formularies in drugs accounting for more than one percent of WCIS drug payments. Appendix A contains a full listing of all drugs accounting for more than 1 percent of WCIS payments.

While most of the drugs in WCIS are handled similarly across formularies, the purpose of Table 4.1 is to highlight that differences in the formulary ground rules create differences in the NDCs that are addressed in each formulary. A given formulary may not list drugs from certain manufacturers, repackaged drugs, or particular formulations. For example, ACOEM covers all or none of the NDCs within an active ingredient because the treatment guidelines do not differentiate between types of formulations. Nearly all drugs reported in WCIS are in either an oral form or a topical form. For example, diclofenac sodium is prescribed in both oral and gel forms. Appendix A also describes the main drug forms for the most prescribed WCIS drugs in more detail.

The topical analgesics (including capsaicin, menthol, and methyl salicylate; lidocaine and menthol; and capsaicin, lidocaine, menthol, and methyl salicylate) account for many of the differences across formularies. Medi-Cal does not cover OTC topical analgesics and therefore does not list these products in its formulary. Some high-volume OTC topicals are combinations of OTC drug ingredients, such as capsaicin, menthol, and methyl salicylate (a pain-relief ointment or lotion). The combination may not be addressed in the formulary, but the individual ingredients may be. For example, both ACOEM and ODG address each ingredient used in the capsaicin/menthol/and methyl salicylate ointment but not that combination of ingredients. For purposes of Table 4.1, we assumed that only combination drugs that match the drug listings are included in the formulary. However, we note that the ODG formulary rules indicate

Table 4.1
Differences in the Percentage of WCIS 2013 Prescription Payments Addressed in Each Formulary, by Selected Active Ingredient

	Percentage of Payments in Formulary					
Ingredient	**WCIS**	**ODG**	**Washington**	**Medi-Cal**	**ACOEM**	**Ohio**
Capsaicin/menthol/ methyl salicylate	5	0	100	0	0	100
Tramadol hydrochloride	5	93	93	15	100	93
Diclofenac epolamine	1	100	100	99	0	100
Ondansetron	1	0	100	100	0	100
Cyclobenzaprine hydrochloride	1	70	68	69	100	100
Capsaicin/lidocaine/menthol/ methyl salicylate	1	0	100	0	0	0
Aripiprazole	1	100	100	100	0	100
Lidocaine and menthol	1	0	100	0	0	0
Eszopiclone	1	100	100	100	0	100
Morphine sulfate	1	100	67	100	100	100
Capsaicin/menthol	1	0	100	0	0	0
Zolpidem tartrate	1	96	98	99	0	44
Hylan polymers A and B	1	0	100	100	0	0
Esomeprazole magnesium	1	100	100	100	0	100
Modafinil	1	100	91	91	0	100

SOURCE: RAND Analysis of WCIS 2013 data and formulary files from the sponsors.

NOTES: Bills for drugs used in compounding and discontinued drugs were excluded from the totals and percentages in the table. Please see Appendix A for a detailed description of the assumptions used for each formulary.

that, if a compounded drug contains any "N" ingredient, the drug is defined as an "N" drug. The guidelines are not clear about whether this rule also applies to compounded drugs that are prepared by registered drug establishments for commercial distribution, such as OTC topicals, and precompounded drugs (as opposed to drugs that are compounded by a pharmacy).

Other drugs have certain forms that may not be addressed similarly across formularies, such as tramadol hydrochloride (a synthetic opioid). Medi-Cal only covers the 50 mg tablet of tramadol hydrochloride from certain manufacturers. One other relatively high payment drug—zolpidem tartrate (Ambien)—has both an oral and a sublingual form, and Ohio stopped covering the sublingual form in 2014.

Note that a drug may be discussed in the treatment guidelines but not be included in the formulary listing. For example, ondansetron (Zofran), an antiemetic drug, is discussed in the ODG guidelines, but because it is not in a high-volume therapeutic class, it is not listed in the formulary. Hylan polymers A and B (Synvisc) injections are used to treat knee pain and would not be included in the drug formulary unless the formulary includes drugs that are administered in a care setting.

Differences in Preferred Drugs

We next examine whether differences in preferred drugs (which we define as drugs that do not require PR) exist for the same conditions across formularies. We limited the conditions to knee, shoulder, and low-back injuries because WCIS is limited in the amount of clinical nuance needed to mimic condition categories found in the ACOEM drug recommendations.

We received electronic versions of the formulary drug listings that operationalize the PR rules (nonpreferred drugs) by NDC for Washington L&I, ODG, and Medi-Cal. As discussed earlier, Washington L&I has three main approval levels, depending on the therapeutic class. For simplicity, we assumed any drug not marked as "preferred" requires PR. ODG has simplified decision rules in place, with a Y/N indication for each NDC on whether the drug requires PR.[2] Medi-Cal marks the PR criteria at the NDC level as well. The Ohio formulary lists PR criteria at the active ingredient level. We received two different files at the active ingredient level, so some assumptions were made about how the PR criteria apply to individual NDCs within an active ingredient (see Appendix A). All drugs requiring approval for certain conditions, requiring step therapy, or having quantity limits were considered to require PR as a simplification step for this analysis. The Ohio files did not include NDC-level linkages, and we needed to make assumptions to establish preferred or nonpreferred status for individual NDCs. These assumptions may create an over- or underestimate of the number of NDCs in each active ingredient that may require PR in practice.

ACOEM does not contain PR criteria, so we established criteria using some simple decision rules. We identified first-line therapies if the formulary information for prescribers detailed that the drug was a recommended first-line treatment.[3] We required PR for any recommended drug that is not a first-line therapy and for all drugs not recommended. We identified some recommended drugs that were unclear on whether the recommendation intended the active ingredient to be a first-line therapy. For purposes of Table 4.2, we categorized these drugs as *nonpreferred* (*requiring PR)*. This provided a conservative estimate (erring on the side of requiring PR for more active ingredients than would likely happen in practice).

It is important to note that we derived a simple "yes-or-no" rule for each ACOEM recommendation in the guidelines and have flagged those that would require clinical review to confirm whether the drug would be preferred in practice across all conditions.[4] We created categories for the ACOEM recommendations: whether the drug is recommended as a first-line, second-line, or subsequent therapy; whether the drug is recommended but unclear on whether the drug is a first- or second- line therapy; whether the drug is not recommended; and finally, whether the drug has no recommendation. These recommendations can vary by the specific

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[2] The ODG makes some preferred status distinctions based on whether a drug is prescribed for a mental health condition or for pain. Because we limit the conditions in this analysis to low-back, shoulder, and knee injuries, we use the preferred rules for these drugs that apply when prescribed for pain.

[3] Our analysis is based on the formulary effective in March 2016 and does not include revisions effective June 2016.

[4] We considered whether to also take the strength of the evidence into account in determining the preferred status of the drug. However, this requires clinical judgment that was not appropriate to apply for our comparative purposes. Also, strength of evidence might have limited discriminatory power. For example, within the low-back injury category/acute phase category, all the NSAIDs are listed as "Yes: Limited Evidence (C)" for radicular pain including sciatica and as "Yes: Strong Evidence (A)" for other low-back injuries. It also adds additional complexity to the drug formulary because the evidence level for the recommendation can vary. For example, the evidence level for diclofenac potassium (Cataflam, Voltaren®) varies from strong evidence for acute low-back pain, moderate for perioperative management, and chronic and subacute low-back pain to limited and insufficient evidence for radicular pain, including sciatica.

injury, phase (acute or chronic), and pain type. For each drug ingredient, we generated counts of the number of times a drug falls into the given recommendation category across the three conditions (knee, shoulder, low back). We then applied a general preferred status rule to the active ingredient, depending on which category had the majority of recommendations and which needed further clinical review to establish nonpreferred status. Active ingredients were considered nonpreferred if they are generally not recommended as a first-line therapy or if the recommendations are unclear, warranting further clinical review. Further explanation of the PR rules that we derived for ACOEM can be found in Appendix A. If an ACOEM-based formulary were adopted, more-nuanced criteria might be used either to determine whether a drug should be preferred across all conditions or, alternatively, whether the preferred status should be limited to specific conditions and whether some recommended drugs that are not identified as first-line therapies should also be preferred.

In contrast to Table 4.1, Table 4.2 presents the drug ingredients by the number of fills (volume) rather than by spending. Spending may not correlate with underlying drug volume if expensive brand-name drugs or unique dosage strengths for generic drugs are being dispensed. Analyzing by volume gives an idea of the actual number of PR requests that would be filed under each formulary if it were implemented in California without additional modifications.

We assigned the NDCs reported in the WCIS for each drug ingredient into one of three categories: (1) NDC does not match an NDC in the formulary (and presumably would be nonpreferred); (2) the drug is nonpreferred in the formulary (requires PR); and (3) the drug is preferred (does not require PR). We accumulated the number of fills (prescription line items) in each category by active ingredient and divided by the total number of fills for the active ingredient.

Table 4.2 thus shows, by drug, the percentage of WCIS lines that would fall into the three categories. For example, acetaminophen-hydrocodone bitartrate accounts for 10 percent of all drug lines dispensed to injured workers with back, knee, or shoulder injuries. Under the Washington formulary, 3 percent of the WCIS lines did not match the Washington NDCs (e.g., Washington does not cover repackaged drugs or unique dosage strengths), and another 3 percent would require PR (e.g., brand-name drugs). The remaining 94 percent would not require PR.

Table 4.2 shows that there is within-formulary variation in the percentage of fills in WCIS that would not require PR. For ODG, Washington L&I, Medi-Cal, and Ohio, the variation is due to differences in application of ground rules mentioned at the beginning of this chapter. In contrast, for ACOEM, the RAND-derived PR recommendations are applied uniformly at the active ingredient level, regardless of condition. Because we assumed that all NDCs were addressed under ACOEM, either 100 percent or 0 percent of the WCIS lines would require PR for the given active ingredient. In practice, the state could set up the formulary ground rules so that some versions of the active ingredients (e.g., oral or generic versions) could be considered preferred. Other active ingredients, such as the gastrointestinal agents (e.g., omeprazole), are commonly prescribed in conjunction with other active ingredients (such as NSAIDs) to mitigate side effects. These drugs had unclear recommendations on whether they were first-line treatments in the ACOEM recommendations, so they are nonpreferred under our rules. However, clinical review could reasonably determine these are preferred drugs when prescribed with an NSAID.

There are also some significant differences across formularies for a given drug ingredient. One of the most important differences is in the handling of opioids. For example,

Table 4.2
Percentage of 2013 WCIS Fills (lines) by Preferred Status for Knee, Shoulder, and Low-Back Injuries, by Formulary

Ingredient(s)	% of Knee, Shoulder, and Low-Back Lines in WCIS	Washington (% of lines)			ACOEM (% of lines)			ODG (% of lines)			Ohio (% of lines)			Medi-Cal (% of lines)		
		Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR
Acetaminophen/ hydrocodone bitartrate	10	3	3	94	0	100	0	<1	0	100	<1	100	0	3	76	21
Ibuprofen	6	2	1	96	0	0*	100*	5	0	95	<1	0	100	2	4	94
Omeprazole	6	7	2	90	0	100*	0*	0	0	100	0	0	100	<1	97	2
Tramadol hydrochloride	6	4	27	69	0	100	0	2	0	98	2	98	0	26	3	71
Naproxen sodium	4	9	1	90	0	0*	100*	1	<1	98	0	100	0	2	98	0
Cyclobenzaprine hydrochloride	4	6	3	91	0	100	0	3	1	96	0	100	0	4	96	0
Gabapentin	3	8	3	89	0	100*	0*	3	2	95	3	0	97	4	2	94
Carisoprodol	2	<1	99	0	0	100	0	0	100	0	0	100	0	1	99	0
Naproxen	2	2	2	96	0	0*	100*	0	0	100	0	0	100	3	7	90
Nabumetone	2	1	<1	98	0	0	100	0	0	100	0	0	100	<1	0	99
Zolpidem tartrate	2	9	18	74	100	0	0	1	15	84	14	0	86	<1	16	84
Tizanidine hydrochloride	2	7	12	81	0	100	0	<1	0	100	0	100	0	5	95	0
Celecoxib	2	<1	100	0	0	100*	0*	<1	0	100	0	0	100	<1	<1	100
Diclofenac sodium	2	8	42	50	0	100*	*	<1	100	0	0	100	0	<1	73	26
Capsaicin/menthol, methyl salicylate	2	<1	93	7	100	0	0	100	0	0	0	0	100	100	0	0
Acetaminophen, tramadol hydrochloride	2	<1	1	98	0	100	0	<1	0	100	0	100	0	1	99	0
Lidocaine	2	<1	98	2	0	100	0	<1	100	0	<1	0	100	<1	99	0
Etodolac	1	4	<1	96	0	0	100	<1	0	100	0	0	100	<1	100	0

Table 4.2—Continued

Ingredient(s)	% of Knee, Shoulder, and Low-Back Lines in WCIS	Washington (% of lines)			ACOEM (% of lines)			ODG (% of lines)			Ohio (% of lines)			Medi-Cal (% of lines)		
		Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR
Oxycodone hydrochloride	1	<1	52	47	0	100	0	<1	51	48	0	100	0	<1	61	39
Menthol	1	6	<1	94	0	100*	0*	100	0	0	<1	0	100	100	0	0
Orphenadrine citrate	1	<1	100	0	0	100	0	<1	99	0	<1	99	0	<1	100	0
Duloxetine hydrochloride	1	<1	100	0	0	100*	0*	0	0	100	0	0	100	<1	2	98
Acetaminophen	1	2	2	96	0	100*	0*	0	0	100	<1	0	100	2	7	91
Acetaminophen/oxycodone hydrochloride	1	10	3	87	0	100	0	<1	0	100	0	100	0	<1	59	41
Pregabalin	1	0	100	0	0	100*	0*	0	0	100	0	0	100	<1	100	0
Meloxicam	1	3	3	95	0	100	0	<1	0	100	0	0	100	<1	0	100
Acetaminophen/codeine phosphate	1	4	<1	95	0	100	0	<1	0	99	<1	100	0	<1	11	89
Docusate sodium	1	30	18	53	100	0	0	100	0	0	0	100	0	28	4	68
Methocarbamol	1	<1	2	98	0	100	0	<1	0	100	<1	100	0	1	99	0
Alprazolam	1	10	3	87	100	0	0	0	100	0	0	100	0	<1	99	0
Ketorolac tromethamine	1	6	88	6	0	100	0	<1	10	89	4	96	0	6	94	<1
Diazepam	1	<1	5	95	100	0	0	1	99	0	1	99	0	<1	3	96
Triamcinolone acetonide	1	<1	95	4	100	0	0	100	0	0	0	0	100	<1	41	58
Menthol/methyl salicylate	1	<1	24	76	100	0	0	96	4	0	100	0	0	100	0	0
Morphine sulfate	1	8	75	17	0	100	0	<1	83	17	0	100	0	<1	52	48
Trazodone hydrochloride	1	<1	<1	100	0	100	0	<1	100	0	0	0	100	<1	<1	100
Amitriptyline hydrochloride	1	1	<1	98	0	100*	0*	<1	0	100	0	0	100	<1	0	99

Table 4.2—Continued

Ingredient(s)	% of Knee, Shoulder, and Low-Back Lines in WCIS	Washington (% of lines)			ACOEM (% of lines)			ODG (% of lines)			Ohio (% of lines)			Medi-Cal (% of lines)		
		Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR	Not in Formulary	Requiring PR	Not Requiring PR
Pantoprazole sodium	1	7	3	90	0	100*	0*	0	100	0	<1	100	0	<1	98	2
Diclofenac epolamine	1	<1	100	0	100	0	0	0	100	0	0	0	100	<1	100	0
Ketoprofen	1	0	<1	100	0	0	100	0	<1	100	0	0	100	<1	<1	100

SOURCE: RAND analysis of WCIS 2013 and formulary files from the sponsors.
NOTES: The * denotes that clinical review of the ACOEM recommendations is needed to confirm the preferred or nonpreferred status of the active ingredient. Celecoxib, for example, may likely be considered a first-line treatment, but the majority of recommendations were not specific about whether it is. It has therefore been marked as nonpreferred for ACOEM pending further clinical review. Bills for drugs used in compounding and discontinued drugs were excluded from the totals and percentages in the table. Please see Appendix A for a detailed description of the assumptions used for each formulary.

ODG treats several opioids, including acetaminophen-hydrocodone bitartrate and tramadol hydrochloride as preferred therapies, while ACOEM does not. ODG does not require PR for zolpidem tartrate (Ambien); ACOEM does not address this drug, so under our assumptions, it would require PR. Differences in manufacturer restrictions and dosage limits also drive some of these differences.

Uniformity of PR Requirements Across Conditions in ACOEM

The ACOEM drug recommendations contain much more nuance by condition than the other formularies, which rely on simpler formulary rules that for the most part are not condition specific. Although the other formularies generally apply the same preferred or nonpreferred status rule regardless of the condition for which the drug is prescribed, the underlying treatment guidelines may recommend the drug only for specific conditions. For example, the ODG formulary classifies pregabalin (Lyrica) as a "Y" drug (preferred), but the treatment guidelines recommend the drug for neuropathic pain conditions and fibromyalgia and not for acute pain.

Instead of condition-specific PR requirements, other policies may be used to enforce treatment guidelines that vary by condition. Tennessee and Oklahoma have an ancillary policy that requires PR if the prescribed drug is not consistent with the treatment guidelines. This approach puts the onus on the prescribing physician to know the specifics of the treatment guidelines; in contrast, any variations in the drug recommendations across conditions in the ACOEM treatment guidelines are embedded in its formulary recommendations. The ACOEM approach directly links the formulary recommendations to the treatment guidelines, and the extent to which the recommendations actually vary across conditions will affect whether any condition-specific PR requirements are necessary. Condition-specific PR requirements complicate processing drug bills because diagnostic information is needed to distinguish between which prescriptions require PR and which do not. The payers and pharmacies must have condition-specific information, such as diagnosis codes, that are present at the time the prescription is dispensed. Most of the time, the condition information is not transmitted to the pharmacy when a prescription is dispensed. Assessing the information technology needed to ensure that this type of condition-based approach could be implemented at the point when the injured worker picks up the prescription from the pharmacy is beyond the scope of this review.

Table 4.3 compares the ACOEM recommendations for drugs in ACOEM's anti-inflammatory class across knee, shoulder, and low-back injuries. We found that recommendations for individual active ingredients tend to be uniformly applied across the conditions, so a drug that we have defined as nonpreferred in any one condition is generally considered nonpreferred in all three conditions. For example, celecoxib (Celebrex) is a recommended drug, but the recommendations are nearly uniformly unclear on whether the drug should be a first-line treatment across conditions. Meloxicam (Mobic) is almost always listed as a second-line treatment across conditions and should be considered a nonpreferred treatment. Drugs not requiring PR also tend to be handled the same way across conditions, although there are some PR requirements for a given subinjury, phase, or pain type or level. For example, naproxen is most commonly not recommended for use when it is used in conjunction with iontophoresis; otherwise, it is a recommended first-line therapy and would not require PR.[5]

[5] Iontophoresis transmits a drug into the body through electrical current. We therefore assume that the naproxen form is the gel in the cases referencing iontophoresis, although the ACOEM guidelines do not specify the form of the active ingredient.

Table 4.3
Summary of ACOEM Recommendations for Low-Back, Shoulder, and Knee Conditions and RAND-Derived Preferred Status for Anti-Inflammatory Class, by Active Ingredient

	Total Yes Recommendations That Are					
Analgesics, Anti-Inflammatory	First-Line Therapies	Secondary (or beyond) Therapies	Unclear Whether First-Line Therapies	Total Not Recommended	Total No Recommendation	Preferred Drug (RAND-specified)?
Adalimumab (Humira)	0	0	0	7	0	No
Celecoxib (Celebrex®)	0	0	33	0	2	No*
Diclofenac potassium (Cataflam, Voltaren®)	32	0	1	0	2	Yes
Diclofenac sodium, misopro (Arthrotec®)	0	0	15	0	0	No*
Esomeprazole, naproxen (Vimovo)	0	0	0	30	0	No
Etanercept (Enbrel)	0	0	0	7	0	No
Etodolac (Lodine)	32	0	1	0	2	Yes
Famotidine, ibuprofen (Duexis)	0	0	0	30	0	No
Fenoprofen calcium (Nalfon)	32	0	1	0	2	Yes
Flurbiprofen (Ansaid)	31	0	1	0	2	Yes
Golimumab (Simponi)	0	0	0	7	0	No
Ibuprofen (Motrin)	32	0	1	1	2	Yes*
Indomethacin (Indocin®)	32	1	0	0	2	Yes
Ketoprofen (Oruvail®)	32	0	1	0	2	Yes
Ketorolac tromethamine	0	0	0	32	0	No
Meclofenamate sodium (Meclomen)	31	0	1	0	2	Yes
Mefenamic acid (Ponstel)	31	0	1	0	2	Yes
Meloxicam (Mobic)	0	32	1	0	2	No
Nabumetone (Relafen)	32	0	1	0	2	Yes
Naproxen (Aleve, Naprosyn)	32	0	1	7	2	Yes*
Naproxen sodium	32	0	1	7	2	Yes*
Oxaprozin (Daypro)	31	0	1	0	2	Yes

Table 4.3—Continued

Analgesics, Anti-Inflammatory	Total Yes Recommendations That Are: First-Line Therapies	Total Yes Recommendations That Are: Secondary (or beyond) Therapies	Total Yes Recommendations That Are: Unclear Whether First-Line Therapies	Total Not Recommended	Total No Recommendation	Preferred Drug (RAND-specified)?
Piroxicam (Feldene)	0	0	0	32	0	No
Sulindac (Clinoril)	32	0	1	0	2	Yes
Tolmetin sodium (Tolectin®)	32	0	1	0	2	Yes
Total	476	33	63	160	34	

SOURCE: Authors' analysis of the MDG Rx Guidelines, the Reed Group.

NOTES: Counts are for each indication (type of injury, pain type, and phase for which the listed drug was addressed in the guidelines). An asterisk indicates that the drug recommendations need further clinical review to establish preferred status. For example, celecoxib may likely be considered a first-line treatment on clinical review but has been assigned nonpreferred status because the majority of recommendations are not clear about whether the drug is a first-line therapy. Please see Appendix A for a detailed description of the assumptions used for each formulary.

Conclusions

As California DWC moves toward implementing a formulary, decisions on the ground rules highlighted at the beginning of the chapter will have important effects on access to drugs for injured workers and important implications for administrative burden on providers and payers and the medical necessity dispute-resolution process.

Key findings from the comparisons across formularies include the following:

- Generally, the existing WC formularies address the high-volume drugs used by California's injured workers. If California were to adopt one of the existing formularies, one issue is whether the drug listing should be supplemented with other high-volume or high-expenditure drugs used in the California WC program. If the default policy is that a drug is nonpreferred and thus requires PR if it is not on the listing, the focus should be on whether there are other first-line therapy drugs or low-cost, low-risk drugs that should be considered preferred treatments to minimize the administrative burden.
- The formularies have different ground rules for which active ingredients, formulations, and generic-versus-brand distinctions are preferred. The most important issue is how to reconcile any PR differences between the formulary and the MTUS guidelines. The differences in formulations and generic-versus-brand policies are not as important but would need to be addressed if DWC elects to create a California-specific formulary that draws on the existing formularies.
- In terms of active ingredients, the most important differences are in the preferred status for opioids. ODG lists some opioids as not requiring PR, while the RAND-derived preferred status for ACOEM recommendations would require PR for all opioids. Washington considers many narcotics on the drug listing as preferred, but the listing includes only oral generic versions, and PR would be required for the brand names.
- The formularies that are used in conjunction with the treatment guidelines have different approaches to handing variation in the treatment recommendations across conditions. ODG has a simple yes-or-no preferred status for most drugs. If physicians prescribe consistent with the treatment guidelines, this simplifies the prescribing and bill-processing systems. However, to the extent the practice guideline recommendations differ by condition, this increases the likelihood that medically inappropriate drugs may be dispensed. ACOEM creates a more direct link between the treatment guidelines and recommendations by making condition-specific recommendations. This reinforces the treatment guidelines for the prescribing physician and reduces the likelihood that medically inappropriate drugs are dispensed but complicates the bill processing. However, using our PR rules, most drugs would have the same status across conditions in the ACOEM formulary.

CHAPTER FIVE

Formulary Implementation Policies

This chapter discusses topics that DWC will need to consider in implementing the drug formulary. We identified these topics by reviewing the regulatory policies that states adopted when a WC formulary was implemented.[1] Two states with WC formularies that we included in our review are single-payer WC agencies that have adopted their own formularies: Washington L&I and Ohio BWC. Three other states with WC formularies have implemented the ODG formulary: Oklahoma, Tennessee, and Texas. Each of these states have adopted WC formulary rules that suggest policy options that DWC might consider.[2]

Our discussion of each topic was further informed by our interviews with state officials and California stakeholders, presentations at the DWC public hearing, and available literature on specific topics. The topics we cover in this chapter include the following:

- whether the formulary should apply to drugs administered in outpatient care settings
- whether the formulary should include OTC drugs, intrathecal drugs, physician-administered drugs, and drugs that are not commonly used for WC conditions
- what utilization management and dispute-resolution process should apply to formulary drugs
- whether there should be a first-fill policy for drugs prescribed immediately following injury
- whether the formulary should include cost-saving tools, such as restrictions on physician dispensing, stronger rules on prescribing generic versions of brand-name drugs, and therapeutic interchange
- whether special policies should be adopted for refills of drugs dispensed prior to the effective date of the formulary.

Chapter Six discusses the process for updating the formulary and the role of the P&T committee.

[1] Except where noted, we relied on these documents in our descriptions of how the states have addressed these topics and have included them in the list of references.

[2] Three other states have implemented WC formularies—Delaware, Nevada, and North Dakota—but have not issued a broad set of implementation policies and are not discussed in this chapter. Delaware's rules (§2322B) simply state that the Workers' Compensation Oversight Panel is to adopt, recommend, and maintain a formulary that will include a ban on repackaging fees and adoption of a preferred drug list. The panel derived its drug list from the Delaware Medicaid formulary. In 2015, Nevada's Division of Industrial Relations announced that the ACOEM formulary had been approved for use in the state's WC program as a tool for making informed decisions about the benefits provided to injured workers (Godwin, 2015). There are no implementing rules. North Dakota has adopted a limited set of instructions regarding the process for requesting PR and the criteria for approving a brand-name drug when a generic version is available. Unlike the states that we review in this chapter, the drug listing is not integrated with North Dakota's medical treatment guidelines.

Applicability of Formulary

Labor Code §5307.27 provides that the WC formulary applies to all prescribers and dispensers of drugs provided to injured workers. The AB 1124 statement of legislative intent specifies that the formulary does not apply to care provided in an emergency department or inpatient setting.

Care Settings

When considered together, the Labor Code and statement of legislative intent raise two issues regarding the care settings to which the formulary applies. The first is whether the formulary should apply in outpatient care settings, such as a doctor's office or clinic. Typically, drugs are *administered* to the patient in care settings, while drugs are *dispensed* by a pharmacy or a physician to be taken by or administered to a patient at home.[3] The use of the term *dispensed* in §5307.27 may imply that the determining factor is whether the drug will be taken at the patient's home, rather than the type of health care provider that provides or supplies the drug. This policy approach would also address the second issue, namely whether take-home drugs provided at discharge from inpatient or emergency room care are subject to the formulary. Consideration should be given to clarifying both issues in the formulary rules.

The Ohio BWC rules do not define *outpatient medication* and include some physician-administered injections on the drug listing. Oklahoma, Tennessee, and Texas define the formulary as applying to drugs that are prescribed and dispensed for "outpatient use," without defining outpatient use. The Washington L&I formulary listing explicitly states that the outpatient formulary does not apply to clinical settings, including physician offices and clinics. Washington does not permit physician-dispensing or outpatient injections.

A potential complication in excluding physician-administered drugs occurs if the formulary includes injectable versions of some or all the active ingredients. The ACOEM formulary lists corticosteroid injections as a recommended second line of therapy for selected conditions but has advised us that all formulations of a drug are included in the formulary drug listing. According to WLDI staff, the ODG formulary drug list includes only oral drugs unless another form is specified on the listing. A few types of injections are listed on the formulary (e.g., buprenorphine, diclofenac sodium, ketorolac). Corticosteroids are listed only in their oral form.

As a practical matter, this would not be problematic if the formulary rules required PR for these injections (PR would be required regardless of whether the formulary were applicable to the injections). If the formulary does not apply to physician-administered drugs, however, an inconsistency between the definition of the formulary applicability and the formulary drug listings should be avoided. This could be done by either an across-the-board exclusion of physician-administered drugs from the formulary drug list (they would still be addressed by the treatment guidelines) or by expanding the formulary's applicability to separately payable drugs administered in outpatient settings that are addressed by the MTUS. The formulary would not include drugs that are bundled into the payment for an outpatient encounter. Under

[3] Under the California Business and Professions Code §4016, *administer* means "the direct application of a drug or device to the body of a patient . . . by injection, inhalation, ingestion, or other means." Section 4024 defines *dispense* as furnishing drugs on prescription from a physician or nonphysician practitioner or a physician or nonphysician practitioner acting within the scope of his or her practice furnishing drugs directly to a patient.

the OMFS, the exclusion would apply to drugs that are bundled into the facility fee payments for outpatient clinics and ambulatory surgery center services and minor drugs that are bundled into the practice expense portion of the OMFS for physician services. WC-covered physician-administered injections are separately payable under the OMFS.

Types of Drugs

Over-the-Counter Drugs

California's Labor Code specifies the entities to which the formulary applies (all prescribers and dispensers) but not the types of drugs that should be included in the formulary. ODG and ACOEM include both prescription and some nonprescription (OTC) drugs in their formularies. The Ohio and Washington L&I formularies list only prescription drugs but also cover OTC drugs that are written on standard prescription forms. Requiring a prescription is consistent with the WC rules in other states and provides a mechanism for the injured worker to obtain the nonprescription drugs at no cost.

The rules for states using the ODG formulary specify that the formulary includes all FDA-approved prescription and OTC drugs. The Texas and Oklahoma formulary rules provide additional guidance that is specific to OTC medications: The prescription should include the appropriate strength and quantity of the medication "that is reasonably required by the nature of the compensable injury. The doctor shall prescribe OTC medications in lieu of a prescription drug when clinically appropriate."

Intrathecal Drugs

Intrathecal delivery systems (implantable drug-delivery systems [IDDS]) inject analgesics directly into the spine. The continuous infusion rate and bypassing of the brain allow smaller doses of analgesics and reduce side effects (Bottros and Christo, 2014). The MTUS (ODG) guidelines for chronic pain address the use of IDDS, which is recommended only as an end-stage treatment alternative for selected patients and conditions.[4] Medications used in the IDDS are typically compounds of FDA-approved drugs for intrathecal use and off-label use of other analgesics that have not been FDA-approved to be used intrathecally (Bottros and Christo, 2014). Because the IDDS is for outpatient use, the issue is whether drugs used in the pump should explicitly be included or excluded from the drug formulary. The IDDS uses compounded and infusion drugs; therefore, it is probable that PR will always be required, which is consistent with current policies. Oklahoma and Texas have rules that specifically pertain to drugs used in the IDDS. Explicitly addressing these drugs provides an opportunity to develop IDDS-specific rules regarding the frequency and circumstances for which PR is required for refills. If no changes in the PR rules are considered appropriate, there is no reason to specifically address IDDS in the formulary rules.

Drugs Uncommonly Prescribed for WC Conditions

States with WC formularies have different policies for handling therapeutic classes that are not typically indicated for WC conditions (Table 5.1). Ohio and Washington limit their formu-

[4] When the low-back pain guidelines are updated, they will take precedence over the ODG. The ACOEM guidelines would similarly require PR.

Table 5.1
Comparison of State Policies for Drugs That Are Uncommon for WC Conditions

State	Regulatory Policy
Ohio	The formulary listing includes only drugs in therapeutic classes that the BWC P&T committee has determined to be reasonably related to or medically necessary for a compensable condition (relatedness classes). Changes in the relatedness classes must be made by the P&T committee. Drugs that are not indicated for the related classes are not covered, with one exception. With PR, BWC may cover medically necessary new FDA drugs or new indications for existing drugs that are not on the formulary for up to 180 days to allow time for the P&T to review the drug's status.
Oklahoma	Formulary rules indicate that it includes all available FDA-approved drugs other than the drugs listed on the ODG formulary as requiring PR and "drugs that are not preferred, exceed, or are not addressed by the ODG in effect on the date of treatment." The excluded drugs require PR.
Tennessee	Formulary rules adopt the ODG formulary but also include all available FDA-approved drugs. Formulary rules do not address therapeutic classes that are not included in the ODG formulary, and the regulatory intent is not clear. The rules state that "Y" drugs on the ODG listing should be filled without delay if they are appropriate for the worker's condition but do not mention drugs that are not in the ODG formulary. Retrospective review is allowed for drugs that are not appropriate for the worker's condition.
Texas	The formulary rules do not address therapeutic classes that are not included in the ODG formulary. Instead, the rules indicate that the formulary includes "all FDA-approved drugs" and that, other than the drugs listed on the ODG formulary as requiring PR, "all other FDA-approved drugs are available for use without PR" but are subject to retrospective review of medical necessity.
Washington	The formulary assigns a "D" status to therapeutic classes that are not covered because they are rarely needed for WC conditions. Temporary treatment of an unrelated condition may be allowed through PR if these conditions directly retard recovery of the accepted condition.

laries to therapeutic classes that are commonly prescribed for WC conditions and provide an exceptions process to obtain noncovered drugs.

Because treatment guidelines address only drug therapies considered for common WC conditions, the formularies that are derived from the treatment guidelines (ODG and ACOEM) by definition include only drugs that are commonly prescribed for WC conditions. The three states that have adopted the ODG guidelines include "all FDA-approved drugs" in their formularies. Only Oklahoma has a clear policy that PR is required for drugs that are not addressed by the ODG guidelines. Both the Texas and Tennessee rules provide that drugs that are not on the ODG formulary may be prescribed and dispensed without PR but would be subject to retrospective review. Retrospective review is discussed in greater detail in the next section of this chapter.

Utilization Management and Dispute-Resolution Process

Under California's current medical necessity dispute-resolution process, a determination that a pharmaceutical or other medical treatment is medically necessary involves several components:

- Care should be consistent with the MTUS.
- The claims administrator (or a UR organization with which the payer has contracted) must have a UR process to review the medical appropriateness of care. UR may occur prospectively, based on an RFA; concurrently, for inpatient care; or retrospectively, after the care has been provided. A prospective RFA must be acted on within five working days. If additional information is reasonably required, and request for the information is made within five days, the decision must be made within 14 days of first receipt of the

RFA. If the additional information requested within the first five days is not received or if there are circumstances permitted by regulation, such as need for testing, a conditional denial may be issued delaying the decision until the additional information is received. When there is a request for expedited authorization due to an urgent medical need, the decision must be made within 72 hours of the request. Only a UR physician may modify or deny care.

- The claims administrator may also provide for an internal UR appeals process on a voluntary basis that does not affect the formal appeal process for an adverse UR decision.
- An injured worker may request that an adverse UR decision be reviewed by an IMR organization. The appeal must be filed within 30 days of the UR decision. The IMR decision must be issued within 30 days of receipt of the related medical documentation unless an expedited appeal request has been filed.
- Expedited UR or IMR reviews are conducted when an injured worker faces an imminent and serious threat to his or her health or "the normal time frame for the decisionmaking process would be detrimental to the injured worker's life or health or could jeopardize the injured worker's permanent ability to regain maximum function." The UR decision must be made within 72 hours. An expedited appeal for IMR requires submission of medical documentation with 24 hours and a decision within three days of receipt of the documentation.

In the discussion that follows, we assume that the current medical necessity dispute-resolution process will continue to apply to medical necessity pharmaceutical treatment issues. Chapter Seven addresses potential changes in the process for pharmaceuticals.

Underpinning all WC formularies is the assumption that care will be provided consistent with the state's coverage policies, including any medical treatment guidelines. Washington L&I and, to a lesser extent, Ohio BWC have developed policies for specific therapies. Texas has used the ODG medical treatment guidelines since 2007, and Oklahoma and Tennessee adopted the ODG guidelines at the same time they adopted the ODG formulary.[5] As discussed in Chapter Three, California's MTUS is developed from multiple sources and is not fully consistent with any existing drug formulary. Chapter Seven discusses approaches California might consider in reconciling any differences in the ACOEM or ODG formularies with the MTUS.

In this section, we examine state UR policies for drug prescriptions and the appeal process that may be used if proposed treatments are denied. Under California's current UR process, all drug therapies are subject to UR, and most UR occurs prospectively.[6] Eliminating PR for MTUS-recommended drug therapies that meet specified criteria (e.g., first-line therapies indicated for the worker's condition) is an important mechanism for achieving legislative intent that appropriate drugs be provided expeditiously while minimizing administrative burden and associated costs. When drugs that do not require PR are prescribed, both point-of-sale bill-processing protocols and retrospective UR are safeguards to ensure that the drugs are medically appropriate for the worker's condition. An appeals process for drugs that are denied for being inconsistent with the MTUS provides further assurance that an injured worker has access to evidence-based medically appropriate drugs.

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[5] Tennessee also has chronic pain guidelines.

[6] A few claims administrators have implemented a policy that exempts designated providers from requesting authorization for specific types of drugs.

Prospective Review

Table 5.2 summarizes the PR requirements of the states with WC formularies. Consistent with California's terminology, we use *PR* to mean a process that reviews the medical necessity of a proposed drug therapy before the drug is dispensed. Other states use other terminology to describe this process, for example, *prior authorization* and *preauthorization*. Chapter Three discusses the available information on the processes and criteria used to establish drug-specific PR policies for the drug formularies.

Regardless of the formulary structure that DWC adopts, the policies of states adopting the ODG formulary are most relevant, and the Texas experience is the most informative because it has been operational longer than the other two ODG states and because Texas was already using the ODG medical treatment guidelines. As discussed in Chapter One, the volume of prescriptions per claim dropped when the formulary was implemented, and the proportion attributable to N-drugs fell disproportionately relative to other drugs. Texas adopted "all FDA-approved drugs" for the formulary and stipulated that formulary drugs that exceed or are not addressed by the treatment guidelines do not require PR. Arguably, this creates at least three vulnerabilities: (1) Drugs may be prescribed and dispensed that are not recommended for the injured worker's condition; (2) second-line therapies may be dispensed before a medically appropriate first-line therapy is considered; and (3) physicians may prescribe drugs

Table 5.2
PR Policies for WC Formularies

State	Regulatory Policy
Ohio	Only the drugs listed in the formulary are covered. The formulary requires PR for a limited number of drugs—e.g., Gabapentin (sustained release), Yohimbine HCL—and for FDA-approved new drugs or new indications for existing drugs. PR may also be used to obtain coverage for • compounded sterile parental drugs (injectable medications) • nonsterile compounded drugs that contain one to three FDA-approved active ingredients and only one prescription drug from a specific drug therapeutic class (as defined by the American Hospital Formulary Service Drug Information) • off-label usage. In addition, managed care organizations may approve drugs for the treatment of obesity, infertility, noncompounded injections that cannot be self-administered, smoking cessation drugs, and take-home drugs dispensed during an inpatient or outpatient hospital encounter.
Oklahoma	PR is required for • drugs with an "N" status on the ODG Drug Formulary • any compounded drug • any investigational or experimental drug • drugs that are not preferred, exceed, or are not addressed by ODG • intrathecal drug regimens and refills involving changes in drug regimen or physician. The payer may deny payment if PR was not requested when required. If the payer fails to respond to the PR request within 72 hours, the request is deemed approved.
Tennessee	UR does not apply to OTC drugs. It applies to prescription drugs prescribed for more than 90 days from the initial prescription. PR is required for • drugs with an "N" status on the ODG Drug Formulary • any compounded or topical drug • any investigational or experimental drug that does not have a "Y" or "N" listing on the ODG formulary.
Texas	PR is required for • drugs with an "N" status on the ODG Drug Formulary • any compounded drug containing an ingredient with "N" status • any investigational or experimental drug • intrathecal drug regimens and refills involving changes in drug regimen or physician.
Washington	PR is required for specific therapeutic drugs or classes as listed on the Washington State formulary and L&I wraparound formulary.

by consulting ODG's Appendix A but not the treatment guidelines. Because there are no prospective or point-of-sale safeguards for these drugs, retrospective review is needed to ensure that the dispensed drugs are medically necessary. It is problematic to establish financial liability on retrospective denials because the physician prescribed the drug and the pharmacy dispensed the drug in good faith. Retrospective review is minimized if PR is required not only for specified drugs but also for proposed drugs that are either not recommended as first-line therapies, inconsistent with the treatment guidelines for the injured worker's condition, or not addressed by the treatment guidelines for the injured worker's condition.

A strict application of the PR requirement outlined above would make specific policies redundant for other problematic therapies, e.g., compounded drugs, experimental or investigational drugs, and off-label usage. However, because these drugs have been vulnerable to abuse, an explicit PR requirement avoids any misinterpretations. Types of drugs that might merit a specific PR rule include the following:

- *Compounded drugs.* The rule should define compounded drugs and include the different forms of administration. The FDA notes that compounded drugs that have not been verified to meet FDA quality standards may have associated health risks. One danger is the "possibility that patients will use ineffective compounded drugs instead of FDA-approved drugs that have been shown to be safe and effective" (FDA, 2015). Because the treatment preference for most patients should be an FDA-approved drug, consideration should be given to requiring PR for any compounded drug. Similarly, commercially marketed compounded OTC medications could require PR if one or more of the ingredients does not have FDA approval or an FDA final monograph, which would encompass the topical ointments and creams commonly prescribed for injured workers.[7]
- *Off-label usage of FDA-approved drugs.* When the FDA approves a drug, the labeling for the drug includes the indications, dosage, and form for the drug. Off-label drug use involves prescribing and dispensing drugs for indications, dosages, or formulations that the FDA has not approved (FDA, 2016b). The AB 1124 statement of legislative intent indicates that the formulary should provide guidance on the injured worker's access to evidence-based medically necessary drugs used for non–FDA-approved indications. This could be accomplished by requiring PR for off-label drug usage that is not addressed by the MTUS. The MTUS Medical Evidence Search Sequence would then be used to determine whether off-label usage that is not addressed by the treatment guidelines is medically appropriate.
- *Experimental or investigational drugs.* All three states using the ODG formulary require PR for investigational or experimental drugs "for which there is an early, developing scientific evidence demonstrating the potential efficacy of the treatment but which is not yet broadly accepted as the prevailing standard of care" (Texas formulary rule). This definition describes the type of experimental or investigational drug that might be covered using evidence-based criteria. However, the rule should require PR for any experimental or investigational drug that is not FDA-approved regardless of early evidence about its potential efficacy.

[7] The across-the-board PR requirement for topicals (Tennessee policy) does not appear necessary. Most of the abuse occurs with OTC topical ointments (including ointments with a combination of ingredients) that are not FDA-approved, for which PR should be required.

In addition to drug ingredients that require PR, PR might be considered for other prescribing practices, such as physician-dispensed drugs and the use of generic versus brand-name drugs. Both practices are discussed below, under "Cost-Saving Tools," but there is also a medical appropriateness aspect to prescribing these drugs.

PR might also be waived under some circumstances. We discuss waiving PR for first fills following injury later. Another potential policy would be to provide payers the flexibility to waive PR requirements for specific prescribers, dispensers, or drugs, consistent with the flexibility accorded a claim administrator to waive its requirements for prospective UR for specific services or providers under current UR rules. We discuss this policy in Chapter Seven.

Oklahoma formulary rules encourage both PR requests and prompt UR determinations. Failure to request PR entitles a payer to deny payment, but a PR request that is not responded to within 72 hours is deemed approved.

Point-of-Sale Enforcement

Point-of-sale enforcement of PR rules is key to avoiding retrospective denials. Point-of-sale enforcement can also involve bill-processing screens to review whether the prescribed drug is indicated for the injured worker's condition. In terms of state policies, Ohio and Washington are both single-payer states that enforce PR and other drug formulary policies by maintaining online, point-of-sale authorization and adjudication systems through PBMs. A state-level approach is not feasible for California and other multipayer states; rather, enforcement is more likely to occur through PBMs under contract with the payer. Other than Tennessee, we did not find state policies pertaining to point-of-sale enforcement. This is not surprising; arrangements between the various entities involved in the adjudication process determine the claims processes. These entities include a claims administrator and its agents (PBM, UR organization), pharmacies, and pharmacy billing services. The Tennessee policy indicates that drugs that do not require PR "should be filled without delay *if they are appropriate for the nature of the injury being treated*" (emphasis ours). This language permits point-of-sale bill-processing screens to ensure consistency between the injured worker's injury and the indicated uses of the drug. Chapter Seven discusses the operational aspects of point-of-sale enforcement and bill-processing screens.

Retrospective Review

Retrospective review provides protection for the payer to ensure that dispensed drugs not requiring PR were medically appropriate and indicated for the injured worker's compensable injuries. The need for retrospective review is limited if effective PR and bill-processing screens are employed before the drug is dispensed. Ohio and Washington do not need retrospective review because of their point-of-sale bill-processing and adjudication systems. Oklahoma does not have formal UR rules and embeds retrospective review into its medical fee schedule dispute-resolution process.

The rules Tennessee and Texas employ are the most relevant for California because retrospective review occurs within the framework of their UR policies for medical necessity determinations (Table 5.3). As noted earlier, neither the Texas nor the Tennessee rules require PR for drugs that exceed or are not addressed by the treatment guidelines. Not requiring PR for these situations increases the likelihood that some drugs are being dispensed that are not medically appropriate for the injured worker's condition. Texas permits a retrospective audit for medical necessity that must be completed within 45 days. If there is a retrospective medical neces-

Table 5.3
Retrospective Review Policies for WC Formularies

State	Regulatory Policy
Ohio	Not applicable, given the point-of-sale adjudication system.
Oklahoma	Does not have formal UR rules. An employee, payer, or pharmacist may request a statement of medical necessity from the prescribing physician, who must provide the statement within 14 days. The rules for retrospective review are embedded in policies for resolution of fee disputes.
Tennessee	Retrospective review is allowed only for drugs that are not appropriate for the injured worker's diagnosis. The denial is applied prospectively to the next refill prescribed by the physician.
Texas	Drugs that are prescribed and dispensed without PR are subject to retrospective review for medical necessity under the state's process applicable to other medical services. A physician who prescribes services that exceed, are not recommended, or are not addressed by the treatment guidelines is required to provide documentation on request. Drugs prescribed consistent with the treatment guidelines are presumed reasonable, and any denial must be supported by evidence-based medicine that outweighs the presumption of reasonableness. The payer is not liable for services that are determined to be medically unnecessary and is entitled to ask for a refund from the entity receiving the payment for the medically unnecessary drug.
Washington	Not applicable, given the point-of-sale adjudication system.

sity denial on a dispensed drug, the payer is not liable for the drug and is entitled to request a refund from the dispensing pharmacy (or pharmacy bill-processing agent). The injured worker may not be billed for the prescription. According to interviewees, denials are occurring less frequently than the treatment guidelines would warrant to avoid friction and the additional administrative costs of an appeal.

Tennessee rules limit retrospective review to drugs that are not appropriate for the injured worker's diagnosis. The intent is to limit review only to confirming that the drug is indicated for the worker's diagnosis and, for example, not to reviewing whether the guidelines prefer a different drug as a first line of therapy. Tennessee addresses the liability issue by specifying that only the next refill prescribed by the physician may be denied. The payer (or the PBM under contract with the payer) is liable for the initial prescription of the drug. The policy provides incentives to enforce PR and treatment guidelines at the point of sale.

Appeal Process

In this section, we discuss the appeal processes that apply when PR results in a medical necessity denial, summarized in Table 5.4. These denials occur *before* the drug is dispensed, and the appeal process is a safeguard that the worker has timely access to medically appropriate drug therapies.

Generally, the state's appeal process for other medical treatments applies to drugs that are prescribed and identified as medically inappropriate prior to being dispensed. Texas and Tennessee have created an additional safety value by providing a mechanism to allow an injured worker to continue on previously prescribed and dispensed drug(s) throughout the duration of the appeal process if failure to dispense the drug would create a potential medical emergency. In both states, a determination request must be filed with the WC program's medical director within 15 days of the initial UR decision; the potential medical emergency must be documented in the request for PR; and an appeal must also have been filed in accordance with the state's regular medical necessity dispute-resolution process. The medical director's determination is effective until a final IMR determination is issued. In Texas, the volume of medical interlocutory orders during initial implementation was small. For California, a separate appeal

Table 5.4
Appeals Process for Medical Necessity Denials for WC Formularies

State	Regulatory Policy
Ohio	The BWC may override bill-processing denials for formulary dosage or duration limitations when medically necessary and appropriate. BWC may also approve up to 180 days for drugs that are not on the formulary for the injured worker's condition.
Oklahoma	Disputes are resolved by filing a request for hearing before an administrative law judge.
Tennessee	An expedited determination may be requested from the WC program's medical director if the denial of a previously prescribed and dispensed drug for an injury poses an unreasonable risk of a medical emergency and if (1) the request is filed within 15 days of the adverse UR decision; (2) the potential medical emergency is documented in the prospective approval request; and (3) a request for reconsideration or independent review has already been filed. The medical director's determination is in effect until a final determination is made on the medical necessity of the drug.
Texas	IMR process applies. If a denial poses an unreasonable risk of a medical emergency that was documented in the PR request, a medical interlocutory order may be requested from DWC within 15 days from the date of the denial, provided an IMR appeal has been filed. The order expires with the issuance of the IMR decision.
Washington	A prescriber may request that L&I review a denial.

process appears unnecessary because the IMR regulations already provide a mechanism for expedited appeals. This issue is discussed further in Chapter Seven.

First Fills Following the Injury

A first-fill policy allows a temporary supply of a prescription drug to be dispensed immediately following the injury. Under this type of policy, the drug is dispensed to meet the immediate needs of the injured worker while information on the worker's claim is in early development, when the information needed to review a request for PR may not yet be available in the claims administrator's systems. The policies other state WC formularies use vary and may include drugs that otherwise require PR in the first-fill policy (Table 5.5). Washington and Texas make the first fill contingent on a confirmation that a notice of injury has been filed; in the California context, such a policy could be used to encourage timely filing of Form 5021, Doctor's First Report of Occupational Illness or Injury (DFR).

The Ohio rule became effective February 1, 2015, and applies to the first fill of designated prescriptions at the most common dosing schedules for up to 10 days for the conditions listed in the notice of injury. No more than one drug per therapeutic class is permitted, and no compounded drugs are eligible for the first-fill policy. PR is required for formulary drugs that are not on the first-fill drug listing. The primary purpose of the Ohio policy is to provide an injured worker with necessary drugs before a determination is made on the compensability of the claim. This objective is not directly relevant to California's WC program because the Labor Code provides for up to $10,000 in medical expenditures before a compensability determination is made and before the claim is accepted or denied. However, there may be value in a more-targeted PR rule for first fills so that there are fewer delays in getting initial prescriptions filled. For example, PR might still be required for chronic pain drugs but be waived for specific acute pain drugs in common dosing schedules that would otherwise require PR.

Table 5.5
First-Fill Policies in WC Formularies

State	Regulatory Policy
Ohio	First-fill policy applies to a specific list of drugs and quantities unless medical documentation is submitted to support a different formulary drug. Approval is for one drug per therapeutic class for up to 10 days. Compound drugs are excluded. Prescriber must write "work-related injury" on the prescription.
Oklahoma	No regulatory provision for first fills, but PBMs may have a policy.
Tennessee	Rule covers prescriptions from an authorized provider that are appropriate for the prescribed injury presented to a pharmacy within 7 days of an alleged or accepted WC claim, even if the prescribed medication is status "N." First fills are not subject to UR, and the employer is responsible for the payment.
Texas	Rule allows a sufficient supply for the first 7 days following the date of injury if, prior to providing the pharmaceutical services, the prescriber obtains both a verification of WC insurance coverage and an oral or written confirmation that an injury has been reported. Drugs that otherwise do not require PR are not subject to UR. If a drug would otherwise require PR, PR is not required for the first fill, but the prescription is subject to retrospective review. The first-fill policy does not apply to investigational drugs.
Washington	Rule covers drugs prescribed during the first visit to the doctor completing first report of injury regardless of claim acceptance (no other limitations in rules).

Cost-Saving Tools

Physician-Dispensed Drugs

Among the five states with WC formularies, Ohio and Washington do not allow physician dispensing, and Texas law limits it to quantities that are necessary to meet the "immediate needs" of patients.[8] The formulary rules for Oklahoma and Tennessee (the two states that allow physician dispensing) do not distinguish between physician-dispensed drugs and other drugs dispensed for outpatient use.

In addition to Ohio and Washington, several nonformulary states (Montana, New York, Rhode Island, and West Virginia) do not cover physician-dispensed drugs through their practice acts or specifically for their WC programs (HeliosComp, 2015). As in Texas, the Massachusetts Board of Registration in Medicine limits quantities that physicians may dispense to those that are necessary for the treatment of the patient until a prescription can be filled by a pharmacy (Massachusetts Board of Registration in Medicine, 2015). Other states have sought to reduce the financial rewards for physician dispensing for WC patients by adopting pricing rules comparable to the OMFS rules for repackaged drugs; several states do not allow a dispensing fee (HeliosComp, 2015). Chapter Seven discusses options DWC might consider for physician dispensing.

Generic Versus Brand-Name Drugs

AB 1124 expressed legislative intent that the formulary consider "use of generic or generic-equivalent drugs in the formulary pursuant to evidence-based practices, with consideration

[8] *Immediate needs* are defined as the "amount of prescription drug needed for proper treatment until access to a pharmacy" is possible and is deemed to be the amount necessary for a 72-hour period. The physician may not charge the patient for the drugs. In addition, physician dispensing in rural areas and physician-dispensed samples provided at no cost are permitted (22 Texas Administrative Code §169).

being given to use of brand-name medication when its use is cost-effective, medically necessary, and evidence-based." Prior to the implementation of the drug formulary, Labor Code §4600.1 requires dispensing of FDA-approved substitutable generics unless a generic is not available or unless the prescribing physician specifies in writing that a nongeneric (brand-name) drug be dispensed. This provision will no longer apply after the drug formulary is implemented; as a result, the DWC will need to address the use of generics in its formulary rules.

The OMFS for pharmaceuticals is based on the Medi-Cal fee schedule, which has special pricing rules for multisource generic drug products that are available for retail community pharmacies to purchase.[9] The allowances are significantly lower when a generic drug is dispensed, particularly when the FUL is applicable to a multisource generic.

California's Business and Professions Code §4073 permits a pharmacist to substitute a generic equivalent unless the prescriber personally indicates "Do not substitute" or uses similar language on the prescription. The drug formulary rules provide an opportunity to strengthen the requirements for brand-name prescriptions consistent with §4073. Among the states that have similar policies requiring that the generic equivalent be dispensed unless the prescriber includes "dispensed as written" or similar language on a prescription for a brand-name product, Oklahoma and Texas require that the prescriber maintain documentation in the injured worker's medical record (see Table 5.6). Presumably, this documentation would be available if the payer decided to use retrospective UR to review the medical need for the brand name. Ohio and Washington require PR if a brand name is prescribed when a generic is broadly avail-

Table 5.6
Policies for Use of Generic Drugs in WC Formularies

State	Regulatory Policy
Ohio	Brand-name drugs are not covered when generic equivalent is widely available unless the prescribing physician requests PR for the brand name because the "injured worker has a documented, systemic allergic reaction, which is consistent with known symptoms or clinical findings of a medication allergy and has tried other generic drug(s)."
Oklahoma	Doctors must prescribe generic prescription drugs when available and clinically appropriate. If the prescriber determines that a brand-name is medically necessary, the prescription must indicate that the brand name should be dispensed, and the prescriber must maintain evidence in the patient's medical record justifying the brand name.
Tennessee	Generics are not addressed in the formulary guidelines but in the fee schedule policies. Injured workers should receive only generic drugs or single-source brand-names with no generic equivalent unless the prescriber writes "dispense as written" or "no substitution allowed" in their own handwriting. Injured workers who want a brand name when a generic is available may do so at their own expense.
Texas	Doctors must prescribe generic prescription drugs when available and clinically appropriate. If the prescriber determines that a brand-name is medically necessary, the prescription must indicate that the brand name be dispensed, and the prescriber must maintain evidence in the patient's medical record justifying the brand name. Injured workers who want a brand name when a generic is available may do so at their own expense.
Washington	Prescriptions are filled with generic drugs unless the provider indicates that substitution is not permitted. Typically, only the generic is on the preferred drug list, and the prescriber is required to seek PR for a brand name.

[9] The Federal Upper Limit (FUL) applies to these drugs. The Affordable Care Act changed the methodology for determining the FUL. California implemented the new FUL methodology effective April 15, 2016. The Affordable Care Act sets the FULs at no less than 175 percent of the weighted average (based on utilization) of the most recently reported manufacturer prices for the generic drug products (Centers for Medicare and Medicaid Services [CMS], 2016).

able. Ohio restricts its brand-name exception to situations in which the injured worker has a documented systemic reaction consistent with a medication allergy and has tried generic drugs.

Therapeutic Interchange

Therapeutic interchange occurs when prescribers authorize patients to receive a drug similar to the drug initially prescribed. The drugs do not have therapeutic equivalence, but the entity maintaining the therapeutic interchange program (such as a P&T committee) has found them to have a similar therapeutic effect. A pharmacist must receive permission from a prescriber to make a therapeutic interchange. Permission may be obtained on a prescription-by-prescription basis through PR for nonpreferred drugs in the therapeutic class or through a contractual arrangement between a provider and insurer. For example, Washington physicians may enroll in the Endorsing Practitioner Therapeutic Interchange Program, which reduces the need for PR for drugs listed in the Washington State formulary.

Therapeutic interchange creates an opportunity to dispense less costly alternatives to a prescribed drug. Among the WC formularies, only the Washington State formulary provides for transparent decisions on therapeutic interchange (Washington State Legislature, 2009). As discussed in Chapter Three, a P&T committee reviews the medical evidence to determine whether drugs within the same drug class that are not therapeutically equivalent have similar outcomes and therapeutic effects. A separate evaluation is then conducted for drugs that have similar therapeutic effects to take comparative costs into consideration in deciding which drugs with similar therapeutic effects should be included on the preferred drug list.

In developing their preferred drug lists, the Washington L&I, Ohio, and Medi-Cal formularies also consider therapeutic interchange but less transparently. For the L&I formulary, a PBM under contract with the state takes both medical evidence and costs into account in its recommendations for which drugs should be included on the preferred drug list. In Ohio, the P&T committee considers therapeutic interchange in developing its formulary recommendations. Cost is one criterion used to determine the Medi-Cal preferred drug list and can be the deciding factor when the other criteria do not distinguish between drugs. These formularies encourage therapeutic interchange by requiring PR for the nonpreferred drugs in the therapeutic class.

The ACOEM and ODG guidelines discuss alternative drug therapies within the same drug class and, for some drug classes, discuss whether the therapeutic effects are similar for drugs that do not have therapeutic equivalence. Comparative cost information is provided but is not taken into account in the formulary recommendations.

Legacy Prescriptions

The implementation of a new drug formulary means that previously covered drugs are subject to new rules, including additional authorization requirements or complete exclusion from the new formulary. Therefore, states implementing a WC formulary have established a transition process for "legacy" claims (claims with dates of injury occurring before the new formulary implementation). The transition process allows the treating physician time to discuss the use of an appropriate alternative drug or complete an authorization request, as needed. Implementation policies are also important for injured workers receiving drugs that are affected by formulary updates.

The states with WC programs have taken different approaches to a transition period:[10]

- Texas created a transition policy by injury date. All injuries occurring before the effective date of the formulary (September 1, 2011) were not subject to the formulary rules and PR until two years later (September 1, 2013). There are no special transition rules for legacy prescriptions affected by a formulary change.
- Tennessee created a transition policy by date of prescription. The effective date for refills and medications that were being used before January 1, 2016 (shortly after the final rule was filed with the Tennessee Department of State) were given an additional six months (or until January 1, 2017) to transition to the new rules. There are no special transition rules for legacy prescriptions affected by a formulary change.
- Ohio created a transition policy by type of drug product. The only significant difference for legacy drugs at the time the formulary was implemented was the removal of carisoprodol products from the list of covered drugs. BWC allowed three months for transition to a different muscle relaxant. When the formulary is revised, affected prescriptions are given two to six months (depending on the drug in question) to move to another formulary drug.

Texas and Tennessee have an ODG-based formulary. Although the states do not have transition policies for legacy prescriptions affected by formulary changes, ODG's policy is to provide advanced notice to the states of additions to its N-list that can then be used to notify system participants. For example, Texas issued a notice on October 21, 2015, that effective February 1, 2016, fentanyl transdermal patches and MS-Contin would change from "Y" to "N" status (Zurek, 2015).

An initial transition may be less important for California's WC program because the MTUS has been in effect since 2004, and UR typically occurs for all prescriptions on a prospective basis. Unlike the other states, implementation of the WC formulary should reduce the number of prescriptions that require PR. Nevertheless, a transition for existing prescriptions could be helpful when there are unintended consequences or when other issues arise during initial implementation. Chapter Six discuses a transition for prescriptions affected by a formulary.

[10] Instead of providing for a transition policy, Oklahoma's formulary is effective only for injuries occurring on or after February 1, 2014. The effect is to provide injured workers with two standards of care, depending on their date of injury, which is contrary to California's objective to provide all injured workers with the same evidence-based medical care.

CHAPTER SIX

Formulary Updating Process and Policies

Chapter Three provided an overview of the updating process for existing drug formularies. In this chapter, we further elaborate on a process for identifying newly approved drugs and other drugs requiring review, a mechanism for incorporating scientific evidence into the review process, issues related to the P&T committee, and how public input might be obtained during the update process.

Labor Code Requirements

Labor Code §5307.29 outlines a process for updating the drug formulary no less than quarterly. To facilitate keeping the drug list current, changes to the drug list may be made through an order posted on the DWC website.

The administrative director is required to establish an independent P&T committee to review and consult with the administrative director on the relative safety, efficacy, and effectiveness of drugs within a drug class during the updating process. In addition to the DWC medical director, the committee is to have six allopathic or osteopathic physicians or pharmacists. Committee members are to have knowledge or expertise in one or more of the following: (1) clinically appropriate prescribing of covered drugs, (2) clinically appropriate dispensing and monitoring of covered drugs, (3) drug use review, and (4) evidence-based medicine.

Labor Code §5307.29 also addresses conflict-of-interest issues. First, a committee member may not have been employed by a pharmaceutical manufacturer, a PBM company, or a company engaged in the development of a pharmaceutical formulary for commercial sale during his or her term and the 12 months prior to appointment. Second, a committee member must not have a substantial financial conflict of interest, according to standards established by the administrative director. The administrative director may disqualify a potential or current member of the committee if a substantial conflict of interest exists. Finally, a committee member must agree to keep all proprietary information confidential to the extent required by existing law.

Guiding Principles

The guiding assumptions that were outlined in Chapter Two pertain to the updating process, as well as to the initial drug formulary: The update process should be transparent and evidence based, and cost considerations should be secondary. The P&T committee's involvement in the

update process should promote these principles and provide a process for considering cost-saving opportunities through therapeutic interchange.

Updating Process

California's process for updating its drug formulary will depend on how the formulary is structured and the reliance that is placed on existing formulary developers. Conceptually, the formulary should be a single integrated drug listing that is consistent with the MTUS guidelines. As discussed in Chapter Seven, two different approaches might be used to accomplish this: (1) DWC could adopt both the formulary and guidelines of either ACOEM or ODG, or (2) DWC could develop an MTUS formulary that is derived from the applicable ACOEM or ODG guidelines for different conditions. In this section, we consider features of the update processes other states use that might be applicable to the California WC updating process. In the next section, we discuss the role of the P&T committee.

The existing drug formularies reviewed in Chapter Three use different processes for updating their formularies. Further details can be found in Chapter Three, but to summarize, Washington State, Ohio BWC, and Medi-Cal use independent committees to review the drug formularies and advise the agencies on changes to the respective drug listings. Washington L&I relies on recommendations from a PBM under contract to the state for updates to its wraparound formulary. WLDI updates the ODG formulary as frequently as monthly based on changes in the treatment guidelines that affect the formulary drug listing. The Reed Group indicates that the ACOEM formulary will be updated quarterly. A PBM will review the formulary quarterly to eliminate drugs that are removed from the market and make other changes needed to keep the formulary current with the FDA-approved drug list. However, changes in drug recommendations, including the addition of new drugs, will be accomplished through ACOEM's process for updating guidelines and will occur less frequently because of the rigor of the process.

The updating rules for the states using the ODG formulary are not codified. The rules for two states—Oklahoma and Tennessee—explicitly adopt the ODG guidelines and any updates, while the Texas rules do not address updates. The rules for the three states do not specify any special treatment for claims that are affected by a deletion of a drug from the "Y" list. In practice, ODG sends each state an updated version of its appendix days in advance of its effective date, and the states post these on their websites so that providers and payers have notice of upcoming changes before they are effective.

Ohio's rules specify that the formulary be reviewed and updated annually, if needed. Ohio's P&T committee makes recommendations to the BWC administrator and chief medical officer on changes to the list. Revisions to the formulary go through Ohio's rulemaking process and include a public hearing on the proposed changes. The final update is posted on BWC's website. Since the formulary was adopted in 2011, it has been updated eight times.

Updates to the Washington State and L&I formularies are handled differently, but neither involves rulemaking. For the Washington State formulary, the P&T committee deliberations complete the first step in the update process. In the second step, Milliman (an actuarial consulting firm) conducts confidential cost analyses that take into account the rebates that the agencies receive from drug manufacturers. Based on the P&T committee's recommendations and the cost analyses, the agency heads make the final decisions on any changes to the

preferred drug list, which are then posted on the Health Care Authority's website. In the past, L&I has made adjustments in the state preferred drug listing to be consistent with the medical treatment guidelines, e.g., PR requirements for long-release opioids. Any updates to the L&I formulary generally occur as part of the annual update in the Fee Schedules and Payment Policies, which are posted on the L&I website. Recommendations are made by ModaHealth, the PBM for Washington State's Rx Services, which in turn relies on input from MediImpact Health Care Systems, Inc. MedImpact provides pharmacy network management and prescription drugs processing for the state.

Pharmacy and Therapeutics Committee

In this section, we discuss the P&T committee rules applicable to the committees involved in the Washington State, Ohio, and Medi-Cal formularies. The states that have adopted ODG guidelines and formulary do not have P&T committees.

Operating Policies

Ohio

The Ohio P&T committee consists of BWC's pharmacy program director and five to 13 voting members who are physicians and pharmacists. Terms of appointment are for one year but may be renewed. The P&T committee is required to meet at least three times a year and to respond to requests for action on issues submitted by the BWC administrator, chief of medical services, chief medical director, or pharmacy director. The responsibilities of the P&T committee include annual review of the formulary, development and approval of PR criteria and proposed medication treatment guidelines, review and approval of BWC's UR policies, and procedures for specific medication issues. BWC's policies and procedures are related to the bureau's authority to act on certain requests for temporary changes in the formulary pending the P&T committee's review. The rules specify that the P&T committee is to make decisions based on "current medical literature and generally accepted best clinical practices." The P&T committee develops its own policies and procedures, which the BWC administrator approves. In addition to the timely submission of its recommendations, the P&T committee is required to submit an annual report to BWC that is incorporated into the annual report of BWC's pharmacy program director. The rules also charge the P&T committee with reviewing the professional performance of pharmacies and BWC's PBM. BWC is proposing to add review of provider prescribing patterns and practices to the P&T committee's responsibilities.[1]

Washington

The P&T committee for the Washington State formulary has a minimum of ten members who are appointed to staggered three-year terms. Members must be actively practicing in their clinical areas of expertise throughout their terms of appointment. The P&T committee meets at least quarterly. The meetings are open to the public. Meeting transcripts and a summary of the committee's votes are posted on the website (Washington State Health Care Authority, 2016).

[1] BWC enrolls pharmacies and providers in the WC program. Its P&T committee performs peer review according to generally accepted standards of pharmacy practice and may recommend sanctions and termination of a pharmacy provider determined to have consistently failed the standards of care.

The P&T committee is charged with evaluating available evidence on the relative safety, efficacy, and effectiveness of prescription drugs in a therapeutic class and to make recommendations to the participating agencies regarding the development of a preferred drug list. Two features of the process distinguish the Washington State P&T committee process. First, the P&T committee reviews evidence-based research generated by an organization that is independent of conflict-of-interest issues. Second, the P&T committee focuses solely on the medical evidence issues; cost considerations are incorporated in a separate process.

Washington is part of a consortium of states with a broad portfolio of programs, including Medicaid and state employee health programs in addition to WC, that sponsor reviews by Oregon Health and Science University's DERP.[2] The P&T committee's reviews are based solely on the DERP reports or on other evidence from contractors. For existing classes, three basic types of reviews are completed: a full update to an existing class review; literature scans for new drugs, indications, or safety warnings; and expanded scan reports for old classes that do not require a full update but that do need a new-product review. The DERP reviews include the identification of the most clinically effective drug or drugs from among the class of drugs reviewed. This evidence allows the P&T committee to determine whether there is sufficient evidence of similar safety, efficacy, and effectiveness for the drugs in a class to allow therapeutic interchange.

Medi-Cal

The MCDAC consists of at least one representative from each of the following groups: physicians, pharmacists, schools of pharmacy or pharmacologists, and Medi-Cal beneficiaries. While technically not a P&T committee, the MCDAC is charged with providing scientific and medical analysis and recommendations to the Department of Health Care Services regarding the addition or deletion of any drug from the contract drug list (list of drugs not requiring PR), including the comparative therapeutic effects of drugs. The MCDAC does not typically review the addition of new drug strengths, dosage forms, or product formulations of drugs that are already listed. As noted in Chapter Three, the five review criteria are safety, efficacy, essential need, misuse potential, and cost. The cost evaluation is done without access to the confidential manufacturer rebate information. Each MCDAC member makes a separate advisory recommendation. The process does not involve public input.

Conflict-of-Interest Issues

Conflict-of-interest rules are needed to ensure that a committee member does not have financial interests that could influence his or her drug recommendations. Each of the formularies that we reviewed has conflict-of-interest policies regarding current or past employment by pharmaceutical manufacturing firms, PBMs, or entities with a direct interest administering the health care program. As discussed above, AB 1124 contains similar provisions. The Washington State formulary has additional rules pertaining to conflict of interest:

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[2] Because DERP's agenda is set by the consortium, the reviews are likely to be less focused on drugs used for worker's injuries than another evidence-based research center that is more open to individually sponsored research might be. Washington L&I has addressed this problem through its wraparound formulary, but the wraparound process is less transparent and does not separate evidence-based independent research and cost considerations. DERP is part of the Pacific Northwest Evidence-Based Practice Center, which is one of 13 independent evidence-based practice centers sponsored by the Agency for Healthcare Research and Quality (2015).

- disclosure of any potential conflict of interest, including any remuneration, grants, or other compensation from a pharmaceutical manufacturer or PBM
- no substantial financial conflict of interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant monies
- self-recusal from discussion and decision on an entire drug class if there is a material conflict with any drug in that class; failure to previously disclose the material conflict is grounds for dismissal.

Completion of a conflict-of-interest disclosure form is part of the application process; the form must be kept current, with new forms required annually.

Medicaid

P&T committee conflict-of-interest policies have received some scrutiny in recent years. Nguyen and Bero (2013) examined the strength of the publicly available written conflict-of-interest policies for state Medicaid programs, based on four high-level criteria: (1) whether the policy was available to the public, (2) the requirements for disclosure, (3) the policies associated with recusal associated with conflict of interest, and (4) the process for reviewing conflict-of-interest disclosures. The specific characteristics associated with each of these criteria were based on a model policy issued by the Public Health Service. Nguyen and Bero were able to obtain written conflict-of-interest policies for only 27 of the 48 state Medicaid programs that serve fee-for-service patients. California Medi-Cal responded to the authors' request for information, but did not provide an official written document and was therefore not included in the final analysis.

Of the 27 Medicaid policies, 67 percent required P&T committee participants to provide a written disclosure, and 52 percent incorporated a requirement that the participant must self-recuse when a conflict is present. Forty-one percent incorporated specified monetary limits for defining a conflict of interest, and 30 percent assigned reviewers to examine the conflict-of-interest disclosures. Only 15 percent specified banned relationships, in which certain ties to pharmaceutical manufacturers would be considered conflicts of interest. The authors concluded that a model conflict-of-interest policy could help strengthen the ability of P&T committees to ensure there are no conflicts of interest in committee decisions.

Medicare Part D

Federal law and regulations require Medicare Part D P&T committees to "prevent conflicts of interest from influencing members to give preference to certain drugs" (Department of Health and Human Services, Office of the Inspector General [OIG], 2013). In addition, Medicare Part D specifically requires at least one physician and at least one pharmacist on the P&T committee be free from conflict of interest relative specifically to the Part D plan sponsor and pharmaceutical manufacturers. The OIG conducted an evaluation of the conflict-of-interest policies for the Medicare Part D P&T committees in 2010 (OIG, 2013), and concluded that the conflict-of-interest policies should be strengthened to further guard against conflicts of interest.

More specifically, OIG found that P&T committees generally had "limited definitions of conflicts of interest" and that many of the committees left the conflict-of-interest determination and management tasks up to the members of the committee, rather than using a review approach to evaluate the likelihood of a conflict of interest. OIG also found that CMS did not

adequately oversee the requirement that each P&T committee have at least one physician and pharmacist who were free of conflicts of interest with the sponsor and manufacturers. OIG issued five recommendations encouraging CMS to strengthen oversight of the P&T committees.[3] In February 2015, CMS issued a final rule incorporating some of OIG's recommendations into regulation. CMS now requires P&T committees to have clear policies for how they meet the conflict-of-interest requirements, requires these policies to incorporate objective third-party reviews of reported conflicts of interest, and requires a procedure for managing the recusal process in the event a conflict of interest is identified (42 Code of Federal Regulations 423.120(b)(1)).

[3] CMS rejected two recommendations as unnecessary, given the centers' oversight and review of plan formularies for discriminatory practices; agreed in part with two recommendations; and agreed with the final recommendation that CMS strengthen its oversight of the specific requirement for committee membership.

CHAPTER SEVEN

Preliminary Implementation Plan

This chapter synthesizes our findings and recommendations for the drug formulary into a preliminary implementation plan. The plan is preliminary because aspects of the drug formulary still require further analysis and rulemaking before a final implementation plan can be developed. The plan first addresses the structure of the drug formulary and what would be needed to implement a formulary that is based on the MTUS. It then discusses the ancillary policies that affect how pharmacy prescriptions would flow through the bill-processing and medical necessity determination processes.

Formulary Structure

Alternatives for the Formulary Structure

As noted in Chapter Two, California's WC formulary should adhere to three main criteria: (1) The formulary drug list should be evidence-based and consistent with the MTUS; (2) cost considerations are important but secondary; and (3) the process and policies for determining the drug list and recommendations should be transparent. California has limited time to develop its own formulary before having to implement it, so we initially assumed that the DWC would prefer to adopt an existing formulary, then modify it to better fit the California context over time. However, as discussed below in greater detail, this may not be feasible because no existing formulary is fully consistent with the current MTUS.

While each criterion poses challenges in structuring and maintaining the formulary, the first is potentially the most problematic. The MTUS already incorporates ACOEM treatment guidelines for most conditions and, to a limited extent, ODG for chronic pain and postoperative surgical physical medicine. Both sets of guidelines have drug recommendations associated with the treatment guidelines for common WC medical conditions. One difference is that the ODG guidelines cover mental health and stress-related conditions, while ACOEM does not currently address this topic. [1]

Establishing a single, integrated formulary that is consistent with the MTUS requires one of two approaches: (1) Adopt both the formulary and guidelines of either ACOEM or ODG, or (2) develop a California-specific WC formulary (which we call the MTUS formulary) that

[1] DWC posted a proposal to adopt the ODG Mental Illness and Stress guidelines on the DWC Forum on February 5, 2016. The closing date for comments was February 16, 2016. As of July 15, 2016, formal rulemaking had not taken place. The MTUS contains 2004 ACOEM guidelines on stress-related conditions that were dropped from the third edition of ACOEM in 2011. The Reed Group advises that work is under way on a new behavioral health chapter that will be completed in 2018.

is derived from the applicable MTUS guidelines (e.g., the ACOEM guidelines for body parts, the ODG guidelines for chronic pain, and DWC's opioid guidelines). The rationale behind the MTUS formulary is that the MTUS guidelines should drive the formulary decisions, rather than the formulary decisions driving the MTUS guidelines. The MTUS formulary could be comprehensive and could integrate all the drug therapy guidelines in the MTUS or could initially focus on the highest expenditure and/or highest volume drugs that are currently covered for the WC population. Adopting one of the other formularies that we examined (Washington State L&I, Ohio, or Medi-Cal) would raise major issues of making the adopted formulary consistent with the MTUS.

Through the rulemaking process, California has already adopted guidelines that it believes incorporate the best available evidence base for the medical care provided to injured workers. However, these guidelines are outdated and need to be updated for most clinical topics. Therefore, the implementation of the formulary offers an opportunity to review the sources for the treatment guidelines, ensure that they continue to be the most appropriate source for standards of care that meet the needs of California's injured workers, and determine whether additional clinical topics should be added.[2] Ideally, DWC would implement updated guidelines before or coincident with the formulary so that the updated guideline recommendations would be reflected in the formulary drug listing. However, developing a MTUS formulary involves significant trade-offs between ease of implementation and adherence to the MTUS. Table 7.1 summarizes the considerations that might affect the choice of formulary structure. For each option, some or all MTUS guidelines would need revisions to reflect more-recent standards of care. Arguably, implementing a new guideline is likely to be more burdensome on providers and payers than revising an existing guideline. For example, if an existing guideline is revised, providers and claims adjustors could concentrate on the portions that have been updated, but if a new guideline is implemented, they would need to become familiar with an entirely new guideline. An updated guideline is also likely to require less-extensive changes in bill-processing screens and UR protocols than a new guideline. On the other hand, the ongoing administrative burden is likely to be less if all guidelines draw from the same developer. The guidelines would already be internally consistent, so there would be no need to reconcile any differences in treatment recommendations and providers, and payers would only need to reference one guideline set. A hybrid approach would be to incorporate treatment guidelines from a single developer into the MTUS but to develop a MTUS formulary drug listing. The PR requirements would be derived from the MTUS guideline drug recommendations, but the drug listing would be tailored to the California WC context and maintained with the input of the P&T committee. This would also allow DWC to incorporate other features into the drug listing, such as a first-fill policy and whether generic and OTC versions of the drug are available, that would enhance the accessibility and usability of the drug listing for patients, prescribers, pharmacists and payers.

[2] ACOEM-based clinical topics that have not been incorporated into the MTUS include interstitial lung disease (2015), occupational asthma (2014), and hip and groin (2011). ODG has chapters on pulmonary, hip and pelvis, and hernia conditions. ODG also has chapters on mental health and stress-related conditions and head conditions. ACOEM does not currently have condition lines on these topics, but guidelines for traumatic brain injury and behavioral health are under development.

Table 7.1
Implementation Considerations in Determining Formulary Structure

	Adopt		
Considerations	**ODG Guidelines and Formulary**	**ACOEM Guidelines and Formulary**	**Updated MTUS Guidelines and Formulary**
Consistency with current MTUS	ODG-based MTUS guidelines cover chronic pain and postsurgical physical medicine.	ACOEM-based MTUS guidelines cover most clinical topics, but the MTUS uses the 2004 version of the guidelines, rather than the most recent guidelines.	Depends on updating decisions. Revised ACOEM-based guidelines and 2016 versions of ODG guidelines for chronic pain and DWC opioid guidelines would be the most consistent with current structure.
Adherence to evidence-based information in determining which drugs require PR	Yes-or-no rules on PR ignore condition-specific variation in some treatment guidelines.	Formulary rules do not include PR requirements; presumably, DWC would develop PR rules based on condition-specific drug therapy recommendations.	Assumes that PR rules would be based on specified criteria and that condition-specific PR rules would be established when needed.
Ease of implementation	Could be implemented off the shelf.	Requires developing PR rules based on specific criteria and clinical review.	Requires developing PR requirements based on specific criteria and clinical review and integrating the different guidelines into a single formulary.
Scope and currency of guidelines	Most comprehensive option for WC-related conditions with ongoing updating process.	Does not have mental health guidelines; guidelines for head disorders and behavioral health under development. Some clinical topics have not been updated since 2011, but revisions are in progress.	Does not have guidelines for pulmonary diseases or head disorders; ACOEM-based guidelines (including for stress-related conditions) have not been updated since implemented in 2004 and would need to be updated.

Adopt an Existing Formulary and Guidelines

For several reasons, the ODG formulary would be easier to implement. It is already in use by several WC programs and has been operationalized through NDC codes. The "Y/N" structure of the formulary PR rules makes it easier to operationalize because it does not require diagnostic information when processing most pharmacy bills. (Some drugs used for both pain and mental health conditions require a diagnosis.) However, it also means that important nuances of condition-specific treatment guideline recommendations are not reflected in the PR recommendations and that the onus is on the prescriber to be familiar with the actual treatment guideline recommendations The treatment recommendations from which the drug listings are derived are evidence-based and are updated regularly to incorporate new evidence. The ODG guidelines are more comprehensive than the ACOEM guidelines, but the methods used to develop them have been less rigorous (Nuckols et al., 2014) and the methodology used to derive the PR requirements when there are condition-specific variations in the guideline recommendations is not transparent. Because only the MTUS chronic pain guidelines and postsurgical physical medicine guidelines are ODG-based, adoption of the ODG guidelines would represent a major departure from the current MTUS guidelines.

The MTUS consists predominately of ACOEM-based guidelines, so implementing both ACOEM treatment guidelines and formulary is likely to represent less change than implementing the ODG guidelines and formulary. A more rigorous and transparent process has

been used to develop the current ACOEM guidelines, but fewer clinical topics are addressed (although several new topics are under development). Implementing a formulary based on the ACOEM guidelines would require more initial investment than adopting ODG. Adopting an ACOEM-based formulary would require steps that adopting the ODG formulary would not: (1) identifying the drug ingredients that are addressed in the treatment guidelines, (2) establishing PR requirements for formulary drugs based on the relevant MTUS treatment guidelines, (3) organizing a formulary drug listing by active ingredient, and (4) operationalizing the formulary through an NDC drug listing.

Establish an MTUS Formulary Based on MTUS Guidelines

If the current MTUS structure is retained, updating the MTUS would involve adopting more-recent versions of the ACOEM-based MTUS guidelines and integrating them with the new DWC opioid treatment guidelines and the ODG-based chronic pain guidelines. Because the MTUS consists predominately of ACOEM guidelines, the administrative burden of developing a California-specific MTUS formulary should not be significantly more administratively burdensome than adopting an ACOEM formulary (assuming that the MTUS ACOEM-based guidelines are first updated to the most recent available ACOEM guidelines). The steps outlined in the previous subsection for an ACOEM formulary would also be required for an MTUS formulary based on the current MTUS structure. In addition to the investment needed to operationalize the ACOEM drug recommendations into a formulary drug listing with PR recommendations, any conflicts between the ODG and ACOEM recommendations for individual drugs would need to be resolved by adopting clear rules on precedence. As discussed in Chapter Four, some ODG chronic pain recommendations for a particular drug do not align with the ACOEM condition-specific recommendation for using the drug for chronic pain. We assume that the priority that DWC specifies for the different treatment guidelines would also apply to the formulary drug recommendations. This additional step could be eliminated if DWC decided to take the hybrid approach of incorporating treatment guidelines from a single developer into the MTUS but developing its own MTUS formulary drug listing.

The initial MTUS formulary could be a comprehensive integration of all drug therapies addressed in the updated MTUS guidelines or could initially focus on the high-volume drug ingredients or therapeutic classes and expand over time (the approach Washington L&I and Ohio BWC have used). The drugs that are not addressed in the formulary drug listing would require PR. A comprehensive formulary is feasible only if DWC has the resources to undertake these developmental activities or makes arrangements with a qualified entity to perform this task. The arrangements have import for the administrative burden of both implementing the formulary and updating it in the future.

It would be less resource intensive to implement an initial MTUS formulary that addressed only the high-expenditure drug ingredients (and potentially other drug ingredients assigned to the same therapeutic class). For example, just 45 drug ingredients account for 0.5 percent or more of total drug expenditures (exclusive of bulk ingredients used in compounding). Taken together, they account for 83 percent of total drug expenditures.

Operationalize Steps for Three Formulary Alternatives

In this section, we discuss major activities that would be needed to structure each formulary option and operationalize the formulary for pharmacy bill processing. Ancillary formulary policies and other activities are discussed in the next section. Table 7.2 summarizes the steps

Table 7.2
Summary of Steps Required to Develop a Formulary

Developmental Step	ODG Formulary	ACOEM Formulary	MTUS Formulary
Identify the drug ingredients that would be included in the formulary	Completed	Required	Required
Establish PR recommendations for each drug ingredient, based on the relevant MTUS guideline(s)	Completed	Required	Required
Establish formulary ground rules	Required	Required	Required
Create formulary listing by drug ingredient	Completed	Required	Required
Link online formulary listing to treatment guidelines	Completed	Completed by condition only	Optional
Operationalize formulary using NDC codes	Completed	Required	Required

and their applicability to the three options. We assume that the responsibility for carrying out each step would be determined through negotiation and agreements reached between DWC and the formulary developer.

Determine the Drug Therapies That Would Be Included in the ACOEM or MTUS Formulary

The first developmental step would apply to both the ACOEM and the MTUS formularies. The ACOEM formulary is organized by condition and does not have a listing by drug ingredients. If an ACOEM formulary were adopted, the drug therapies that would be included need to be identified. We assume that these would be all the drug therapies that are addressed in the ACOEM clinical topics.

Developing an MTUS formulary would also begin with this step but could either (1) be based on the high-volume or high-cost drug ingredients or (2) include all drug therapies addressed in the updated MTUS guidelines. If the formulary were to include all the drug therapies with recommendations in the MTUS, the drug therapies addressed in each of the relevant MTUS sections would be identified. Only the drug therapies in the ACOEM body part chapters included in the MTUS would need to be compiled (which include recommendations on drug therapies for chronic pain in the relevant body part chapter). To this listing, the drug therapies addressed by the other portions of the treatment guidelines (DWC for opioids and ODG for chronic pain) but not in the ACOEM body part chapters would be added.

Establish PR Recommendations for Each Drug Ingredient

The second developmental step of assigning PR criteria to drugs is also needed for both the ACOEM-only and MTUS formulary options. AB 1124 anticipates that the P&T committee will be established coincident with the formulary's implementation so that the P&T committee will not be in place to consider the initial drug recommendations. Our analyses in Chapter Four suggest that the initial criteria could be relatively straightforward to apply, i.e., drug therapies that are recommended for first-line therapy do not require PR when they are prescribed consistent with the treatment guidelines.

As discussed in Chapter Four, there is duplication in the drugs addressed in the body part chapters for chronic pain and the ODG chronic pain guidelines. The recommendations regarding whether a drug therapy is a first-line therapy are often but not always the same. Where they differ, DWC would need to establish rules describing which guidelines have pre-

cedence over others and implement these rules in the formulary drug listing. The modified-ODG chronic pain guidelines adopted for the MTUS in July 2016 exclude ODG guidelines pertaining to opioids (which gives precedence to the DWC opioid guidelines also adopted in July 2016) and stipulate that, when a patient has chronic pain and both the ODG-based chronic pain guidelines and the ACOEM-based body part guidelines address the treatment, the chronic pain guideline applies. Because the ACOEM-based guidelines are outdated, this order of precedence is appropriate. However, as the ACOEM-based clinical topics are updated, the order of precedence merits reconsideration. We also assume that DWC's final guideline for opioid usage will have precedence over treatment guidelines for opioids in either the ACOEM- or ODG-based sections of the MTUS.

As noted in Chapter Four, the ACOEM recommendations for a given therapy may vary depending on the injured worker's condition. These are not PR recommendations but rather state whether a drug is recommended; is not recommended; or, for some drugs with insufficient information or for which the clinical panel was not able to come to consensus, has no recommendation. As our working assumption for the formulary, we developed a general PR rule that assumed that a drug ingredient would not require PR if it is generally identified as a first-line therapy. It would require PR if it is generally not recommended as a first-line therapy or if the recommendation is unclear and requires clinical review. In formulating the actual PR recommendations, clinical review should be used to determine whether different condition-specific recommendations for some drug ingredients are significant enough to establish condition-specific PR requirements. The types of issues that could be addressed through clinical review include the following:

1. *Reducing the condition-specific variation in PR requirements for an active drug ingredient.* We found that there were condition-specific differences in treatment recommendations that may not merit different PR requirements. Some differences seem minor and could probably be eliminated (e.g., drug has no recommendation for a condition or the recommendation does not specify first-line therapy when the drug is recommended as a first-line therapy for other conditions). Other differences might be handled by highlighting exceptions in the treatment recommendation in the formulary listing but not adopting a condition-specific PR requirement for the drug. For example, one way of treating naproxen used in iontophoresis would be to waive PR for naproxen but indicate on the drug listing that it is not recommended for iontophoresis. Other differences might require a different PR requirement for certain conditions or drug formulations. An alternative approach for naproxen would be to explicitly require PR only when used with iontophoresis or for the gel form of the drug.
2. *For the MTUS-based formulary only, reviewing any differences in the drug ingredient PR requirements based on the applicable ACOEM and ODG treatment guidelines that have been incorporated into the MTUS.* In Table 4.2, a number of these differences were for opioids, which we assume would have PR recommendations based on the DWC opioid guidelines. Others stem from ODG's across-the-board PR rules, which do not reflect the condition-specific nature of some recommendations in its treatment guidelines. A comparison of the relevant ODG-based chronic pain treatment guidelines with the ACOEM clinical topic guidelines for disorders involving chronic pain will help inform whether different PR rules are medically appropriate and should be retained or eliminated.

3. *Determining whether treatment guidelines addressing drug formulations, strengths, or treatment duration should be built into the PR requirements.* Some drugs in ACOEM are specifically listed by form (e.g., lidocaine injection), but most are solely at the active ingredient level.
4. *Determining whether any low-risk, low-cost drug therapies that are not on the initial drug listing (because they are not addressed in the treatment guidelines or are not high volume or high cost) should be added to the list as not requiring PR.* By default, a drug that is not listed would require PR, so this step would eliminate an unnecessary administrative burden.
5. *Identifying whether any high-risk or high-cost first-line therapies might warrant PR for the initial prescription and/or for refills.*

The objective of this step is to establish PR recommendations for each drug ingredient that provide a clear rule for when PR is required to ensure that the proposed treatment is consistent with the MTUS. If DWC undertakes this activity, the criteria and rationale for any modifications to the initial results should be discussed as part of the rulemaking process. This would make the process for determining the PR requirements transparent and provide an opportunity for public comment on the process and results. After the formulary is implemented, the P&T committee could review and recommend any changes in the PR requirements as part of its update process.

Appendix B compares ODG and RAND-derived ACOEM PR requirements for active ingredients accounting for more than 1 percent of paid bills in WCIS. It also illustrates possible PR requirements for an MTUS drug listing, assuming the current structure but updated ACOEM-based guidelines. As discussed above, deriving PR requirements from the drug recommendations in the ACOEM guidelines and formulary requires clinical review. An MTUS formulary derived from the current multisource guideline structure would also require establishing an order of precedence for the different guidelines. We derived the PR requirements for the MTUS formulary in the following order of precedence: DWC opioid guidelines, updated ACOEM-based guidelines, and ODG-based chronic pain guidelines for treatments that are not addressed in the ACOEM-based body part chapters for workers with chronic pain. If DWC decides to retain the current guideline structure, the actual PR requirements would depend on how the ACOEM-based drug recommendations are operationalized into PR requirements using clinical review and the order of precedence set for the guidelines.

Establish Formulary Ground Rules

The third step is to establish additional ground rules related to the PR requirements that we discussed in Chapter Four. All three options will require this step. Key ground rules to consider are (1) the PR rule for active ingredients that are not listed in the drug formulary (including compounded drugs) and (2) the forms or routes of administration, dosage strengths, and brand-name versions that are addressed by the listing for active ingredients listed in the formulary. Unless the ground rules address these topics, prescribers and payers are likely to be confused about how to handle different drugs. As discussed in Chapter Four, existing WC formularies differ in both their ground rules and whether they are readily available to the public. The formulary ground rules should be posted together with the drug listing and should be subject to the same updating rules as the drug listing. For simplicity, the "default" answer should apply across the board but drug-specific exceptions when warranted could be noted on

the drug listing. For example, this might include PR requirements for a drug ingredient that does not otherwise require PR if the dosage strength or duration exceeds a specified limitation or an unusual formulation is prescribed.

There should also be clarity about the drug therapeutic classification scheme. The therapeutic classes allow a prescriber or pharmacist to easily determine what drug alternatives might be available under the MTUS for drug ingredients with similar therapeutic purposes. They are also needed if any PR requirements are listed at the therapeutic class level rather than at the drug ingredient level. Washington L&I takes this approach for drug classes that are not commonly used for WC conditions. If the ground rules provide that any drug that is not listed in the formulary requires PR, it is less important to know what drugs fall into a given therapeutic class.

The formularies we evaluated in Chapter Four use different therapeutic classification schemes. ODG has developed its own system to classify the drugs in its appendix listing. The proprietary systems for therapeutic classifications, such as First Databank (used by Washington L&I and Medi-Cal), Medispan (used by ACOEM and Ohio) or RED BOOK (used by RAND) have the advantage of being known to pharmacists and providing analytic tools that facilitate classifying drugs into different categories (e.g., therapeutic class, dosage forms), identifying whether there are generic equivalents of the drug, and determining whether a specific NDC is for bulk or repackaged drugs, etc. The proprietary systems typically involve licensing fees and limit what data elements can be made publicly available. If using a proprietary system becomes problematic, another alternative is the Medicare Model Guidelines developed by the U.S. Pharmacopeial Convention for use by Medicare Part D Prescription Drug Plans (U.S. Pharmacopeial Convention, undated). This listing of therapeutic classes is in the public domain.

Create Formulary Listing by Drug Ingredient

The fourth step applies to the ACOEM or MTUS formulary options. It is unnecessary for an ODG formulary because ODG's appendix is a formulary listing by ingredient. As discussed earlier in this chapter, ACOEM's formulary drug listing is by condition and not by ingredient. After the drug ingredients to be included in the formulary are identified and after PR and ground rules have been developed for either an ACOEM or MTUS formulary, a listing by drug ingredient should be developed consistent with the other decisions. One approach would be to limit the listing to preferred drugs that do not require PR; alternatively, the listing could include both drugs that require PR and those that do not. If a prescriber is contemplating a drug that requires PR, the second approach has the advantage of identifying alternatives in the same therapeutic class that do not require PR. The listing should be organized by therapeutic class and should provide the following information for each drug ingredient: name; PR rule, if both preferred and nonpreferred drugs are listed; any condition-specific qualifications to the rule or limitations on duration or dosage; whether a generic equivalent and/or OTC drugs are available; and whether PR is waived under a first-fill policy.

Link Online Formulary Listing to Treatment Guidelines

Linking the formulary back to treatment guidelines in an easy way to facilitate the use of the guidelines among prescribers. ODG has an online drug formulary listing that links to the respective treatment guideline. ACOEM's formulary tool links by condition to the treatment guidelines and drug recommendations. An optional enhancement would be to link the ACOEM drug listing (which would need to be developed) to the treatment guidelines. Ideally,

a MTUS formulary would have similar links to encourage prescribers to consult the treatment guidelines before choosing a medication. However, this may not be feasible if the multisource structure for the MTUS guidelines is retained. If electronic links are not feasible, the prescriber could still be referred to the applicable treatment guidelines posted on the DWC website.

Operationalize the Formulary Using NDC Codes

The ground rules and PR requirements for the formulary should be operationalized through an electronic listing of the NDCs that the formulary addresses. This listing would need to be created for either the ACOEM or MTUS formulary and would need to be updated at least quarterly to reflect changes in how drugs are being marketed. ODG already has an NDC listing for the drugs addressed by its formulary.

An NDC listing, which is typically developed by a PBM, serves two purposes. First, it can be incorporated into the online look-up function for prescribers and pharmacists. Second, and most important, it standardizes the formulary structure across payers and bill-processing systems. It will be important to consult with PBMs and pharmacy bill processors on the structure of the listing, particularly with regard to how to any condition-specific exceptions to the PR rule or limitations on dosage strength or duration should be incorporated into the electronic file.

Recommendations

The MTUS should drive the decisions on the formulary structure so that both treatment guidelines and formulary incorporate evidence-based standards of care that best meet the needs of California's injured workers. Priority should be given to updating the MTUS guidelines. In doing so, the advantages and disadvantages of retaining the current multisource structure should be weighed.

The formulary drug listing and PR requirements should be derived from the MTUS guidelines in effect as of the implementation date. Generally, PR should be waived for drugs that are first-line therapies or are otherwise low-cost, low-risk recommended drugs that are prescribed consistent with the MTUS guidelines. Condition-specific PR requirements should be imposed sparingly when there are significant differences in the drug recommendations.

Ancillary Implementation Policies

In addition to determining the formulary structure and ground rules, it will be important to establish, through rulemaking, policies governing how the formulary will be implemented and integrated with the medical necessity dispute-resolution process and the OMFS. Table 7.3 summarizes the implementation policies that will need to be addressed in the formulary rules or through modifications to existing regulations.

Establish Ancillary Formulary Policies

Chapters Five and Six described the policies that other states have adopted in implementing their WC formularies. In this section, we summarize the policies that the formulary rules will need to consider and identify the options that appear to be most closely aligned with California's WC context. Except with respect to the updating process, these rules are unlikely to vary based on the decisions made on formulary structure.

Table 7.3
Summary of Major Policy Development Steps

Step	Description
Establish ancillary formulary policies	Define how the formulary applies by setting and drug type; describe PR policies; address policies for special types of drugs (OTC, brand-name versus generic, etc.); and describe the update process and P&T committee rules
Make conforming changes to UR/IMR rules	Clarify how the formulary integrates with UR/IMR rules and the RFA process, and consider policies that would accelerate the PR time line for pharmaceuticals
Make conforming changes to OMFS	Review policies for formulary drugs that do not have OMFS prices

Applicability of the Formulary

The rule should define the term *outpatient drug* by addressing type of setting and types of drugs that are subject to the formulary rules.

Type of Setting

The most straightforward approach to defining outpatient use would be to define the term to mean drugs dispensed to be taken or administered to a patient at home. *Home* should be defined to include institutional settings in which the patient resides and receives prescription drugs that are separately payable under the OMFS, such as a nursing home or assisted living facility. Drugs that are administered in a clinical setting, including physician-administered drugs furnished during an outpatient encounter, would be excluded from the definition (but would be subject to UR rules for nonformulary therapies).

Types of Drugs

Because the formulary is derived from the treatment guidelines, the drug listing will be limited to drug ingredients that the guidelines address. Because the formulary will not include therapeutic classes that are uncommonly associated with a WC condition, the rule should specify how these drugs should be addressed. Texas's broad definition, encompassing all FDA-approved prescription and nonprescription drugs, signals that injured workers will have access to all medically appropriate drugs when the formulary is implemented. However, this definition works *only* if the rules specify that PR is required for any drug not included in the formulary drug listing or not addressed by the MTUS. For the latter, the rule should emphasize that the prescriber should describe why the drug is medically necessary and indicated for the worker's compensable condition. Washington and Ohio establish a stronger "signal" by distinguishing drugs that are uncommonly used for WC conditions from other drugs that require PR. However, as a practical matter, the policy is no more restrictive than a broader definition coupled with PR for any drugs that are not in the formulary listing.

PR Requirements

The section of the rule laying out the PR requirements is key if the formulary is to achieve AB 1124's objective of "providing appropriate medications expeditiously while minimizing administrative burden and associated costs." The PR requirements discussed in conjunction with the formulary structure pertain to identifying first-line medically appropriate drugs for WC conditions. However, additional PR requirements should be considered to provide further assurance that the proposed therapies are consistent with the MTUS and are cost-effective. In

Table 7.4, we suggest PR policies for three types of drugs: preferred drugs (drugs that do not require PR on formulary), nonpreferred drugs (drugs listed on formulary as requiring PR), and drugs that are not on the formulary drug listing. These labels are for discussion purposes only.

A drug is preferred only when it is prescribed and dispensed in accordance with the MTUS. PR should be required if the drug therapy is not indicated for the worker's condition in the MTUS or the proposed treatment regimen exceeds the dosage or duration recommended in the treatment guidelines. We discuss PR for brand-name drugs below under the section on cost-saving provisions.

Generally, nonpreferred drugs require PR. Two situations that we can envision in which PR might not be required are when (1) a drug meets the first-fill criteria and (2) a payer waives PR (using its prior authorization authority). Both situations are discussed below in separate subsections. Nonlisted drugs should always require PR unless the prescription is affected by a payer's prior authorization policy that waives PR. As discussed later, there is no strong policy rationale for including nonlisted drugs, which are typically not used to treat a WC condition, in a first-fill policy.

The above drug categories apply to FDA-approved drugs. The rule should also require PR for non–FDA approved drugs. In addition to compounded drugs and investigational or experimental drugs, the rule should explicitly include topical ointments containing a combination of OTC ingredients, such as methyl salicylate or menthol. These high-volume WC "private label" products are not FDA-approved but have an assigned NDC and are marketed at substantially higher prices than their OTC counterparts with similar drug ingredients (Healthesystems, 2013). Intrathecal drugs are usually compounded sterile solutions but should be mentioned separately because there may be occasions when a single drug ingredient is prescribed and dispensed. However, there is no need to specifically identify intrathecal drugs unless specific PR requirements for IDDS are appropriate. Last, consideration should be given to developing PR rules for physician dispensing or curtailing the practice altogether (as discussed in a separate subsection below).

Under Labor Code §4600.2, contracts with pharmacy benefit networks cannot limit the availability of formulary drugs. While PBMs may not establish more-restrictive policies, con-

Table 7.4
Summary of Suggested PR Requirements

Drug Classification	When Is PR Required?
Preferred drug	Only when • The drug is prescribed in a dosage or duration that exceeds MTUS guidelines. • The drug is not indicated in the MTUS guideline for the injured worker's compensable condition. • The drug is for a brand name affected by the generic drug policy.
Nonpreferred drug	Always unless • A first-fill policy is applicable. • Payer grants a waiver.
Nonlisted drug	Always unless waived by payer.
Other potential policies	• Non–FDA approved drugs – Compounded drugs – Investigational or experimental drugs – OTC combination drugs • Non–FDA approved intrathecal drugs • Certain physician-dispensed drugs

sideration should be given to allowing payers to liberalize the formulary listing, e.g., remove PR requirements for an NDC. If the formulary does not incorporate duration into the PR rules, another issue will be whether payers could be allowed to require PR after the duration recommended in the treatment guidelines is met.

First-Fill Policy

As discussed in Chapter Five, most states provide a first-fill policy that allows the pharmacy or physician to dispense drugs in the period immediately following the date of injury and before the compensability determination is made. The primary objective is to avoid delays in starting medically appropriate drug therapies. In the other states, the lack of a compensability determination is one source of delay. However, California has a provision allowing up to $10,000 in medical payments before the compensability determination is made, so initial drug dispensing should be timely regardless of whether a compensability determination has been made. PR is the other source of delay in dispensing first fills that is relevant in the California context. A drug that does not require PR should not be affected by the first-fill policy. Crafting a first-fill policy for drugs that require PR involves several policy choices: the time frame following date of injury to which the policy applies, the drugs that may be prescribed and dispensed under the policy, any limits on the duration of the initial prescription, and any other conditions on coverage under a first-fill policy. The policies that other states with WC formularies have adopted show a range of options for each policy (see Chapter Five). Most PBMs guarantee a network pharmacy's payment for the first fill. So, in addition to injured workers and prescribers, the other beneficiaries of the policy would be PBMs in the case of network pharmacies, nonnetwork pharmacies, and physicians who practice in-office dispensing.

A first-fill policy for opioid treatment merits close attention. DWC's new opioid treatment guidelines do not address specific drug ingredients that could be incorporated into a formulary but rather discuss best practices for safe and effective prescribing of opioids for acute (up to four weeks), subacute (four to 12 weeks), and chronic (three months or more) pain and treatment protocols to prevent or reduce long-term opioid usage. The key recommended practices for acute pain are listed in the box on the next page. The question is whether the first-fill policy should allow a short course of opioid treatment for severe acute pain without PR and, if so, under what circumstances and for which drugs and strengths.

Physician Dispensing

As discussed in Chapter Two, physicians dispense a substantial percentage of pharmaceuticals. Physician dispensing raises quality and cost concerns because physicians typically submit paper bills, making physician-dispensed bills are less efficient to process. Arguably, attempting to address these concerns through the OMFS is not sufficient, and consideration should be given to circumscribing the conditions under which physicians may dispense drugs without PR. Several options might be considered:

- *Allow physician dispensing for the first fill following date of injury without PR, but require PR for all other physician-dispensed drugs.* This would allow the injured worker to begin treatment promptly but would increase the administrative burden for other physician dispensing relative to prescribing drugs for pharmacy dispensing. It is different from the status quo in that physician-dispensed drugs after the first fill would only be covered if authorized under PR. The payer would not be liable if the drug did not receive PR authorization.

DWC Opioid Treatment Guideline Summary for Acute Pain

- Opioid medications are not the first line of treatment for pain and should not in general be used for mild injuries. Other therapies, such as non-opioid medication, appropriate physical activity, and complementary/alternative modalities such as yoga and acupuncture should be used first.
- Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or other therapies will not provide adequate pain relief or are contraindicated for medical reasons. They should only be prescribed at the lowest dose that provides pain relief, for a limited time, and with no refill, prior to reassessment.
- Opioids for acute pain treatment should be tapered to zero within two weeks whenever possible.
- Although all doses of opioids carry risks, providers should be increasingly vigilant for doses above 80 mg/day morphine equivalent dose (MED), as the known risk of adverse events rises while the evidence for increased benefit remains weak.
- Short-acting opioids may be indicated for a limited duration to manage moderate to severe post-operative pain and to obtain sleep, especially in the immediate post-operative period.

SOURCE: Quoted from DWC, 2016c, pp. 1–2.

- *Address physician dispensing through pharmacy network standards.* Labor Code §4600.2 allows a payer to contract with a pharmacy, group of pharmacies, or pharmacy benefit network to provide pharmaceuticals. Regulations implementing this provision have not been issued, but some payers have implemented the provision based on the statutory requirements. Some payers have used this provision to limit physician dispensing.[3] AB 1124 amended this provision to subject network contracts to the formulary but also to specify that "such contracts may not limit the availability of medications otherwise prescribed pursuant to the formulary based on whether the pharmacy services are provided within or outside a *medical provider network*." The formulary rules should clarify the meaning of this provision and confirm that physician dispensing can be curtailed within a *pharmacy network*. Simultaneously issuing standards for reasonable access to pharmacies would provide reassurances that injured workers have reasonable access to pharmacy services if physician dispensing were curtailed.
- *Curtail physician dispensing in the formulary rules.* As discussed in Chapter Five, several states prohibit physician dispensing altogether, while others permit it only by exception or as a first-fill policy. For example, Florida's and Nevada's new laws on WC physician dispensing limit dispensing of schedule II or III drugs to an initial 15-day supply. All

[3] For example, Zenith Insurance Company (2016) requires injured workers to obtain medications from a pharmacy participating in its network. Physician dispensing is allowed only for intrathecal pain pump medications, antivirals, and antibiotics. The State Compensation Insurance Fund has taken a different route and curtailed physician dispensing through its MPN contracts. The fund limits MPN physician-dispensing of opioids to a maximum three-day supply.

controlled substances prescribed beyond the initial supply must be filled by a pharmacy (Nevada Legislature, 2015). A policy that restricts physician-dispensing to certain drugs is likely to be more straightforward to implement than a rule that provides for physician dispensing based on pharmacy availability or "emergency" situations. It could allow drugs that are medically appropriate for common WC conditions that do not require PR but not allow drugs that require PR. The PR requirement is problematic to implement for drugs that are typically dispensed during a patient office visit.

- *Further reduce financial incentives.* The financial incentives for physician-dispensing could be reduced by further refining the OMFS (as discussed later, under "Consider Changes to OMFS Policies").

Physician dispensing represents a trade-off among patient convenience and compliance, protections against dispensing of medically inappropriate drugs, and reasonable fee schedule allowances for medically appropriate drugs. DWC might consider a multipronged approach to achieve this balance:

- Patient convenience could be addressed through policy that exempts prescriptions immediately following an injury from UR (as discussed earlier, under "First-Fill Policy"). Also, the administrative director could address standards for reasonable access to pharmacies available under pharmacy networks (as discussed earlier).
- The prescribing of medically unnecessary drugs for the patient's condition could be addressed by requiring PR for any physician-dispensed drug unless the prescription is exempt from UR based on a first-fill policy. This policy should also apply medical evidence–based criteria to brand-name prescriptions when a generic is available and to drugs with unusual formulations. If PR is not obtained, the physician would be liable for the cost of the physician-dispensed drug if the drug is denied retrospectively.
- The OMFS policies could be revised to protect against unreasonable allowances for drugs with unusual formulations and to consider other changes to the fee schedule allowances. For example, several states do not allow a dispensing fee.

Payers could address physician dispensing through their contracts with MPN physicians and other practitioners or through their pharmacy network rules. Several nonformulary states have adopted this type of restriction. As discussed in Chapter Five, other states do not cover physician-dispensed drugs or limit the amount to the quantity that a patient needs until the prescription can be filled by a pharmacy.

Generic Versus Brand-Name Prescribing and Dispensing

AB 1124 expressed legislative intent that the formulary consider "use of generic or generic-equivalent drugs in the formulary pursuant to evidence-based practices, with consideration being given to use of brand-name medication when its use is cost-effective, medically necessary, and evidence-based." Policy decisions in implementing this policy include the following:

- Whether the policy applies any time a generic drug is available or only when there are multiple sources for the generic drug. For example, the Medicaid FUL is triggered when there are at least three manufacturers of the drug. In our view, availability of the drug from multiple sources is reasonable in setting an appropriate price but is unnecessary in

requiring generic substitution. The therapeutic equivalent available at the lowest price, which could be the brand name for some drugs, should be dispensed.

- Whether a "dispense as written" brand-name prescription would require PR before the drug is dispensed or only documentation in the medical record supporting why the brand name is medically necessary (that would be available on request under retrospective review). Despite the current requirement for generic drugs, about 5 percent of FDA-approved drug lines and 10 percent of payments are for brand-name drugs that are prescribed when a generic brand is available (Figures 2.7 and 2.8). Requiring PR reduces the incentive to prescribe brand names and provides assurance that the higher cost drug is medically necessary. However, it also increases UR adjudication costs.

Over-the-Counter Drugs

Because the MTUS contains guidelines pertaining to OTC drugs, we assume that the formulary drug listing will include nonprescription drugs. A policy question is whether the formulary rules should encourage prescribing OTC drugs across the board (i.e., the Texas and Oklahoma approach) or only note drug ingredients where the guidelines discuss OTC alternatives.

In reviewing the ACOEM recommendations, we found instances of the OTC drugs being addressed but did not find instances that explicitly favor OTC over prescription drugs, in keeping with the policy of the recommendations not directly addressing cost considerations. At best, a preference is implied. For example, the recommendation for omeprazole (Prilosec®) notes that the prescription versions are significantly more expensive than OTC preparations. The implication is that the OTC should be preferred, but in keeping with ACOEM's policy of not making cost-based recommendations, this is not explicit.

A regulatory preference for OTC drugs when medically appropriate and less costly is unlikely to affect prescribing or dispensing practices unless supported by a PR rule or a point-of-sale bill-processing screen that would trigger a discussion with the physician about whether an OTC drug would be medically appropriate. Further, a branded OTC version may be more costly than a generic prescription. PR rules could be established to incentivize the use of less-costly OTC alternatives by either requiring PR for a prescription drug that would not otherwise require PR or waiving PR for the OTC alternative if the drug would otherwise require PR. We do not recommend either policy because of the complexities of implementing them across the board. However, a general policy supporting prescribing of OTC drugs when medically appropriate and less costly could lend support to payer (and PBM) efforts to encourage cost-effective prescribing practices on a drug-by-drug basis.

Therapeutic Interchange

The ACOEM or ODG treatment guidelines and formulary recommendations do not take cost considerations into account.[4] In our view, this is an advantage because it makes the process for determining which drug therapies are medically appropriate separate from the process of determining which among medically appropriate therapies with similar outcomes are less costly and should be considered for therapeutic interchange. Regardless of the decision on the basic formulary structure, any decisions to establish preferential treatment for less costly therapeutic

[4] Both formularies list comparative costs of different drug therapies. Further analysis is needed to determine whether they are relevant to the WC program, given the OMFS and lack of cost-sharing.

alternatives require (1) a medical assessment of whether different drug ingredients within the same drug class have similar therapeutic outcomes and (2) an assessment of the cost differences between the therapies. Both assessments should be transparent and free of conflict-of-interest issues.

The Washington State formulary process for determining therapeutic interchange is a prototype for a transparent evidence-based process for making decisions on therapeutic alternatives (Chapter Six). Adopting a similar process would require DWC to enter into an arrangement with an independent evidence-based practice center to provide scientifically based information to support the P&T's quarterly review process. Further, DWC would need to establish a mechanism for comparing the costs of the drugs. This need not be as complicated as the Washington process because only one program is involved and because there are no rebate issues. DWC staff or an entity without conflict-of-interest issues would need to make the decisions.

Cost savings are generally the motivating force behind therapeutic interchange. The need to implement an evidence-based formulary by July 1, 2017, is already an administrative challenge without the added burden of incorporating cost considerations into the initial formulary. Instead, the formulary rules could provide for incorporating cost considerations (therapeutic interchange) into the drug formulary over time through the update process.[5] One role of the P&T committee could be to review the evidence and make recommendations about which drugs within a drug class have similar therapeutic effects. Based on these recommendations and review of OMFS allowances and average daily dosages, the administrative director could limit recommended drugs to the less costly alternatives among the drugs with similar therapeutic effects. Because California is a multipayer state and has no enrollment process for providers furnishing WC services, a system like Washington's Endorsing Practitioner and Therapeutic Interchange Program is unlikely to be feasible, at least in the short term.

Update Process

Labor Code §5307.29 requires that the formulary be updated no less often than quarterly. Ideally, updates in the formulary drug listings should be driven by updates in the treatment recommendations, but the two updates may not happen concurrently. One reason is that the guideline developers (ACOEM, ODG, and DWC) use different review and update processes. A second reason is that the Labor Code requires different administrative processes for updating the treatment guidelines (rulemaking) and the formulary (posting changes on the DWC website).

In addition to updates to the drug recommendations, the NDC listing needs to be kept current. The NDC-level list may need to be updated more frequently than the drug listing as new drugs enter the market or as current NDCs are no longer marketed.

P&T Committee Rules

As discussed in Chapter Six, the Labor Code specifies the composition of the P&T committee, its general role, and conflict-of-interest requirements. The duties of the P&T committee

[5] If there is a need to include these considerations in the initial drug formulary, it might be possible to draw on the findings of the Washington State P&T before the cost considerations, which are pertinent to Washington government programs and the rebates they are able to negotiate with drug manufacturers, are incorporated into the Washington State formulary. We were advised that these decisions are only available in the P&T committee minutes and decisions, many of which do not relate to drug therapies common for WC conditions.

will be shaped by the formulary structure DWC decides to adopt. The statute states that the P&T committee is to consult on "available evidence of the relative safety, efficacy, and effectiveness of drugs within a class of drugs in the updating of an evidence-based drug formulary," which seems to imply providing advice on therapeutic interchange (discussed above). If either the ACOEM or MTUS formulary is adopted, the P&T committee could also provide recommendations about when PR is required. In addition, consideration should be given to addressing potentially outdated drug therapy guidelines through the P&T committee. This could be accomplished by empowering the P&T committee to make PR recommendations using the MTUS Medical Evidence Search Sequence. This would not change the guideline recommendations but could involve adding or deleting a drug listed on the formulary or modifying the PR recommendation. This issue is discussed in greater detail later, under "Medical Evidence Search Sequence."

Transparency and public input into the updating process should be facilitated through the rules adopted for the P&T committee. Additionally, the P&T rules will need to consider conflict-of-interest issues. Across the formularies that we considered in Chapter Three, the Washington State formulary has both the most transparent process for making P&T recommendations and the most stringent conflict-of-interest requirements.

Implementing Changes to the Drug Formulary Listing

The Labor Code permits posting of changes to the drug formulary without going through the rulemaking process. Posting with a delayed effective date (e.g., 60 days from posting) should provide prescribers, pharmacists, and payers time to address alternative drug therapies for injured workers who would be affected by the change and make the necessary system changes.

Keeping the MTUS Guidelines and Formulary Rules Consistent

One objective is to keep the formulary and guidelines consistent with the best available evidence concerning drug therapy recommendations. Two important issues are (1) different updating requirements for the formulary and the guidelines and (2) potentially outdated treatment guideline recommendations.

Under the Labor Code, changes in the medical treatment guidelines must be accomplished through rulemaking, while changes in the formulary may be accomplished through a posting on DWC websites. The guidelines and formulary are likely to become inconsistent over time unless revisions in the drug treatment guidelines can be implemented simultaneously with the changes in the formulary. For example, assume that DWC adopts the ODG guidelines for mental health. ODG issues an update to its guideline for mental health services that affects the PR recommendation for a mental health drug therapy. DWC could post the formulary update, but implementation of the revised treatment guideline would be delayed until the rulemaking process is completed, approximately six months later. If emergency rulemaking cannot be used to address the inconsistency and make the treatment guidelines consistent with the best medical evidence, consideration should be given to seeking statutory authority to allow posting changes in the MTUS treatment guidelines for drug therapies simultaneously with changes in the formulary.

The second issue involves potential situations in which a treatment guideline becomes outdated and inconsistent with best medical evidence. On a case-by-case basis, this inconsistency can be handled through the medical necessity dispute-resolution process. However, this is an inefficient way to handle outdated guidelines and can delay an injured worker's receipt

of medically appropriate drugs. Timely updates in the underlying treatment guidelines should avert this situation. Outdated guidelines are less likely to occur with ODG-based guidelines, which are updated on a flow basis, than with ACOEM-based guidelines, which are themselves typically updated periodically through complete review and revision of individual chapters in the guidelines. The Reed Group has indicated that a treatment guideline would be updated without waiting for the chapter revision if the new evidence would have an important patient care impact. However, there is no established track record for determining the circumstances under which this would occur.

Make Conforming Changes to UR/IMR Rules and Procedures

The drug formulary is part of the MTUS and is compatible with the general construct of the medical necessity dispute-resolution process. Changes might be warranted for some aspects of the process, however, to reduce administrative burdens and costs for ensuring that drug therapies are medically appropriate.

PR Requirement

Current rules anticipate that a physician will request PR for a proposed treatment but do not require that this occur. If PR is not requested, the services are subject to retrospective review. For pharmaceuticals, retrospective review occurs most often for drugs that are dispensed by physicians and nonnetwork and compounding pharmacies. Liens are filed for many of these prescriptions to obtain payment.

If the formulary is to meet its objective to provide appropriate medications expeditiously while minimizing administrative costs, the PR requirement for drugs should be mandatory (and initiated with a physician's RFA). The rules should also set out the process and policies that apply when a drug is prescribed and/or dispensed without the prerequisite PR. We assume that a pharmacy bill would be generated in this situation and would be sent either to the PBM, in the case of a network pharmacy, or to the payer, in the case of physician-dispensed or nonnetwork pharmacy. The rules should consider different scenarios for drugs requiring PR:

1. A point-of-sale screen identifies that a prescription has not had the prerequisite PR and approval. Current UR rules do not specifically address screening occurring during a pharmacy transaction (point-of-sale edits). The rule should clarify whether the screening should trigger formal UR with or without a physician's RFA and whether a rejection of the prescription based on a condition-specific PR requirement (rather than an across-the-board PR rule) constitutes a medical necessity denial.
2. A drug bill is presented after the prescription is dispensed so that point-of-sale screens are not applicable, and retrospective review determines the prescription is not medically appropriate. The rule should clarify whether the dispenser—the physician or pharmacy—is liable for the cost of the prescription.
3. A drug bill is presented after the prescription is dispensed, and no retrospective review occurs (i.e., the prescription passes bill-processing screens), or retrospective review determines the drug is medically appropriate. This scenario would not appear to require any special rules, but the payer or PBM might consider educating the prescriber and/or dispenser in this situation about the PR rules.

Prior Authorization

Current UR rules allow a claims administrator (or UR organization with which the claims administrator has contracted) to prior authorize selected services. Prior authorization waives the requirement that a provider submit a RFA before furnishing the affected service. Prior authorization is a tool that claims administrators can use to eliminate unnecessary administrative burdens and to create incentives for practitioners to provide services consistent with the MTUS. While the details of the policies differ widely across claims administrators (and most do not provide for prior authorization),[6] prior authorization is used primarily for services furnished shortly after injury that are likely to be medically necessary and/or for providers whose patterns of care are consistent with the MTUS guidelines. The formulary PR rules should allow this practice to continue with respect to outpatient drugs.

PR Request Form

At the January 2016 public hearing, suggestions were made that DWC consider a faster PR process for pharmacy bills to minimize delays in filling prescriptions. While facilitating timely dispensing is an appropriate and important goal, we are concerned about creating a separate process for pharmacy bills. In our view, the proposed treatment plan for an injured worker needs to take into account the medical appropriateness of both prescribed medications and other therapies. The claims administrator should be able to see the total plan of care proposed for the injured worker, including both drugs that require PR and those that do not.

However, the RFA process could be more efficient if RFAs were consolidated with the reports the WC program requires—the DFR and the Progress Report (PR-2). Currently, the RFA is submitted with one of these reports or comparable information, but some information that is required for the RFA is duplicative of information requested in the WC-required reports. In another RAND study, we are recommending that DWC consolidate these forms, and we understand that DWC is considering revisions that would eliminate the duplication.

Creating a consolidated form that could be filed electronically would make the entire PR process more efficient and could also facilitate PR when applicable to any of the proposed drug therapies. A consolidated form that has the following characteristics would facilitate PR of the drug therapies:

- The consolidated form would include updated information on the patient's condition(s) (diagnoses).
- The section of the form dealing with plan of treatment would separate drug therapies from other therapies.
- The section on drug therapies includes checkboxes to indicate whether PR is not required or, if it is required, the reason. The checkboxes would relate to the reasons PR might be required (not addressed by the formulary, exceeds the dose or duration in the MTUS, compounded drug, etc.).
- The section on drug therapies would include a free text box to explain why the treatment is medically appropriate. It would include an explanation of what information is needed to document medical necessity that is specific to the box checked for why PR is needed (failed trial of first-line therapy, more-recent medical evidence, etc.).

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[6] A claims administrator's prior authorization policies are described in its UR plan filed with DWC.

- There are models (e.g., Ohio BWC and Medi-Cal) for pharmacy RFAs (electronic and paper) that could be used to design a section for pharmacy on an integrated treatment plan.

Our assumption is that electronic submission of the forms and adherence to the PR formulary requirements would enable prompter adjudication of pharmacy bills without establishing a separate review process. Ideally, the forms would be submitted before the prescription is presented at a pharmacy. We are uncertain how often this would actually happen because the prescription is typically written during an evaluation and management visit, but strategies to encourage timely submission of the forms might be considered. For example, timely submission of the DFR is an important factor in initial PR decisions. Currently, there is no payment for these reports. Incentivizing electronic reporting of DFRs with proposed treatment therapies could be an important element of reducing the time required for obtaining the diagnostic information related to the patient's injury needed to process pharmacy bills. As discussed in Chapter Five, Texas and Washington also make their first-fill payment contingent on having confirmation that a DFR has been filed. For initial prescriptions requiring PR, PR requirements for refills could be tied to the MTUS recommendations on treatment duration to avoid unnecessary PR.

Medical Evidence Search Sequence

The formulary is part of the MTUS. As a result, medical necessity determinations are subject to the Medical Evidence Search Sequence found in §9792.21.1 of California's UR/IMR regulations. The search sequence applies when a medical condition or injury is not addressed by the MTUS or when the MTUS presumption of correctness is being challenged. Confirming that the Medical Evidence Search Sequence applies to medical necessity determinations for drug therapies may address any concerns that the medical appropriateness of drug therapies may be determined using outdated medical information. For the WC formulary, more-recent medical evidence could potentially affect two different policies: (1) whether a drug is inappropriately classified as a second-line therapy, for which PR is required, and (2) whether the proposed drug is medically appropriate if a first-line therapy is not effective. Both policies should be evidence based, and the prescriber should be entitled to submit additional evidence consistent with the Medical Evidence Search Sequence.

Bill-Processing Screens

Currently, the UR plans do not address either the interface between a PBM's point-of-sale bill-processing system and the claims administrator or the respective responsibilities of each party in the medical necessity dispute-resolution process. Each claims administrator or external UR organization that performs UR for the claims administrator must file a plan that describes its UR policies and procedures. The plan needs to address any services that are authorized without requiring an RFA from the physician and the distinction between services that may be approved by a claims adjustor and those that must be elevated for clinical review. Only a physician may deny or modify proposed treatment.

Different types of bill-processing screens are employed for pharmaceutical claims, some of which appear to be medical necessity determinations. For example, the billing system may screen whether the prescribed drug is indicated for the worker's condition. A drug that is indicated may be approved without involving a claims administrator, while one that is not indi-

cated for the worker's condition should be suspended and referred to the claims administrator for further development.

Consideration should be given to providing guidelines regarding what types of edits would be considered a "medical necessity" determination that should be detailed in the UR plan and would require physician approval of any denial or modification. In addition, the rule should clarify whether the UR plan may allow the point-of-sale screens to (1) approve drugs that require PR and (2) flag prescriptions that require PR because the drug is prescribed in a dosage or duration that exceeds MTUS guidelines or is not indicated for the injured worker's compensable condition.

Retrospective Review

The UR rules should clarify the conditions under which retrospective review would be appropriate. Two situations are likely. In the first situation, despite a mandatory requirement for PR for a given drug ingredient or type of drug, the drug was dispensed without the prerequisite PR. Based on our PR recommendations, this would include compounded drugs, investigational or experimental drugs, brand-name drugs when a generic equivalent is available, nonpreferred drugs, and nonlisted drugs. In this situation, if a retrospective review concludes that the drug is not medically appropriate, the payer should not be liable for the cost of the prescription. In the second situation, a drug that otherwise does not require PR is found to have been prescribed in excess of the MTUS dosage or duration guidelines or is not indicated for the worker's condition. If retrospective review finds the drug is medically unnecessary based on the individual's medical needs for a work-related condition, the payer would be accountable for the first prescription, but refills would not be covered.

Adverse Medical Necessity Determinations

The UR rules provide that adverse medical necessity decisions to delay, deny, or modify a treatment are communicated initially to the requesting physician by telephone, followed by written notice to the requesting physician, injured worker, and injured worker's attorney. There is no requirement that a nonphysician provider of goods and services be notified of the determination.[7] As a result, there could be situations (including under current rules) in which a pharmacy may not be advised of the reasons a pharmacy bill is being denied. Consideration might be given to requiring that a notice be sent to a pharmacy when a retrospective denial is made for a medically unnecessary drug that was dispensed without obtaining the prerequisite PR approval. Under the Labor Code, the supplier would not have a right to appeal the determination but might be more sensitive to the PR requirements in the future. As with other services, only an injured worker or an injured workers' representative (attorney) has the right to appeal an adverse UR determination to IMR.

Consider Changes to OMFS Policies

The OMFS for pharmaceuticals is based on the Medi-Cal fee schedule applicable to fee-for-service beneficiaries. Once the formulary drug list is established and the NDC listing created, consideration should be given to matching the drugs that are included in the formulary listing

[7] Prior to January 1, 2013, the rules provided that a nonphysician provider of goods and services be notified of an adverse UR opinion but not of the rationale, criteria, or guidelines used for the decision. The rule was changed with the implementation of the new IMR process.

with the Medi-Cal fee schedule to ensure that all NDCs have either a Medi-Cal price or are covered by the OMFS rules that apply to drugs that do not have Medi-Cal prices.

Earlier, we discussed potential options for curtailing physician dispensing in the formulary rules. This would be the most direct approach to addressing the issues raised by physician dispensing; an indirect approach would be to remove the financial incentives for physician dispensing. This could involve, for example, eliminating the dispensing fee for physician-dispensed drugs and capping the allowance for a brand-name drug at the price for the generic equivalent. The rules for pricing drugs that do not have Medi-Cal prices should also be reviewed. If neither the NDC for the dispensed drug nor the underlying drug product from the original labeler has a Medi-Cal price, the OMFS rules set the maximum allowable fee at 83 percent of the average wholesale price of the lowest priced therapeutically equivalent drug (§9789.40(b)(2)). This pricing formula has given rise to physician dispensing of new drug strengths or formulations with average wholesale prices that are much higher than those for the commonly prescribed strengths of the same drug ingredient and appear to be prescribed for financial rather than medical reasons (Wang, Thumula, and Liu, 2016). The feasibility of capping the unit price allowed for the drug ingredient at the average unit price for the most comparable strength (or other formulations if applicable) of the drug ingredient on the Medi-Cal fee schedule should be explored.

Pharmaceutical Liens

To the extent permissible under current law, the lien system should not be used to resolve WC pharmaceutical claims. Post-SB 863, medical necessity issues evolving from retrospective review denials or modifications should be addressed by the IMR process, and fee schedule issues should be addressed by independent bill review.[8]

After a decline in the number of liens, there has been a steep increase beginning in 2016. Lien conference records for pharmacy services provided post-SB 863 should be reviewed to determine whether issues precipitating the lien filings could be addressed through clarifications regarding the appropriate venue for resolving disputes. For example, if review indicates that liens are still being filed because the OMFS rules do not have a scheduled maximum for every drug, consideration should be given to clarifying how the allowance is to be determined and specifying that any allowance based on OMFS rules (e.g., compounded drugs, repackaged drugs) should be resolved through independent bill review. If the liens are primarily being filed by nonnetwork pharmacies, it may be necessary to consider further legislative changes to limit the issues that may be resolved through the lien process.

Working Model for Flow of Drug Prescriptions

This section describes the pathways that might occur after the formulary is implemented. The pathways are different when (1) drugs are dispensed by a retail or mail-order network pharmacy or (2) the drugs are dispensed by the prescribing physician or a nonnetwork pharmacy (see Table 7.5).

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[8] On out-of-network issues, *Jose Brambila v Vons Inc.* affirmed that a payer is not liable for medications provided outside the pharmacy network. However, this issue would not preclude filing a lien to recover payment that has been denied because the dispenser is not in the payer's MPN or pharmacy network if there is a dispute over the propriety of treating outside the MPN or pharmacy network.

Table 7.5
Comparison of Flow of Prescriptions after Formulary Implementation (network pharmacy)

	Medication Requires PR	Medication Does Not Require PR
Claims administrator	The RFA goes through the claims administrator's normal UR process. The claims adjustor reviews the RFA and determines whether it can be approved or whether the RFA needs to be elevated for clinical review. There are three possible UR decisions: approve, modify, or deny. UR decisions to modify or deny are subject to IMR. UR notices are sent to the appropriate parties.	Not applicable because PR is not required.
Pharmacy	When the pharmacy receives the prescription, it contacts the claims administrator or PBM to confirm WC eligibility and whether the medication requires PR. If the medication requires PR, the PBM authorizes the pharmacy to dispense the drug and pays the pharmacy (1) if there is a UR authorization number or (2) if the medication passes the claims administrator or PBM's prepayment bill-processing screens. The PBM does not authorize the pharmacy to dispense the drug as prescribed if there is no UR authorization number and if the medication does not pass the PBM's prepayment screens. No further action is necessary if there is a UR decision to modify or deny the medication. If the prescriber did not submit an RFA, the designated entity (PBM, claims administrator, or pharmacy) contacts the prescriber to initiate the UR process.	When the pharmacy receives the prescription, it contacts the claims administrator or PBM to confirm WC eligibility and whether the medication requires PR. If a non-PR medication passes the claims administrator or PBM's prepayment screens for consistency with the MTUS, the PBM authorizes the pharmacy to dispense the drug. If a non-PR medication does not pass the claims administrator or PBM's prepayment screens, the claims administrator or PBM does not authorize the pharmacy to dispense the drug, notifies the physician that PR is required in this particular case, and explains why.
Retrospective review process	Not applicable because PR was required or because the drug passed screening guidelines.	The claims administrator (typically based on data from the PBM) may conduct a retrospective review of prescribed non-PR drugs. Because prepayment screens should identify most situations in which prescribed medications are inconsistent with the MTUS, retrospective review should be limited. If requested, the prescriber is required to submit documentation substantiating that the prescription was medically appropriate. If the medications are determined to be inconsistent with the MTUS, the denial is effective prospectively for any refills. If the prescriber has a pattern of prescribing medically inappropriate medication that continues after educational efforts, the claims administrator should have authority to require PR under additional conditions.

We assume that the formulary rules are derived from the MTUS and classify both prescription and nonprescription medications as preferred drugs or nonpreferred drugs based on their active ingredients and, in some cases, on their condition or mode of delivery.

Prescriber

The prescriber determines the medications that he or she believes are most appropriate for treating the injured worker's condition. In doing so, the prescriber consults the MTUS and formulary to determine the recommended treatments and whether PR is required for any of the medications. If the prescriber concludes that PR is not required, the prescriber either provides the prescription to the injured worker or submits it electronically to the pharmacy. If PR is required, the prescriber submits an RFA to the claims administrator. The RFA should include sufficient information to demonstrate the medical necessity of the medication(s).

Pharmacy

When the pharmacy receives the prescription, it contacts the claims administrator or PBM to confirm WC eligibility and whether the medication is PR or non-PR. A network pharmacy should have direct access to this and other information on the claimant, including diagnosis after the DFR is filed. The pharmacy queries the claims administrator or PBM for authorization to dispense the medication. If the pharmacy dispenses the medication without seeking authorization, the payer is not liable for the drug cost if the drug is subsequently determined medically unnecessary.

A nonnetwork pharmacy (or pharmacy billing service) should have access to the formulary's list of drugs that always require PR but is likely to need to confirm with the payer that a specific prescription is non-PR based on the MTUS and the patient's condition with the claims administrator.

Claims Administrator or Pharmaceutical Benefit Manager

Whether a claims administrator or a PBM adjudicates a prescription depends on how the responsibilities for processing pharmacy bills are allocated between the two and whether the pharmacy is participating in the payer's network. A network pharmacy may be delegated certain functions, e.g., generic substitution or contacting the prescriber about a potential therapeutic substitution. However, neither the PBM nor the pharmacy can modify or deny a prescription unless an adverse UR determination has been made by the claims administrator or its designated UR organization. Typically, the PBM confirms with the claims administrator whether the claimant is WC eligible and reviews whether the prescription is for a PR or non-PR medication that passes its prepayment screens for consistency with the guidelines and advises the pharmacy of its findings. If modifications are appropriate, the arrangements between the claims administrator or PBM and the pharmacy will determine which entity is responsible for contacting the prescriber.

In addition to the bill-review and -processing function described above, the claims administrator or PBM is responsible for a postpayment drug UR program to identify inappropriate prescribing patterns.

Summary and Recommendations

This chapter synthesizes the findings from earlier chapters into a preliminary implementation plan for the formulary. The plan is preliminary because DWC's decisions on an updated MTUS guideline structure will affect the formulary design and the activities that are needed to implement the formulary. We recommend that DWC give priority to updating the MTUS guidelines and, in doing so, weigh the advantages and disadvantages of retaining the current multisource structure. We further recommend that DWC derive a formulary drug listing and PR requirements from the updated MTUS guidelines. This formulary should impose condition-specific PR requirements sparingly when clinical review determines that significant differences in the guidelines warrant such requirements. The ground rules should require PR when a proposed drug therapy is inconsistent with the MTUS guidelines and should continue to integrate medical necessity determinations into the UR and IMR processes. Other ground rules should include policies on first-fill prescriptions, generic versus brand-name dispensing, and preferences for OTC drugs. The formulary rules could provide for incorporating therapeutic interchange considerations into the formulary drug listing over time through the P&T committee and update process.

The rulemaking process will help shape the final formulary structure and implementation policies. However, certain issues may require Labor Code changes before they can be addressed appropriately, including the following:

- authority to post changes in the MTUS treatment guidelines for drug therapies simultaneously with changes in the formulary without rulemaking
- limitations on physician dispensing
- streamlined UR and IMR processes for proposed drug therapies
- authority to cap OMFS fee schedule policies for drugs that are not on the Medi-Cal fee schedule (e.g., OTC topicals and unusual dosage strengths); the need for this authority is less pressing if physician dispensing is curtailed.

APPENDIX A

Detailed Methods and Results for Chapter Four

Methodology

Our comparison of preferred drug status across formularies required us to make some assumptions about which drugs are preferred in a given formulary because we had varying levels of detail for each formulary. Each drug is assigned a unique code (NDC) that details the manufacturer, product, and form of the active ingredient. While drugs are often prescribed at the active ingredient and dosage level, drugs are priced and paid at the NDC level. Our assumptions create differences from how the formularies are operationalized in practice, so our preferred or nonpreferred status for each active ingredient in each formulary should be interpreted with caution.

A given active ingredient will have multiple NDCs indicating different manufacturers (if the drug is a multisource generic drug), forms, routes of administration, etc. We found that not all NDCs for a given active ingredient were addressed in each formulary (see Chapter Four). An assumption applied across all five formularies was that any WCIS NDCs that did not have matches in the given formulary would require PR in practice in California. We eliminated any drugs that were active in 2013 but subsequently eliminated because the NDC listings the formulary developers provide are supposed to be updated regularly and are unlikely to include drugs that are no longer marketed. We now turn to addressing particular assumptions for each formulary.

Washington L&I

We received an NDC-level file for Washington L&I that could be directly matched into WCIS. Washington L&I has four levels of restrictions, and we made the following assumptions about the preferred drug criteria for each level:

1. Preferred drugs do not require PR.
2. Nonpreferred, drugs requiring PR, and the noncovered drugs were all marked as requiring PR.
3. Some "preferred" drugs had quantity limits or manufacturer limitations (repackagers were nonpreferred), so these NDCs were considered nonpreferred.

ACOEM

ACOEM provided us with a detailed drug recommendation listing for all conditions at the active ingredient level, but we had to create and assign the preferred status to each active ingredient. The ACOEM file had to be merged into RED BOOK by drug name to acquire a set of NDC codes. We assumed that any preferred or nonpreferred status would apply to all NDC codes with the given active ingredient.

Each condition category has subcategories for the type of injury; phase (acute or chronic); and pain classification, where relevant (i.e., the recommendation distinguishes between pain levels, such as moderate or severe, and between types of pain, such as radicular). ACOEM's formulary summarizes the panel's treatment recommendations by coding them as "Yes," "No," or "None" and by level of evidence (strong, moderate, limited, and insufficient). Insufficient information would lead to a "None" recommendation, for instance. "Yes" recommendations are not limited to first-line therapies. Because the recommendations may vary across conditions and because the "Yes" recommendations include therapies that should be considered only if a first-line therapy is not effective, the recommendations cannot be equated to the ODG "Yes" or "No" requirements for PR.

For purposes of comparing the PR requirements across conditions in ACOEM, we established the following rules, which are for illustrative purposes only. We categorized the prescribing guidelines into the following categories and used the category with the majority of recommendations across conditions to guide the PR recommendation:

1. PR is required if the recommendation was "No" or "None" for the applicable type, phase, or pain category.
2. Drugs listed with a "Yes" recommendation but also listed as second-line treatments (or beyond) would also require PR.
3. Drugs for which the clinician guidance was unclear were considered to require PR, pending further review from a clinician.
4. If the active ingredient was recommended as a first-line therapy for the condition, PR would not be required. We determined whether something was a first-line therapy using the simple criterion of whether the information for prescribers and claims adjusters indicated that the drug was a recommended first-line treatment. This provided a conservative estimate (erring on the side of requiring PR for more active ingredients than would likely happen in practice).

It is important to note that we applied a simple yes-or-no rule to each recommendation in the guidelines.[1] If the ACOEM formulary were adopted, it is likely that more-nuanced criteria might be used, either in determining whether, for example, a drug used for a low-back condition should be classified as requiring PR or, alternatively, whether the PR classification should

[1] We considered whether to also take the strength of the evidence into account in determining whether to require PR. However, this requires clinical judgment that was not appropriate to apply for our comparative purposes. It might have limited discriminatory power. For example, within the low-back injury, acute phase category, all the NSAIDs are listed as "Yes: Limited Evidence (C)" for radicular pain including sciatica and as "Yes: Strong Evidence (A)" for other low-back injuries. It also adds additional complexity to the drug formulary because the evidence level for the recommendation can vary. For example, the evidence level for diclofenac potassium (Cataflam, Voltaren®) varies from strong evidence for acute low-back pain, to moderate for perioperative management and chronic and subacute low-back pain, to limited and insufficient evidence for radicular pain, including sciatica.

list exceptions for comorbid conditions, duration, or level of evidence. Using less-restrictive criteria in practice will lower the administrative burden of adjudicating PR for each NDC.

Since formularies are operationalized at the NDC level, not at the condition level, we needed to create an active ingredient–level PR criterion. To do so, we calculated the percentage of recommendations for which PR applied across all the drug's recommendations for a given condition. We did this calculation by condition because a given active ingredient could have different PR criteria for another condition.

ODG

We received an NDC-level file for ODG, which facilitated directly matching these files with the WCIS data. We found several discrepancies between the publicly available ODG drug listing and the file of NDC codes we received. Several of the topical ointments and a few common OTC drugs (e.g., aspirin and acetaminophen) were listed in the appendix but were not included in the NDC-level file, likely because of the large number of potential NDCs. We added the NDCs for these drugs to ODG's list, using an active ingredient and form search in RED BOOK. We searched only for the single active ingredient (e.g., capsaicin), not combinations of the active ingredient with other ingredients (e.g., capsaicin and menthol). We limited the forms of these active ingredients to topically administered ointments and orally administered versions of other drugs. The topical drugs were ointments including lidocaine, ketamine, capsaicin, and all salicylates. The oral drugs were acetaminophen, aspirin, lansoprazole, omeprazole, and diphenhydramine hydrochloride. Two additional active ingredients were not found in the 2104 version of RED BOOK: tetrahydrocannabinol and oxycodone with naloxone. Finally, in ODG's list, we found many older NDC codes for drugs no longer in use. For example, there were a variety of NDCs for older versions of Prozac (fluoxetine) that had been but are no longer manufactured by Eli Lilly.

Ohio

We received a listing of drugs filled in Ohio's WC program in the last two quarters of 2015. We assumed the electronic file was the most current version of the drugs and that it would also represent the most commonly prescribed drugs, although some drugs not listed in this file are listed as covered on the PDF public version of the formulary. These additional drugs were added into the electronic version of the Ohio formulary.

List entries included the drug name, form (i.e., tab or capsule), and dosage. To merge this into WCIS, we first merged this into a database of NDC codes by drug name in RED BOOK to create an NDC-level list. Where indicated, we incorporated the form of the drug. This process of matching using text strings introduces some error, likely overestimating the number of covered NDC codes in practice in Ohio. Text strings could not be merged into WCIS directly because of the variation in how the drug names are entered in WCIS (e.g., hydrocodone/acetaminophen versus acetaminophen/hydrocodone).

The PR criteria were listed in the PDF version of the formulary only, and we transferred these manually to the NDC-level list. If a given drug or drugs were preferred for allowable conditions only, all the NDCs were marked as nonpreferred. Other active ingredients had

dosage, step therapy, or quantity limits; for simplicity, all NDCs within the active ingredient were assumed to be nonpreferred if these restrictions were in place. All NDCs in a class were marked as nonpreferred if restrictions indicated they applied to the whole class. It is important to note that this process likely overestimates the number of prescriptions that would require PR in practice in Ohio.

Medi-Cal

We received an NDC-level Excel version of the Medi-Cal fee-schedule list with the treatment request authorization (TAR) field from DWC. We assumed that NDCs not requiring TAR would not require PR. We marked NDCs that required TAR, were not payable even with a TAR, or were payable only if in a compounded drug as requiring PR for our purposes.

Results

Tables A.1 and A.2 present the results of this analysis.

Table A.1
Percentage of WCIS 2013 Prescription Payments Addressed in Each Formulary, by Active Ingredients, Accounting for at Least 1 Percent of Payments

	Percentage of Payments in Formulary					
Ingredient(s)	**WCIS**	**Washington**	**ACOEM**	**ODG**	**Ohio**	**Medi-Cal**
Omeprazole	8	92.3	100.0	100.0	100.0	99.3
Capsaicin/menthol/methyl salicylate	5	100.0	0.0	0.0	100.0	0.0
Oxycodone hydrochloride	5	99.7	100.0	99.7	100.0	100.0
Lidocaine	5	100.0	100.0	100.0	100.0	99.7
Tramadol hydrochloride	5	93.0	100.0	93.3	93.3	15.4
Acetaminophen/hydrocodone bitartrate	4	92.0	100.0	97.1	99.9	91.8
Duloxetine hydrochloride	4	100.0	100.0	100.0	100.0	99.9
Celecoxib	4	100.0	100.0	100.0	100.0	99.9
Pregabalin	3	100.0	100.0	100.0	100.0	99.9
Naproxen sodium	2	90.0	100.0	99.9	100.0	99.3
Gabapentin	2	80.1	100.0	82.1	82.4	81.8
Rabeprazole sodium	2	100.0	100.0	99.5	100.0	100.0
Fentanyl	2	99.2	100.0	100.0	100.0	99.2
Fentanyl citrate	2	100.0	100.0	100.0	44.1	100.0
Diclofenac epolamine	1	100.0	0.0	100.0	100.0	99.2
Diclofenac sodium	1	83.3	100.0	99.6	100.0	99.5
Acetaminophen/oxycodone hydrochloride	1	97.9	100.0	99.8	100.0	99.9
Ondansetron	1	100.0	0.0	0.0	100.0	99.9
Cyclobenzaprine hydrochloride	1	68.2	100.0	69.9	100.0	68.8
Capsaicin/lidocaine/menthol/methyl salicylate	1	99.9	0.0	0.0	0.0	0.0
Oxymorphone hydrochloride	1	97.2	100.0	89.9	100.0	97.2
Aripiprazole	1	100.0	0.0	100.0	100.0	100.0
Lidocaine/menthol	1	100.0	0.0	0.0	0.0	0.0
Eszopiclone	1	100.0	0.0	100.0	100.0	99.9
Morphine sulfate	1	66.8	100.0	99.7	100.0	99.8

Table A.1—Continued

Ingredient(s)	Percentage of Payments in Formulary					
	WCIS	Washington	ACOEM	ODG	Ohio	Medi-Cal
Tapentadol hydrochloride	1	100.0	100.0	100.0	100.0	100.0
Capsaicin/menthol	1	100.0	0.0	0.0	0.0	0.0
Nabumetone	1	99.4	100.0	100.0	100.0	99.5
Zolpidem tartrate	1	97.9	0.0	95.6	44.0	99.4
Pantoprazole sodium	1	97.9	100.0	100.0	99.6	99.9
Hylan polymers A and B	1	100.0	0.0	0.0	0.0	100.0
Tizanidine hydrochloride	1	95.1	100.0	99.6	100.0	97.2
Esomeprazole magnesium	1	100.0	0.0	100.0	100.0	99.8
Buprenorphine	1	100.0	100.0	100.0	100.0	100.0
Modafinil	1	90.5	0.0	100.0	100.0	90.5
Metaxalone	1	100.0	100.0	100.0	100.0	99.8
Bupropion hydrochloride	1	89.5	100.0	100.0	100.0	99.7
Venlafaxine hydrochloride	1	88.9	100.0	100.0	100.0	100.0
Acetaminophen/tramadol hydrochloride	1	99.2	100.0	100.0	100.0	98.9
Carisoprodol	1	98.0	100.0	100.0	100.0	97.2
Etodolac	1	96.6	100.0	100.0	100.0	99.9
Ibuprofen	1	97.6	100.0	97.7	100.0	98.1

SOURCE: RAND Analysis of WCIS 2013 and formulary files from the sponsors.

NOTES: Bills for drugs used in compounding and drugs with deactivated NDCs were excluded from the numerator and denominator for the calculation of the percent of WCIS payments mentioned in each formulary for each active ingredient.

Table A.2
Common Forms for Top Ingredients in WCIS by Percentage of Drug Lines

		Percentage of Lines of Type				
Ingredient(s)	Percentage of Lines in WCIS	Oral	Oral Extended Release	Topical	Injectable	Other
Acetaminophen/hydrocodone bitartrate	9.0	100.0	0.0	0.0	0.0	0.0
Ibuprofen	5.6	100.0	0.0	0.0	0.0	0.0
Omeprazole	5.5	100.0	0.0	0.0	0.0	0.0
Tramadol hydrochloride	4.8	100.0	27.4	0.0	0.0	0.0
Naproxen sodium	3.7	100.0	0.4	0.0	0.0	0.0
Gabapentin	3.4	100.0	0.0	0.0	0.0	0.0
Cyclobenzaprine hydrochloride	3.2	100.0	1.9	0.0	0.0	0.0
Carisoprodol	2.3	100.0	0.0	0.0	0.0	0.0
Zolpidem tartrate	2.2	98.3	16.9	0.0	0.0	1.7
Nabumetone	1.8	100.0	0.0	0.0	0.0	0.0
Naproxen	1.8	100.0	0.0	0.0	0.0	0.0
Tizanidine hydrochloride	1.8	100.0	0.0	0.0	0.0	0.0
Celecoxib	1.7	100.0	0.0	0.0	0.0	0.0
Lidocaine	1.6	0.0	—	99.8	0.0	0.2
Oxycodone hydrochloride	1.6	100.0	53.5	0.0	0.0	0.0
Diclofenac sodium	1.5	49.7	54.2	50.1	0.0	0.1
Duloxetine hydrochloride	1.5	100.0	0.0	0.0	0.0	0.0
Capsaicin/menthol/methyl salicylate	1.5	0.0	—	100.0	0.0	0.0
Acetaminophen	1.3	100.0	0.5	0.0	0.0	0.0
Pregabalin	1.3	100.0	0.0	0.0	0.0	0.0
Acetaminophen/tramadol hydrochloride	1.3	100.0	0.0	0.0	0.0	0.0
Etodolac	1.2	100.0	66.8	0.0	0.0	0.0
Menthol	1.2	0.0	—	100.0	0.0	0.0
Acetaminophen/oxycodone hydrochloride	1.1	100.0	0.0	0.0	0.0	0.0
Orphenadrine citrate	1.0	99.5	100.0	0.0	0.5	0.0

SOURCE: RAND Analysis of WCIS 2013 and formulary files from the sponsors.

NOTES: Bills for drugs used in compounding and drugs with deactivated NDCs were excluded from the numerator and denominator for the calculation of the percent of WCIS payments mentioned in each formulary for each active ingredient.

APPENDIX B

Example Formulary

As an example, RAND merged the ODG and ACOEM lists of drug recommendations together to compare how the two treat each active ingredient and which active ingredients would require PR. These two listings of drug recommendations were chosen because they form the basis for the majority of MTUS guidelines currently in use in California.

Table B.1 compares, for ACOEM and ODG, the active ingredients accounting for more than 1 percent of paid bills in WCIS. We find that both formularies address most high-volume WCIS drugs except for some notable exceptions such as zolpidem tartrate (Ambien, not in ACOEM) and topical combinations such as capsaicin/menthol/methyl salicylate or triamcinolone acetonide (topical corticosteroid).

For ACOEM, the PR criteria are illustrative and based on the drug recommendations for low-back, shoulders, and knees for updated ACOEM clinical topics (from Table 4.3). There are important differences in PR criteria. The notable examples are the opioids where ODG does not require PR for some of these drugs, while the RAND-derived ACOEM PR recommendations would require review for all opioids.

Some of the differences in preferred status between ACOEM and ODG may be resolved on further clinical review. For example, the gastrointestinal drugs such as omeprazole are commonly prescribed with NSAIDs to mitigate the side effects of NSAIDs. These drugs had a "Yes" recommendation in the ACOEM guidelines, but the comments to the prescribers were unclear about whether these drugs are first-line treatments. Ibuprofen, naproxen, and naproxen sodium largely are approved for most instances in the knee, shoulder, and low-back injuries in ACOEM, but not always. That is why these drugs are also marked as requiring further clinical review. The recommendations for several commonly used active ingredients, such as acetaminophen and aspirin, were also unclear as to whether they would be preferred treatments, so these are also marked as nonpreferred requiring clinical review.

In addition to comparing the PR recommendations for ACOEM, we have applied the order of guideline precedence. As discussed in Chapter Seven, the updated MTUS chronic pain guidelines give precedence to the ODG-based chronic pain guidelines over the ACOEM-based clinical topics when the treatment recommendations are at variance. Because we were working with WCIS aggregate files, we were unable to identify which drug line items were prescribed for injured workers with knee, shoulder, and low-back injuries and chronic pain conditions and reversed the order so that the updated ACOEM guidelines have precedence over the chronic pain treatments. As a result, the ODG chronic pain guideline would apply only if the treatment is not addressed in the relevant ACOEM body part chapter. To summarize, the order of precedence in this illustrative formulary is:

1. DWC guidelines for opioid usage
2. Updated ACOEM guidelines for clinical topics (which include recommendations for chronic pain)
3. ODG guidelines for chronic pain treatments not covered in the body part chapters for individuals with chronic pain.

If DWC decides to retain the current guideline structure, the actual PR requirements would depend on how the ACOEM-based drug recommendations are operationalized into PR requirements using clinical review and the order of precedence set for the guidelines.

The DWC guidelines for opioid usage would require PR for all prescriptions (except perhaps under a first-fill policy). If an ACOEM guideline does not address a drug ingredient, PR would be required unless the injured worker had chronic pain and the treatment is addressed in the chronic pain guidelines. We found that only one drug (zolpidem tartrate) that is not addressed in ACOEM would not require PR if the ODG chronic pain guideline were applicable. For this particular drug, ACOEM would have precedence unless the injured worker has chronic pain. If the injured worker has chronic pain, PR would not be required. But if the injured worker does not have chronic pain, PR would be required because the treatment is not addressed in the applicable ACOEM-based guidelines. Two other benzodiazepines that are only in the chronic pain guidelines require PR, so there would be no difference in the PR requirement for injured workers with or without PR.

Table B.1
Comparison of ODG and ACOEM Drug Recommendations, by Active Ingredient with Proposed PR

Ingredient	Therapeutic Class	Subclass	Percentage of Lines in WCIS	In Both ODG and ACOEM[a]	In ODG[a]	ODG Pref. or Not[b]	In ACOEM[a]	ACOEM Pref. or Not[b]	Guideline with Precedence?	Pref. or Not in That Guideline[b]
Acetaminophen/ hydrocodone bitartrate	Analgesics, antipyretics	Opiate agonists	15	1	1	P	1	NP	DWC	NP
Ibuprofen	Analgesics, antipyretics	NSAIDs	5	1	1	P	1	P[c]	ACOEM	P[c]
Omeprazole	Gastrointestinal drugs, misc.	Unspecified (5640010000)	5	1	1	P	1	NP[c]	ACOEM	NP[c]
Tramadol hydrochloride	Analgesics, antipyretics	Opiate agnostics	4	1	1	P	1	NP	DWC	NP
Cyclobenzaprine hydrochloride	Muscle relaxants, skeletal	Muscle relaxants, skel-central	4	1	1	P	1	NP	ACOEM	NP
Naproxen sodium	Analgesics, antipyretics	NSAIDs	4	1	1	P	1	P[c]	ACOEM	P[c]
Gabapentin	Anticonvulsants	Anticonvulsants, misc.	3	1	1	P	1	NP	ACOEM	NP
Carisoprodol	Muscle relaxants, skeletal	Muscle relaxants, skel-central	2	1	1	NP	1	NP	ACOEM	NP
Zolpidem tartrate	Anxiolytic, sedatives, hypnotics	Anxiolytic/sed./hyp., misc.	2	0	1	P	0	—[d]	Depends on whether chronic pain condition present	Depends on which guideline has precedence
Diclofenac sodium	Analgesics, antipyretics	NSAIDs	2	1	1	P	1	NP[c]	ACOEM	NP[c]
Nabumetone	Analgesics, antipyretics	NSAIDs	2	1	1	P	1	P	ACOEM	P
Naproxen	Analgesics, antipyretics	NSAIDs	2	1	1	P	1	P[c]	ACOEM	P[c]
Tizanidine hydrochloride	Muscle relaxants, skeletal	Muscle relaxants, skel-central	2	1	1	P	1	NP	ACOEM	NP
Celecoxib	Analgesics, antipyretics	NSAIDs	1	1	1	P	1	NP[c]	ACOEM	NP[c]

Table B.1—Continued

Ingredient	Therapeutic Class	Subclass	Percentage of Lines in WCIS	In Both ODG and ACOEM[a]	In ODG[a]	ODG Pref. or Not[b]	In ACOEM[a]	ACOEM Pref. or Not[b]	Guideline with Precedence?	Pref. or Not in That Guideline[b]
Acetaminophen/ oxycodone hydrochloride	Analgesics, antipyretics	Opiate agonists	1	1	1	P	1	NP	DWC	NP
Acetaminophen/ tramadol hydrochloride	Analgesics, antipyretics	Opiate agonists	1	1	1	P	1	NP	DWC	NP
Lidocaine	Antipruritics/local anest., S/m	Unspecified (8408010000)	1	1	1	NP	1	NP	ACOEM	NP
Oxycodone hydrochloride	Analgesics, antipyretics	Opiate agonists	1	1	1	NP[b]	1	NP	DWC	NP
Duloxetine hydrochloride	Psychotherapeutic agents	Antidepressants	1	1	1	P	1	NP[c]	ACOEM	NP[c]
Capsaicin/menthol/ methyl salicylate	Skin/mucous membrane ag., misc. (8436000000)	Analgesics, S/M	1	0	0	—[d]	0	—[d]	ACOEM	NP
Acetaminophen	Analgesics, antipyretics	Analgesics and antipyretics, misc.	1	1	1	P	1	NP[c]	ACOEM	NP[c]
Pregabalin	Miscellaneous cns agents	Unspecified (2892010000)	1	1	1	P	1	NP[c]	ACOEM	NP[c]
Etodolac	Analgesics, antipyretics	NSAIDs	1	1	1	P	1	P	ACOEM	P
Menthol	Skin/mucous membrane ag., misc. (8436000000)	Unspecified (8436010000)	1	1	1	—[d]	1	NP[c]	ACOEM	NP[c]
Pantoprazole sodium	Gastrointestinal drugs, misc.	Unspecified (5640010000)	1	1	1	NP	1	NP[c]	ACOEM	NP[c]
Orphenadrine citrate	Muscle relaxants, skeletal	Muscle relaxants-skeletal, misc	1	1	1	NP	1	NP	ACOEM	NP[c]
Acetaminophen/codeine phosphate	Analgesics, antipyretics	Opiate agonists	1	1	1	P	1	NP	DWC	NP
Alprazolam	Anxiolytic, sedatives, hypnotics	Benzodiazepines (anxiolytic)	1	0	1	NP	0	—[d]	Depends on chronic pain	NP

Table B.1—Continued

Ingredient	Therapeutic Class	Subclass	Percentage of Lines in WCIS	In Both ODG and ACOEM[a]	In ODG[a]	ODG Pref. or Not[b]	In ACOEM[a]	ACOEM Pref. or Not[b]	Guideline with Precedence?	Pref. or Not in That Guideline[b]
Meloxicam	Analgesics, antipyretics	NSAIDs	1	1	1	P	1	NP	ACOEM	NP
Ketorolac tromethamine	Analgesics/, antipyretics	NSAIDs	1	1	1	P	1	NP	ACOEM	NP
Morphine sulfate	Analgesics/, antipyretics	Opiate agonists	1	1	1	NP	1	NP	DWC	NP
Docusate sodium	Cathartics and laxatives	Stool softeners	1	0	0	—[d]	0	—[d]	ACOEM	NP
Diazepam	Anxiolytic, sedatives, hypnotics	Benzodiazepines (anxiolytic)	1	0	1	NP	0	—[d]	ACOEM	NP
Trazodone hydrochloride	Psychotherapeutic agents	Antidepressants	1	1	1	NP	1	NP	ACOEM	NP
Methocarbamol	Muscle relaxants, skeletal	Muscle relaxants, skel-central	1	1	1	P	1	NP	ACOEM	NP
Amitriptyline hydrochloride	Psychotherapeutic agents	Antidepressants	1	1	1	P	1	NP[c]	ACOEM	NP[c]
Bupropion hydrochloride	Psychotherapeutic agents	Antidepressants	1	1	1	NP	1	NP	ACOEM	NP
Lorazepam	Anxiolytic, sedatives, hypnotics	Benzodiazepines (anxiolytic)	1	0	1	NP	0	—[d]	Depends on chronic pain	NP

SOURCE: RAND analysis of ACOEM and ODG drug recommendations, as well as pharmacy claims from WCIS.

NOTES: In calculating percentage of lines in WCIS, claims for bulk or compounded drugs or for missing or corrupted NDC codes were excluded. RAND established the preferred status for ACOEM active ingredients according to the methodology laid out in Appendix A. We developed the PR criteria for knee, shoulder, and low-back injuries only, so some drugs are missing from this table either because they are used in the treatment of other conditions or are not in ACOEM's recommended list for any condition.

[a] 1 = yes; 0 = no.

[b] P = preferred; NP = nonpreferred.

[c] Requires further clinical review to establish preferred status.

[d] Drug not listed.

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