

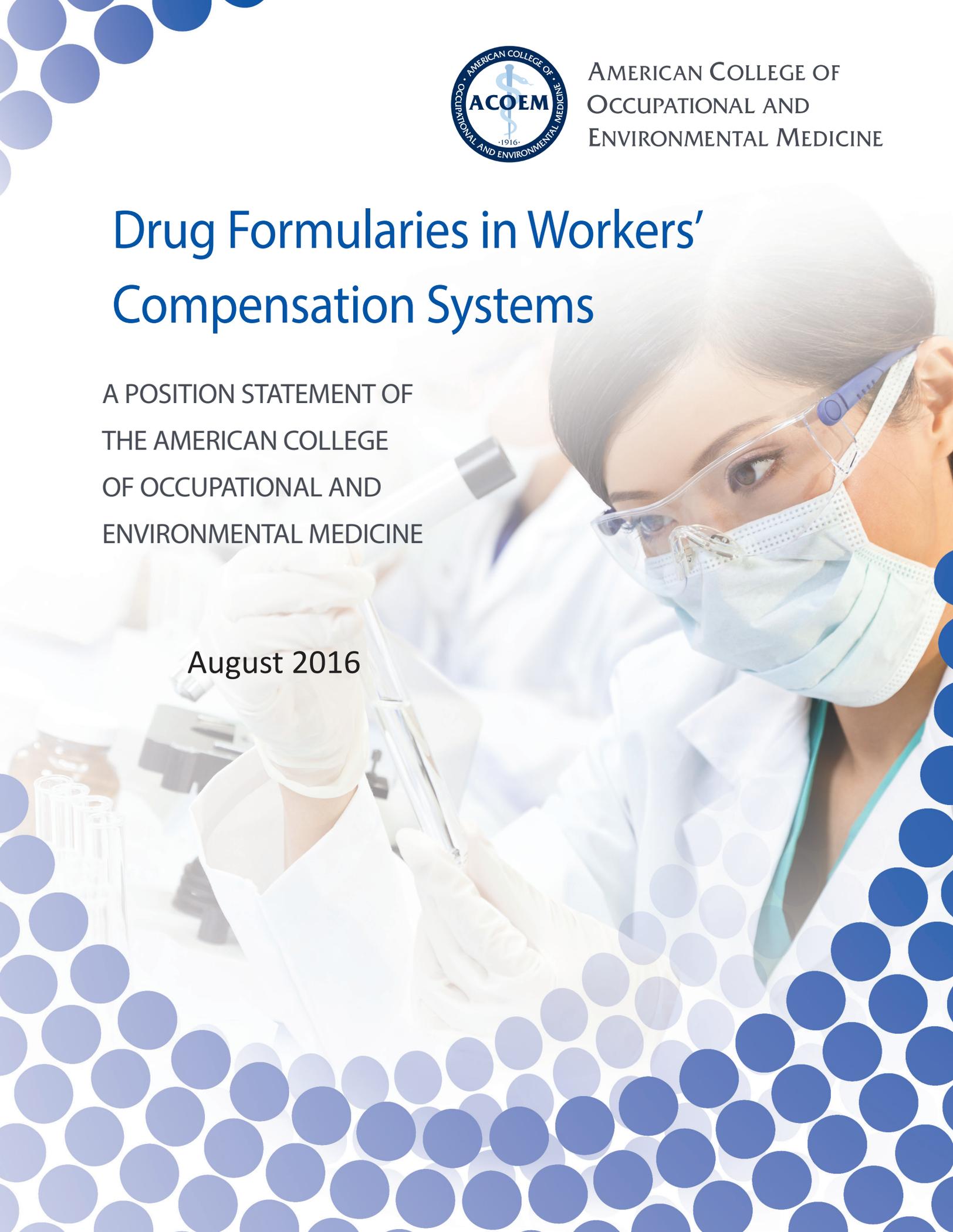


AMERICAN COLLEGE OF  
OCCUPATIONAL AND  
ENVIRONMENTAL MEDICINE

# Drug Formularies in Workers' Compensation Systems

A POSITION STATEMENT OF  
THE AMERICAN COLLEGE  
OF OCCUPATIONAL AND  
ENVIRONMENTAL MEDICINE

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## AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

### ABOUT ACOEM

Founded in 1916, the American College of Occupational and Environmental Medicine (ACOEM) is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. The College represents more than 4,500 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM).

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# Drug Formularies in Workers' Compensation Systems

## *A Position Statement from the American College of Occupational and Environmental Medicine*

### EXECUTIVE SUMMARY AND RECOMMENDATIONS

As a number of states consider establishing workers' compensation formularies, the American College of Occupational and Environmental Medicine (ACOEM) has reviewed how formulary use might affect medical quality and cost in the care of injured workers. ACOEM recognizes that the use of drug formularies has produced significantly lower direct costs for drugs in workers' compensation cases, but also recognizes that if the details of a formulary system are not well managed, formulary use may delay care for some patients and increase administrative costs. Furthermore, ACOEM recognizes that a well-organized formulary system, founded on the principles of evidence-based medicine, can be expected to drive improvements in medical quality.

#### Workers' Compensation Formularies – Benefits vs Risks\*

BENEFITS – proven or likely	ADVERSE CONSEQUENCES – potential
Lower total drug costs	Patients LESS compliant with treatment
Decreased opioid use	Medical decision may not be patient-focused
Diminished use of compounded topical medications	Increased burden for providers
Lower utilization review (UR) costs	Increased UR or other administrative costs

\*See text for detailed discussion and references.

At present, there are two commercially available workers' compensation formularies—the Reed Group formulary based on the ACOEM *Practice Guidelines*,<sup>1</sup> and the ODG® formulary published by Work Loss Data Institute. In addition, five states have adopted their own state-specific formulary systems. This document reviews the key features of formularies and discusses how the use of formularies in general might interact with existing utilization review (UR) processes. State legislators and other policy makers in state labor agencies, in deciding on the details of a workers' compensation drug formulary in their jurisdictions, should consider the following policy issues:

#### 1) **Formulary's Evidence Base:**

ACOEM recommends that a formulary be based on well-documented evidence-based methodology (EBM). Two workers' compensation formularies in current use do so—the Reed Group formulary based on the ACOEM *Practice Guidelines*,<sup>1</sup> and the Washington State formulary based on the Drug Effectiveness Review Project (DERP).<sup>2</sup>

#### 2) **Formulary's Format—Condition-Based:**

ACOEM sees great merit in a condition-based formulary such as the Reed Group's. However, ACOEM cautions that diagnostic categories should not be made so specific as to trigger UR disputes over the details of an ICD-9 or ICD-10 diagnostic code.

#### 3) **Formulary Oversight—Pharmacy and Therapeutics Committee:**

Whether a state chooses to adopt a commercial workers' compensation formulary or craft one that is state-specific, ACOEM recommends that a pharmacy and therapeutics (P&T) Committee, with occupational medicine physicians among its leaders, oversee the formulary's content. The P&T Committee should be charged

with: 1) providing guidance prior to implementation; 2) updating formulary entries at regular intervals, perhaps as often as quarterly; and 3) establishing a set of decision-making criteria for its own use. The P&T's decisions should be public and transparent.

#### **4) *Formulary Implementation and Application:***

ACOEM recommends that formulary regulations be crafted to be consistent with existing UR processes and treatment guidelines. Such formulary regulations should seek to minimize delays in filling prescriptions, particularly for “early fills” or for “critical” medications. When a formulary system is first established, provision must be made for initial ramp-up, particularly for “legacy claims” where patients may already have been using non-formulary medications. In addition, formulary entries should be readily accessible to the public.

ACOEM further recommends that state workers' compensation fee schedules should be revised if necessary, in order to reimburse providers for performing additional time-consuming tasks associated with documenting medical necessity, complying with step-care provisions, and communicating with pharmacy benefit managers (PBMs) and UR agents.

#### **5) *Procedures for Authorization and UR Appeals:***

ACOEM recommends that states establishing a workers' compensation formulary also institute a means by which providers can request authorization for non-formulary medications based on medical necessity. Providers recommending such treatments should be encouraged to propose disciplined and rational clinical trials of certain non-formulary medications, using a hierarchy of medical evidence, when standard treatments have failed or are inappropriate. Additionally, states must implement a robust UR appeals process, allowing providers an additional opportunity to justify medical necessity when disputes with PBMs or UR agents arise.

#### **6) *Measuring the Formulary's Value:***

ACOEM recommends that state laws and regulations establishing a workers' compensation formulary also include provisions to monitor the formulary's value. Over time, states should examine their carrier-reported claims and medical payment data in order to measure drug costs, overall drug utilization, rate of provider use of formulary-approved drugs, and the administrative costs of UR, as well as selected outcome quality metrics such as total claim cost, disability duration, patient satisfaction and compliance, and the rate of adverse effects resulting from treatment delays.

### INTRODUCTION

Drug formularies, widespread in the private group health market for decades,<sup>3</sup> and now embedded in Medicare since the passage of Medicare Part D,<sup>4</sup> have only recently been adopted in certain state workers' compensation systems. In 2006, North Dakota became the first state to adopt a workers' compensation formulary, conceived as an open formulary with certain restrictions as described below. In 2011, Texas became the first state to adopt a closed formulary for its workers' compensation system.<sup>5</sup> Since then, eight other states (Arkansas, Delaware, Nevada, Ohio, Oklahoma, Tennessee, Washington, and Wyoming) have adopted or are in the process of adopting workers' compensation formularies. Several other states are currently considering doing so, based in part on studies demonstrating that formularies can dramatically decrease the direct cost of medications, the costs of utilization review (UR), and the inappropriate use of certain medications including opioids, non-generics, and compounded topical medications.<sup>6</sup>

Other studies have demonstrated that non-formulary drugs account for a disproportionate share—as much as 40%—of total drug costs, while comprising a relatively small proportion of total prescriptions.<sup>7</sup> However, at least one state (Colorado) has recently chosen explicitly not to adopt a workers' compensation formulary, but instead to rely on other UR processes to curtail inappropriate prescribing in workers' compensation cases.<sup>8</sup>

Because setting up a formulary involves multiple policy choices affecting quality, cost, and administrative complexity, the American College of Occupational and Environmental Medicine (ACOEM) has undertaken to summarize some of the clinical and policy issues which state legislative and regulatory bodies should consider if they choose to adopt a workers' compensation formulary in their jurisdictions. In a number of areas described below, ACOEM has crafted specific policy recommendations about workers' compensation formularies.

#### A. *Drug Formularies—Typical Characteristics*

**SUMMARY STATEMENT: Approaches and coverage for existing workers' compensation formularies vary and the strengths and weaknesses among these approaches must be weighed to avoid gaps in coverage and to prevent prescribing restrictions from lowering patient compliance.**

Drug formularies are typically constructed as lists of medications grouped according to some classification scheme, such as the classification system published by the American Hospital Formulary Service (AHFS), and used by the Centers for Medicare and Medicaid Services (CMS).<sup>9</sup> Formularies are sometimes classified as “open” (a simple and non-exclusive listing of drugs covered under the drug plan, frequently with various levels of cost-sharing by the patient), or “closed” (only listed drugs are covered), although considerable overlap exists.

Medicare has established drug coverage rules for pharmacy plans and formularies that can be authorized under Part-D (drug benefits), labeling certain classes of drugs as “protected classes.” More specifically, CMS regards certain classes of drugs on a Medicare formulary as “protected” if those drugs meet criteria for “criticality” (the risk that a delay in filling the prescription will lead to hospitalization, death, or significant morbidity) or “non-interchangeability.” A drug is said to be “non-interchangeable” if no other available drug can reasonably be substituted for it, as is the case with certain anti-viral or chemotherapeutic agents.<sup>10</sup> Drugs in these protected classes must be covered by Medicare Part-D plans, with a guarantee of a prompt fill without a lengthy pre-authorization process.

CMS permits Medicare drug coverage plans to attach restrictions to medications on Medicare formularies, including requirements related to prior authorization, quantity limits, and step therapy.<sup>11</sup> A requirement for “prior authorization” means that the patient and/or the provider must contact a pharmacy benefit manager (PBM) to demonstrate that the prescribed drug is medically necessary. “Step therapy” or the use of “preferred drug lists” (used, for example, in the workers’ compensation systems of Delaware, North Dakota, and Washington) may involve a requirement that the patient must try one or more similar lower-cost drugs before the drug plan will cover the more expensive drug.

However, a recent literature review found that while such restrictions on prescribing led to significant cost reductions, it also resulted in lower patient compliance rates.<sup>12</sup> More research is needed on how formulary policies may impact the balance among cost, promotion of high-quality prescribing, and patient adherence to recommended treatment, in order to establish the overall value of formularies for out-patient medical care.

A comparison of seven available workers’ compensation formularies—those published by Work Loss Data Institute (ODG Formulary)<sup>13</sup> and the Reed Group,<sup>14</sup> and state-specific formularies in Washington,<sup>15</sup> North Dakota,<sup>16</sup> Ohio,<sup>17</sup> Delaware,<sup>18</sup> and Wyoming,<sup>19</sup> illustrates some of the policy options involved in adopting a formulary for use in workers’ compensation systems. Characteristics of these formularies are summarized in Appendix A.

The ODG Formulary includes drugs in 25 different categories,<sup>13</sup> and lists each as “Yes” (recommended) or “No” (not recommended), based on clinical guidance contained in the *ODG Guidelines*. Certain drugs include a notation about conditions for which the drug is not indicated, notably the treatment of pain or insomnia. Otherwise, the ODG formulary is silent about the specific diagnoses or conditions for which the listed drugs might be prescribed and approved.

By contrast, the Reed Group formulary is condition-based,<sup>14</sup> listing diagnoses or types of work-related injuries or illnesses grouped into 11 categories (eight categories of musculoskeletal problems, plus chronic pain, eye conditions, and work-related asthma). The formulary then lists those medications for which the ACOEM *Practice Guidelines* have compiled evidence of efficacy in these diagnostic categories, and labels each drug as “Yes” (recommended), “No” (not recommended), or “No Recommendation.” The Reed Group formulary provides further clinical information about a drug’s indications for use, and the strength of the available medical evidence for the recommendations. The formulary also includes drugs used to treat common medication side effects, such as dyspepsia caused by non-steroidal anti-inflammatory drugs (NSAIDs).

It should be noted that both the ODG and Reed Group formularies are silent about many drugs commonly used for other work-related conditions such as occupational dermatoses, dyspepsia complicating medication use, soft tissue infections, or occupational exposure to infectious agents requiring antibiotic prophylaxis. The Reed Group formulary is silent on many antibiotics and psychiatric drugs. The ODG formulary is silent about H-2 blockers.

Washington State has adopted a customized formulary based on the Drug Effectiveness Review Project (DERP),<sup>2</sup> with a “preferred drug list,” a limited number of drug categories, and an emphasis on generic prescriptions in most categories. In the Washington formulary, each listed drug is categorized as “A” (approved), “PA” (prior authorization required), or “D” (denied).<sup>20</sup>

North Dakota’s workers’ compensation formulary lists drugs in almost all of the AHFS categories. Certain drugs are listed as “non-formulary”; others are designated as “PA” (prior authorization required). The formulary further specifies maximum daily doses for certain medications.<sup>16</sup> Formulary decisions are made by a pharmacy and therapeutics (P&T) committee, based on consensus.<sup>21</sup>

In 2011, the Ohio Bureau of Workers' Compensation adopted a proprietary formulary, listing drugs in many of the AHFS categories. In addition, the Ohio formulary includes a separate list of drugs which may be approved, but which require prior authorization using a written process mandated by the Bureau. The Ohio workers' compensation formulary was last updated in 2014.<sup>17</sup>

In 2012, Delaware adopted a fairly simple formulary based on drugs covered under the Delaware Medical Assistance Program, administered under its Medicaid Program, covering a limited number of analgesics and eye drugs, and categorizing them as "preferred" or "non-preferred." Non-preferred drugs may be prescribed only after at least two preferred drugs have previously been tried.<sup>18</sup>

Wyoming subjects all workers' compensation prescriptions to pre-authorization and in 2014 passed specific rules for documenting medical necessity for the prescription of non-generic drugs, or drugs prescribed for off-label indications.<sup>19</sup> In addition, authorization is to be denied for compounded topical medications. To guide UR decisions, Wyoming has published an extensive list of drugs, categorized according to the Generic Product Identifier (GPI) scheme,<sup>22</sup> and has identified each drug as either "included" or "excluded."<sup>23</sup> Certain drugs are generally to be approved during the first 42 days after a work injury. Thereafter, many drugs are to be excluded, and their continued use must be justified by a provider's discussion of medical necessity.

### ***B. Formularies and Evidence-Based Medicine***

**SUMMARY STATEMENT: Formulary inclusion and exclusion decisions should follow principles of evidence-based medicine (EBM) where evidence exists. Utilization review decisions about prescription authorization should be subject to a robust appeals process, particularly where medical evidence may be lacking or where clinical practice is emerging.**

A decision to include, exclude, or otherwise restrict certain medications in a formulary should optimally follow principles of evidence-based medicine (EBM), including a ranking of the strength of medical evidence about a drug's efficacy and safety.<sup>24</sup> ACOEM's EBM methodology,<sup>25</sup> which underlies the Reed Group formulary, begins with the systematic identification of high-quality research studies. Studies are then graded, taking into account the study design and results, and the highest quality studies are reviewed in detail. The evidence-based methodology used by DERP underlies the Washington state workers' compensation formulary.<sup>26</sup>

Decision-making by UR agents or PBMs must necessarily follow a more flexible approach in applying formulary rules to specific clinical situations. An important clinical principle is that individual variability in the responses to various medications, notwithstanding strong evidence that on average one medication may be superior to another, argues that UR and PBM agents, while still adhering to established hierarchies of evidence,<sup>27</sup> should be cautious in restricting the choice of medications for individual patients where the evidence may be equivocal.

### ***C. Pharmacy and Therapeutics (P&T) Committees***

**SUMMARY STATEMENT: The establishment of a pharmacy and therapeutics (P&T) committee is recommended to provide guidance prior to formulary implementation and to oversee the content and operations of a workers' compensation formulary in a way that is public and transparent.**

It is common practice that hospitals, health plans, or other entities establishing a drug formulary for the group health market will also establish a body of experts, often called the Pharmacy and Therapeutics (P&T) Committee, to oversee the clinical management of the formulary. The P&T Committee will make decisions about including or excluding medications, restricting their use to certain diagnoses, and specifying other conditions for UR approval based on such considerations as clinical urgency or non-interchangeability.<sup>28</sup> The P&T Committee will typically establish a set of guidelines for its own decision-making.<sup>29</sup> ACOEM recommends that a P&T Committee also oversee the content of workers' compensation formularies.

ACOEM further recommends that a workers' compensation P&T Committee include among its leaders one or more occupational medicine physicians, or other physicians with expertise in disability management and other areas of occupational medicine practice, while also including medical, nursing, and pharmacy professionals with expertise in clinical pharmacology, orthopedics, pain management, physical medicine, neurology, psychiatry, ophthalmology, medical ethics, health economics, and/or other relevant specialties. Furthermore, ACOEM recommends that all decisions of the P&T Committee be public and transparent.

The P&T Committee will provide guidance prior to formulary implementation and also reasonably oversee periodic modifications of the formulary, typically done at intervals ranging from monthly to annually. Formularies will need to be updated as new drugs are released or as new information becomes available about drug safety, drug indications, medication side effects, drug-drug interactions, and cost-effectiveness. Policy makers should further specify additional triggers for action by the P&T Committee that might include changes in the manufacturer's guidance for specific drugs, the inclusion of "black-box" or other warnings from the U.S. Food and Drug Administration, and/or petitions from practitioners in the jurisdiction.

### ***D. Learning Lessons from Texas and Other States***

#### **SUMMARY STATEMENT: Lessons can be learned from formulary implementation in other states, including the advisability of notifying stakeholders in advance about formulary requirements.**

A number of states, including Texas, Nevada, and Washington experienced dramatic cost savings after implementing formularies for their state workers' compensation systems.<sup>30</sup> Other states might be expected to experience similar savings.<sup>31</sup>

In setting up its workers' compensation formulary, Texas provided for a 2-year ramp-up interval which featured an administrative dispute-resolution process and the use of petitions by the patient or provider. These administrative processes proved to be particularly important for injured workers already under care who had been prescribed non-formulary medications. An important lesson was that for "legacy claims" injured workers, treating providers, and insurance carriers benefited from being notified about formulary requirements well in advance of the start date, with the goal of avoiding abrupt termination of non-formulary medications and resolving disputes administratively.

Texas also discovered that most change-overs from non-formulary to formulary-approved medications occurred late in the 2-year ramp-up window, suggesting that a shorter ramp-up period, perhaps 6 to 12 months, would be sufficiently long to enable legacy prescriptions to be switched to formulary-approved medications where appropriate.

Tennessee recently adopted the ODG formulary for workers' compensation prescriptions, and allowed an 8-month ramp-up for prescriptions first written after January 1, 2016, and a 14-month ramp-up for prescriptions first written before January 1, 2016.<sup>32</sup>

### E. Workers' Compensation Formularies and the UR Process

**SUMMARY STATEMENT: Processes for prescription approval using a workers' compensation formulary should be harmonized with existing utilization review processes. These processes should be fair and robust in allowing for "step care" and for disciplined clinical trials involving certain non-formulary medications when standard treatments have failed or are contra-indicated. Pre-authorization requirements and restrictions on the use of non-designated pharmacies should not delay the filling of certain prescriptions.**

Successful implementation of a workers' compensation formulary will require integration with a jurisdiction's existing medical treatment guidelines, if any, and UR processes. Among the state workers' compensation programs, 15 have adopted state-specific clinical guidelines. Five states (California, Montana, Nevada, New York, and Utah) have adopted ACOEM's *Practice Guidelines* in whole or in part, while eight states have adopted the *ODG Guidelines*, which rely more heavily on consensus decision-making than do the ACOEM *Practice Guidelines*.<sup>33</sup>

Two states (California and Utah) have adopted a hybrid of the ACOEM, ODG, and other guidelines, which differ in some details and in their use of EBM methodologies. At this time, nearly half of the states have not adopted formal treatment guidelines.<sup>34,35</sup>

Where a workers' compensation formulary exists, UR agents or PBMs will use the formulary to decide whether to authorize payment for prescriptions in a workers' compensation claim. Accordingly, policy makers must determine at what point the approval of prescriptions should happen. For example, approval could occur when a dispensing pharmacist, presented with a workers' compensation prescription, contacts a PBM or other claims agent to request a guarantee of payment for the dispensed medication. Alternatively, for non-formulary medications, the medical provider might be required to send the claims administrator a "request for authorization" form at the time the prescription is written. Patients might then be instructed to wait for a designated pharmacy or PBM to notify them that an authorization decision has been reached and, if affirmative, that the medication can be picked up at a designated pharmacy or delivered to the patient. In either case, the authorization process can delay the filling of a prescription by hours or even days.

Little research has been done on the consequences of delayed prescription fills and whether such delays might contribute to delayed recovery or other adverse outcomes with costs potentially exceeding drug-cost savings. Aware of this problem, especially early in the course of care, a number of carriers and state jurisdictions have instituted specific policies for "first fill" or "early fill" prescriptions, guaranteeing payment to pharmacies filling prescriptions for "approved" medications within the first day, and sometimes up to the first month after filing a new workers' compensation claim.<sup>36</sup> For example, in North Dakota, a pharmacy may fill one set of prescriptions for formulary-approved drugs, provided that the provider has indicated on the prescriptions a date of injury within the past 30 days.<sup>37</sup>

ACOEM also recognizes that principles of patient-centered care should guide policy makers as they craft rules for how quickly workers' compensation prescriptions must be filled in order to assure prompt, courteous, and appropriate treatment of work-related injuries and illnesses. ACOEM further recognizes that the formularies used in Delaware, North Dakota, and Washington, which as previously noted include an extra drug categorization ("preferred drug" or "authorization required") may provide additional guidance for providers, carriers, and PBMs.

Of additional importance, some drugs are recognized to have “off label” efficacy before formal research or evidence-based reviews have validated such use. In cases where formulary-approved drugs or other standard treatments have failed or are contraindicated, alternative approaches should sometimes be tried. Clinicians should not be discouraged from undertaking such individual clinical trials, provided they articulate a rationale for their decisions based on external evidence and conduct the trial in a disciplined way. Accordingly, states implementing a workers' compensation formulary should also assure an accompanying fair and robust appeals process permitting occasional well-reasoned deviations from formulary rules.

ACOEM believes that a UR decision to modify or deny an injured worker's prescription must be communicated by the carrier in writing to the prescribing doctor and injured worker in a clear and prompt manner. In such cases, formulary and UR regulations should assure close communication between PBMs and clinicians. Following discussions with the PBM resulting in non-approval of previously prescribed drugs, the prescribing doctor must also discuss any planned modifications with the injured worker. There must be an adequate time period authorized to assess the clinical effectiveness and lack of adverse effects from these modifications.

Finally, as for all UR systems, where a medication dispute persists despite the above steps, UR processes should include an administrative solution to review the clinical facts and medical necessity of continuing non-formulary medications, or formulary medications for non-formulary indications, and should set the frequency of periodic reevaluations of the need for chronic medications.

Since these additional steps can be time consuming for clinicians, policies for the implementation of a formulary should aim to pay providers for the extra time required for documenting medical necessity, following step-care procedures, and communicating with PBMs and UR agents. Payment to providers may require the establishment of new workers' compensation billing codes in some jurisdictions. As an example, the Arizona Industrial Commission recently approved two new billings codes aimed at reimbursing clinicians \$75 to \$100 for the time required to discuss medical necessity issues with UR agents.<sup>38</sup>

### ***F. Additional Quality Metrics***

**SUMMARY STATEMENT: ACOEM recommends that states measure a range of quality metrics as part of implementing a workers' compensation formulary in order to establish the formulary's true value.**

As noted above, states that have established workers' compensation formularies have seen markedly reduced direct drug costs, related in significant part to reductions in the prescribing of opioids, compounded topical medications, and non-generics.<sup>30</sup> However, these cost savings, while significant, capture only part of the potential gains and losses from the adoption of a formulary system. In many cases, the benefits may also be clinical, resulting from encouraging providers to follow evidence-based guidelines and to substitute more effective drugs for less effective ones.

However, on the “loss” side there may be significant additional administrative and process-induced costs not captured by a simple tabulation of direct drug costs. As previously noted, in group health care settings certain UR practices to limit the use of expensive drugs have been shown to worsen medication compliance with treatment recommendations.<sup>12</sup> Furthermore, administrative efforts to align prescriptions arising in “legacy claims” with a newly established formulary can involve considerable time and effort both for claims administrators and for clinicians.

In order to establish the value of a formulary system, ACOEM recommends that states include specific provisions to measure a broad range of outcome variables in order to assess the impact, efficacy, and cost of formulary adoption, including total claim cost, rates of delayed return-to-work or delayed claim closure, the costs of UR itself, and patient and provider satisfaction. Additionally, the work of the P&T Committee can itself be time consuming and costly, with a risk of poor medical practice if the P&T Committee should fail to update the formulary in a timely manner.

In summary, failing to measure important outcome variables, in addition to direct drug costs—a limited metric—may bias the assessment of the formulary's value. Since workers' compensation systems already tend to suffer from a burden of complex rules and adversarial interactions, policy makers should strive to assure that the formulary processes are both "patient-centric" and "provider-friendly." Along these lines, states might choose to measure the frequency of delays in filling prescriptions and the frequency of administrative errors by providers or PBMs in the process of filling prescriptions. Additionally, states may wish to explore the possibility of assisting medical providers by linking formulary entries with decision-support routines in commonly used electronic health records.

### ***G. Clinical Case Studies: Prompt Fill Challenges***

#### **SUMMARY STATEMENT: Delays in filling a workers' compensation prescription can harm the patient.**

There are many clinical circumstances in which a workers' compensation prescription should be filled promptly and not delayed by UR. Where a workers' compensation formulary is in place, such delays might occur because the formulary is silent about the drug or because the drug is categorized as "non-preferred" or "pre-authorization required."

The following vignettes illustrate cases that may arise from time to time and present challenges for PBMs and claims administrators in assuring that authorization procedures will not delay the rapid filling of certain prescriptions.

#### ***1) Bloodborne pathogen exposure:***

An employee who has suffered a work-related needle-stick injury from a known HIV-positive source must be started on an appropriate and potentially expensive anti-retroviral drug within hours of the work exposure. Such treatment, whether covered under workers' compensation or under Occupational Safety and Health Administration mandated care paid for directly by the employer, must be managed quickly by PBMs or other UR agents. No current workers' compensation formularies include or categorize anti-retrovirals except Ohio's and Wyoming's, with the Wyoming formulary "excluding" anti-retrovirals.<sup>17,23</sup>

#### ***2) Soft-tissue infection complicating a work-related wound:***

An employee who develops a serious infection some days after an initial work-related laceration or puncture wound can often be managed as an outpatient, but he or she will need to be started promptly on systemic antibiotics. Some current formularies are silent about many second- or third-generation antibiotics, which might be required in patients with co-morbidities such as diabetes or other immunosuppressed states.

#### ***3) Acute gout complicating a soft-tissue sprain/strain:***

Gout-prone workers who suffer lower extremity sprain and strains will occasionally develop an acute flare of gout near the affected joint. A delay in starting colchicine or other medications for gout can prolong total temporary disability and result in needless suffering in such patients. Of the seven formularies mentioned above, four are silent regarding colchicine (ODG, Delaware, Ohio, and Washington).

4) *Severe hypertension complicating a workplace violence episode:*

An employee with an accepted claim for workplace stress (e.g., following an episode of workplace violence) may be found to be dangerously hypertensive soon after the work-related assault. A rapid-acting anti-hypertensive medication may need to be started promptly in the outpatient setting. A few of the previously mentioned formularies include and categorize anti-hypertensive medications, but others do not.

5) *Nausea and vomiting complicating heat exhaustion:*

A worker who suffers a mild-to-moderate case of heat exhaustion complicated by modest dehydration can often be orally rehydrated as an outpatient, provided the patient's nausea can be quickly controlled. Most formularies are silent about drugs commonly used for nausea, such as ondansetron or trimethobenzamide, which if started promptly can forestall more expensive care such as IV treatment or hospital referral.

6) *Asthma exacerbation at work:*

An employee whose asthma suffers an exacerbation resulting from a work-related exposure to an airborne irritant may have to be started promptly on bronchodilators and high-dose oral corticosteroids. A few of the previously mentioned formularies are silent about either or both of these treatments.

7) *Deep vein thrombosis:*

An employee with a severe soft tissue contusion or crush injury to the lower extremity may occasionally develop a deep vein thrombosis, requiring immediate hospital treatment for anticoagulation over a few days, followed by a discharge prescription for an oral anticoagulant for several weeks. The discharge prescription must be filled promptly to avoid a gap in anticoagulation. The only formularies mentioning anti-coagulants are those from North Dakota, Ohio, and Wyoming, while the Reed Group formulary includes anti-coagulants when prescribed in the peri-operative period.

### **H. Summary of ACOEM Recommendations:**

ACOEM believes that if a workers' compensation formulary is to be established, a condition-triggered evidence-based formulary is the preferred approach. As previously discussed, policy makers must also establish other administrative processes related to UR, dispute resolution during ramp-up, assurance of non-delayed prescription fills in urgent clinical situations, robust oversight involving a P&T Committee, and careful measurement of outcome variables to assure the overall value of the formulary. To that end, ACOEM believes that state legislators and other policy makers should consider the following questions if they choose to implement a workers' compensation formulary in their jurisdiction, and recommends specific solutions.

1) *What level of evidence should underlie a state's workers' compensation formulary?*

ACOEM recommends that the formulary be based on well-documented evidence-based methods such as those embodied in the ACOEM *Practice Guidelines* and the Reed Group formulary, or in the Washington State workers' compensation formulary.

2) *What type of organizational format should the formulary follow?*

ACOEM sees great merit in a condition-based formulary such as the Reed Group formulary. However, ACOEM cautions that diagnostic categories not be made so specific as to give rise to UR disputes over the details of an ICD-9 or ICD-10 diagnostic code.

3) *How should ongoing quality oversight of formulary content be assured?*

ACOEM recommends that a P&T Committee, with occupational medicine physicians among its leaders, provide guidance prior to formulary implementation and oversee formulary content. The P&T Commit-

tee should then be charged with updating the formulary entries at regular intervals, perhaps as often as quarterly, and establishing a set of decision-making criteria for its own use. All decisions of the P&T Committee should be public and transparent and formulary entries should be readily accessible to the public.

4) *How should the use of the formulary be integrated with existing UR processes?*

ACOEM recommends that formulary regulations be crafted so as to be consistent with other UR processes, to take account of treatment guidelines in current use, and to minimize delays in filling prescriptions, particularly for “early fills” or when “critical” medications are prescribed. When a formulary system is first established, provision must be made for initial ramp-up, particularly for “legacy claims” where patients may already have been using non-formulary medications.

ACOEM further recommends that fee schedules be properly aligned with clinical quality goals in order to incentivize providers to undertake the additional time-consuming tasks associated with documenting medical necessity, complying with step-care provisions, and communicating with PBMs and UR agents.

5) *How should appeals processes be designed related to the use of a workers' compensation formulary?*

ACOEM recommends that states establishing a workers' compensation formulary institute a robust appeals process for providers who for sound clinical reasons choose to prescribe non-formulary drugs or drugs requiring pre-authorization. Providers recommending such treatments should not be discouraged from proposing clinical rationales, based on a hierarchy of medical evidence, or from proposing disciplined and rational clinical trials of certain non-formulary medications when standard treatments have failed or are inappropriate.

6) *How should the formulary's overall value be assessed?*

ACOEM recommends that state laws and regulations establishing a workers' compensation formulary also include provisions to monitor the formulary's value. Across the time of formulary implementation, states should examine their carrier-reported claims and medical payment data in order to measure drug costs, overall drug utilization, rate of provider use of formulary-approved drugs, and the administrative costs of UR, as well as selected outcome quality metrics such as total claim cost, disability duration, patient satisfaction and compliance, and the rate of adverse effects resulting from treatment delays.

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**APPENDIX A: FEATURES OF EXISTING WORKERS' COMPENSATION FORMULARIES**

<b>Formulary</b>	<b>Evidence Base</b>	<b>Format and Organization</b>	<b>Guidance on Medical Conditions?</b>	<b>Guidance on Pre-authorization?</b>
ODG	<i>ODG Guidelines</i>	Detailed listing of drugs in 25 categories	None, except two exclusion types for certain drugs	Drugs are "YES" or "NO"; no additional guidance
Reed Group	<i>ACOEM Practice Guidelines</i>	Condition-triggered plus acute vs. chronic in 44 drug classes	Yes, general condition, plus ICD-9 and ICD-10 codes	Drugs are "Recommended" or "Not recommended," plus strength of evidence
Delaware	Delaware Medical Assistance Program (Medicaid)	3 drug categories, with preferred/non-preferred drugs	None	Drugs are "Preferred" or "Not preferred"; "step care" for non-preferred drugs
North Dakota	State-specific P&T consensus	AHFS listing (partial)	None	Drugs are "OK," "Non-formulary," or "Prior Authorization"
Ohio	State-specific P&T consensus	AHFS listing (partial)	None	Separate listing of drugs requiring written prior authorization
Washington	Drug Effectiveness Review Project (DERP)	19 drug categories	None	Drugs are "OK," "Non-formulary," or "Prior Authorization"
Wyoming	Unstated	64 GPI drug categories	None	Drugs are "Included" or "Excluded" with different categorization for drugs prescribed within 42 days of injury

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