CompPharma

CompPharma Platform on Drug Formularies
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Issue: Applying best practices to state drug formularies to provide patient safety and reduce inappropriate drug utilization by changing prescribing behaviors

A drug formulary is a term used in the pharmacy marketplace to define a list of drugs that can be dispensed without pre-authorization by a payer. Workers' compensation drug formularies contain medications generally used to treat occupational illnesses and injuries. These medications are included in a workers' compensation formulary because they are typically appropriate for first-line therapy for work-related illnesses and injuries, according to evidence-based medicine.

As the "voice" of workers' compensation pharmacy, CompPharma has been asked to provide an industry platform on the use of drug formularies and the enforcement of those formularies via utilization review by state workers' compensation systems. As with all of CompPharma's platforms, it has been written to help protect patient safety, ensure access to appropriate medications, and promote the use of evidence-based clinical guidelines.

Background:
State drug formularies became popular after Texas reported its closed drug formulary's success in controlling drug utilization and changing prescribing habits. Texas implemented its two-phased formulary effective September 1, 2011 for new claims and September 1, 2013 for legacy claims. Legacy claims were those with a date of injury prior to September 1, 2011. Texas ensured compliance with the formulary with a tight utilization review process requiring prior authorization for certain medications.

Texas utilizes an externally created and maintained medication source, the Official Disability Guidelines (ODG) Workers' Compensation Drug Formulary for its list of restricted medications. The Texas closed formulary includes all FDA-approved drugs, other than those on the "N" status list. Medications with an "N" status in the ODG Workers' Compensation Drug Formulary are not considered first-line for treatment of workers' compensation injuries/conditions and are not included on the formulary. Medications with an "N" status in the ODG Workers' Compensation Drug Formulary, experimental and investigational drugs, compounds including "N" drugs, and any non-FDA approved drugs require preauthorization before they can be dispensed. In this prospective utilization review process, the prescribing physician must demonstrate medical necessity for the medication.

Texas has attributed impressive reductions in both the number of claims with prescribed "N" drugs and the cost of "N" drugs to the effective implementation of the formulary. The following are some statistics:

Date	Reduction in # of Claims with	Reduction in Cost of "N"	Reduction in total #

	"N" drug Rx	Drugs	Prescriptions
Oct. 2012	60%	81%	12%
June 2013	59%	80%	9%
March 2014	65%	82%	9%

Texas' formulary implementation schedule recognized and addressed an extremely important aspect of managing claimants taking N-status prescription medications. After prolonged use, an abrupt discontinuation of many of the "N" drugs, specifically opioids and benzodiazepines, could result in a catastrophic situation for the injured worker. Appropriate tapering or reduction in use can take several months and requires special clinical management.

In Texas, there was extensive educational outreach across the entire state by the Division which included all stakeholders, specifically treating doctors, insurers, pharmacies, and injured workers. Texas also had the foresight to create two categories of claimants, "new" and "legacy," and different compliance deadlines for each to allow some phase-in of requesting medical necessity for legacy claims for "N" status drugs.

Physicians needed to request authorization to prescribe "N" drugs to new claimants as soon as the formulary was implemented on Sept. 1, 2011. The authorization process placed a control in front of prescribing and required medical necessity to be the driving factor in medication therapy. The formulary had the intended effect of discouraging utilization of "N" status medications on **new** claims.

Physicians did not need to request authorization for "N" drugs on **legacy** claims until September 1, 2013, two years after the implementation of the formulary on new claims. This enabled prescribers to educate patients and work with them on new drug treatment plans, and if necessary, have drug therapies involving "N" drugs approved by demonstrating medical necessity.

However, the Texas formulary treats all non-restricted medications as if they are medically necessary and appropriate to the injury, regardless of the type of injury or other factors. Thus, pharmacies may fill prescriptions for medications that may not be medically necessary or related to the injured worker's particular condition, bypassing the PBM. Dispensing them under workers' compensation increases workloads, administrative burden and workers' compensation costs while possibly harming or at best not helping the patient recover. This wide access to drugs not on the "N" list does nothing to stop access to inappropriate medications for the work-related injury/illness. If caught during retrospective review, the medication has already been dispensed by the pharmacy, taken by the injured worker, and often paid by the PBM, when a, more appropriate medication may be recommended. For this reason, CompPharma recommends states establish formularies with restricted drug lists, based on evidence, and to allow other medications to process through PBM tools designed to manage patient safety, appropriateness of therapy, medical necessity and compensability.

Since the implementation of the Texas formulary, Oklahoma has also instituted a workers' compensation-specific drug formulary effective February 1, 2014. Like Texas, Oklahoma uses the ODG Workers' Compensation Drug Formulary as the source for its restricted medications requiring preauthorization. In addition, Oklahoma also required **all compound medications** to undergo preauthorization as an important patient safety and medical necessity measure. Unlike Texas, Oklahoma did not address a process for prescribing and filling the unrestricted drugs, so PBMs are still able to manage patient safety, appropriateness of therapy, medical necessity and compensability through the use of appropriate edits and other programs of all "non-N" drugs for Oklahoma.

Some monopolistic states, such as Washington and Ohio, have state formularies for Medicaid and Workers' Compensation. Each of these states has a Pharmaceutics & Therapeutics Committee that services its claims and decides what drugs are automatically covered and which require preauthorization.

Recommendations:
Based on CompPharma's vast experience in the marketplace and clinical expertise, we have identified several key elements essential to an effective formulary states should consider when contemplating and adopting a drug formulary. These include:

Patient Safety and Access – State drug formulary processes must first take into consideration patient access to medications and patient safety. Processes and requirements such as prior authorization, review of medical necessity and emergency medical interlocutory orders (MIOs) ensure that physicians demonstrate a true necessity for usage of any restricted medications and protect the injured worker from potentially catastrophic harm.

Restricted List of Medications - Any state formulary should include a list of restricted medications (e.g., "N" drugs) requiring prior authorization before they are dispensed to injured workers. Preauthorization needs to be conducted in accordance with the state's preauthorization or utilization review mandates; if the state does not have strong utilization review controls coupled with evidence-based medical guidelines, a formulary will be ineffective at best. This will place the state-mandated and specific controls in front of the prescribing physicians and give the formulary regulatory backing. The restricted list should contain medications that are not considered first-line treatment for work-related injuries or illnesses, including compounded medications. Most compounds have not been proven to be safe or effective, nor are they FDA-approved. They are often not medically necessary; they are highly expensive, and evidence-based clinical guidelines indicate compounds are not considered appropriate or first-line treatment for work-related injuries.

Nationally Recognized/Evidence-Based/Workers Compensation-Specific/Independent Source for Drug List
The source of any state formulary's restricted drug list should be based upon nationally recognized evidence-based, workers' compensation-specific guidelines. Any specific pharmacy guidelines should reference appropriate evidence-based medical guidelines for injuries and illnesses occurring in workers' compensation, including pain management guidelines.

Neither the evidence based guidelines that include drug therapy nor the restricted list of drugs should be developed by the state agency or regulatory body. This ensures the process wherein the formulary that is developed is free from outside influence (such as lobbying from pharmaceutical manufacturers and wholesalers and other commercial interests.) Additionally, it would be cost-prohibitive for states to maintain the clinical and administrative staff needed to keep up with new drugs and evolving guidelines to create the list of restricted drugs.

The drug list (regardless of source) and its updates need to be electronic, easily accessible, easily integrated and implemented into the numerous different systems used by retail pharmacies, pharmacy benefit managers, insurance carriers, self-insured employers, third-party administrators, state agencies, and other entities tracking pharmacy data.

Not Interfere with Existing Medication Management Tools – No state pharmacy formulary should interfere with appropriate, clinically sound best practices used by PBMs and payers to manage ongoing pharmacy care and medications that are not on the restricted list. PBMs and payers should be able to use their clinical tools and practices to properly manage ongoing care – prospectively and retrospectively – based upon claim-specific issues.

Consider Existing Statutory and Regulatory Structures or Create Needed Structures - Any state formulary should take into account existing regulatory or statutory structures for prior authorization or review for medical necessity. If required, the legislature or regulatory body should create the rules needed to make the formulary effective. However, these rules should not be so restrictive as to interfere with the provision of care and existing medical management tools utilized by PBMs and payers, thus causing more unintended consequential harm than good.

Education Programs - A crucial area to the success of any state drug formulary is educational outreach to all stakeholders, especially treating physicians, insurers, pharmacies, and injured workers. Elements of an effective educational program should include implementation dates, authorization requirements, classification of new and legacy claims, processes for emergency authorization and appealing an authorization denial, clinical information on tapering, and source and publication of the drug list. The program should provide opportunities for stakeholders to ask questions and offer feedback to the agency and allow the agency to develop a robust FAQ to be used as for guidance as implementation occurs.

Two-Phased Implementation - Recognizing the different treatment needs of existing and new claimants, CompPharma recommends a two-phased implementation of a state drug workers' compensation drug formulary. New claims [those with a date of injury (DOI) on or after the date of drug formulary implementation] should immediately be subject to the drug formulary requirements. Claims with a DOI on or before the original drug formulary implementation date should be considered legacy claims and be subject to the formulary two years following the original implementation date. This will permit proper therapy transition and any necessary tapering efforts. For example, if the formulary implementation date is January 1, 2017, subsequent new claims would be subject to the January 1, 2017 formulary restrictions. Legacy claims with a DOI prior to January 1, 2017 would be subject to the drug formulary effective January 1, 2019 in this scenario.