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

STATE SNAPSHOTS

As part of the 2016 publication, *A Discussion on the Use of a Formulary in Workers' Compensation*, subcommittee members interviewed jurisdictional leaders to learn more about their experiences with implementation of a formulary in workers' compensation. In June 2019, additional states were added and original snapshots were updated. The following snapshots are intended to give insight and lessons learned on the design, implementation, maintenance, and evaluation of a formulary.

Montana (added June 2019)

New York (added June 2019)

North Dakota (no update)

Ohio (updated June 2019)

Tennessee (updated June 2019)

Texas (updated June 2019)

Washington (updated June 2019)

MONTANA

Added June 2019

Quick Facts: In May 2017, SB312 was passed by the Montana legislature authorizing the Montana Department of Labor & Industry to adopt a drug formulary by rule. The goals of implementing a workers' compensation drug formulary in Montana are to (1) reduce the number of potentially dangerous drug prescriptions and (2) improve worker outcomes by reducing disability duration and increasing return to work rates.

Description of the Formulary

Montana uses the ODG formulary, a commercially available formulary owned by MCG.

Off-label Prescriptions

For some medications, the ODG formulary may list in the "Notes" column whether a drug is recommended for off-label uses. (ex. Wellbutrin is "Y" for mental disorders and "N" for pain treatment.) The rules do not otherwise address "off-label" prescribing.

Implementation

Implementation of the formulary was a 2-year process involving multiple stakeholder groups from both inside and outside of Montana. Montana created a Drug Formulary Working Group comprised of various stakeholders and ERD staff who met monthly for approximately 18 months before implementation to incorporate feedback in real time as we developed our rules and outreach process. A Core Team was established within ERD to assist in research and making recommendations or suggestions to the Working Group. The implementation process was completely transparent, and all Working Group meetings were open to all members of the public.

New vs. Legacy Claims

The formulary became applicable for all new claims beginning April 1, 2019 (no retroactive application date). The formulary will become applicable for all legacy claims (claims with dates of injury before April 1, 2019) on April 1, 2020. We received recommendations from outside stakeholder groups to give 90 days to 6 months for legacy claims to come under formulary rules. However, data from NCCI suggested Montana may have a larger share of older claims being prescribed opioids. Therefore, we wanted to give claims examiners and prescribers enough time to notify and work with injured workers currently on nonpreferred medications or higher dosages and to initiate a new treatment plan or to document why current treatment was in the injured worker's best interest.

Stakeholder Engagement

We offered many and varied outreach opportunities beginning in early 2018 to reach as many stakeholders as possible. These included presentations to the Montana Medical Association Legislative Committee, Assistance for Business Clinics, annual workers' compensation

stakeholder meetings, Governor's Conference and Employment Relations Division's Medical Symposium. In addition, we provided outreach sessions in 6 cities across the state in early 2019 and continue to offer one-on-one office visits by our medical officer to providers across the state.

We also submitted an article in the Fall of 2018 to the Montana Medical Association, the Montana Pharmacy Association and the Montana Nurses' Association for distribution to their members or posting on the website for member use. We participated in two webinars in conjunction with ODG. Finally, we provided a follow-up webinar on April 17, 2019, after the formulary had been in effective for 2 weeks, to answer questions regarding implementation. Outreach will continue throughout this year and into next year as the Formulary will apply to legacy claims on April 1, 2020.

Prior Authorization

Prior authorization is decided by the insurer. An insurer may delegate prior authorization decisions to a PBM or other third party with which it contracts, but any decision made by the PBM or third party is binding on the insurer.

Any drug that does not have a "Y" status on the ODG formulary will require prior authorization before the drug can be dispensed. This includes "N" drugs and drugs not listed on the formulary. In addition, all compounds (including those containing only "Y" drugs) and experimental or investigational drugs also require prior authorization. An insurer should not arbitrarily deny medication solely because it is an "N" on the formulary. The claims examiner should consider whether the provider/prescriber has provided sufficient support for the prescribing of a drug that is not listed as "Y" on the formulary. If there is no response from the insurer within 3 business days of receipt of the prior authorization request, the request is automatically deemed approved.

Enforcement

The formulary is considered part of the utilization and treatment guidelines. If a provider prescribes an "N" drug without requesting prior authorization, it is likely not going to be paid by the insurer. It is in the best interest of prescribers to utilize the formulary, to provide documentation for the prescribing on an "N" drug upfront, and to substitute "Y" drugs when appropriate to prevent delays in treatment. The standard of documentation for prescriptions is the same as the standard of documentation for other treatment and services and is outlined in rule.

Dispute Resolution

The dispute resolution process for prescriptions is the same as the dispute resolution process for other treatment and services within the utilization and treatment guidelines, which was in place prior to the formulary. Any party may petition the Department for an Independent Medical Review (IMR) and the Medical Director will issue a recommendation within 14 days from the date of receipt of the request. An IMR is non-binding. Therefore, if any party disagrees with the recommendation made by the Medical Director, the dispute may move to mediation or to the Work Comp Court. Recommendations made by the Medical Director for an IMR are not admissible as evidence into the Work Comp Court.

Montana does have an expedited resolution process, but a request for an expedited review must meet certain criteria (modeled after Texas and Tennessee). An injured worker (or a party

on the injured worker's behalf) may submit a request for an expedited review in cases where the insurer denies a previously prescribed and dispensed medication, in which discontinuation poses the risk of a medical emergency for the injured worker. Once the request is submitted, the Medical Director will issue a recommendation within three business days from the date of receipt of the request.

In the situation where the Medical Director determines discontinuing of a previously prescribed and dispensed medication does not pose a risk of a medical emergency, but the provider/prescriber/injured worker maintains that the drug is medically necessary, the dispute will be rerouted to the standard IMR process. Additional documentation may be submitted if needed, and the time to complete the IMR will be 14 days after the appropriate documentation is submitted minus the time it took to complete the Expedited Case Review. However, if the dispute were to move to the Work Comp Court, the Medical Director's recommendation may be offered in evidence in mediation or the Workers' Compensation Court.

Treatment Guidelines

Montana currently uses the Montana Utilization and Treatment Guidelines, which are a variation of the Colorado guidelines. This was a unique challenge for Montana, as most other states with formularies tended to utilize matching guidelines (i.e. states with the ODG formulary also used the ODG guidelines, states with the ACOEM formulary also used the ACOEM guidelines, etc.). The feedback we received from our stakeholder groups was that switching from our current guidelines was undesirable at this time. In response, our Medical Regulations Officer worked with an internal team to comb the Montana U&T Guidelines for all mentions of medication and compare those to the ODG formulary and found minimal issues. When prescribing medications, providers are to first look to the Montana Guidelines for best treatment practices and then to the ODG Formulary to determine if prior authorization is necessary.

Since the formulary and guidelines are updated periodically, two positions were added within the Montana Provider Group for pharmacists, to assist in identifying any potential discrepancies between the Montana U&T Guidelines and the ODG Formulary in the future.

Utilization Review

Montana does not regulate utilization review as it pertains to workers' compensation. In Montana, this is considered a claims handling process and at the discretion of insurers.

Outcomes

The Montana formulary went into effect for new claims April 1, 2019 and will go into effect for legacy claims on April 1, 2020, so it is still too early to analyze outcomes. However, we anticipate utilizing internal Montana data and Montana data from NCCI in the future to estimate formulary impacts.

Recommendations

Be transparent. Include as many stakeholder groups as early in the process as possible and provide frequent updates into progress and barriers. **Be thorough in your research.** There is much to learn from other jurisdictions that have been through the process. Take lots of notes and do lots of comparisons to find what does and does not fit best in your system. **Outreach, Outreach, Outreach.**

As part of our long-range plan we would have looked at larger venues for outreach opportunities such as nurse, medical association, and pharmacy association conferences. By the time we contacted these groups for opportunities to speak at their 2019 conferences to discuss the drug formulary, they were already booked and by 2020, they will have been working with our formulary for at least 9 months. That was a missed opportunity. Keeping the interest level high and stakeholders engaged for 18-24 months is difficult. It would be productive to see if our workplan could have been spread over a period of 12 months maximum.

For more information, please visit http://erd.dli.mt.gov/work-comp-claims/medical-regulations/formulary.

NEW YORK

Added June 2019

Quick Facts: The Chair has adopted the addition of Part 441 of 12 NYCRR to establish a drug formulary that includes high-quality and cost-effective preauthorized medication. The Notice of Proposed Rule Making was published in the December 27, 2017 edition of the State Register. Notices of Revised Rule Making were published in the October 17, 2018, January 23, 2019 and April 17, 2019 editions of the State Register. A Notice of Adoption was published in the June 5, 2019 edition of the State Register. The amendments will be effective upon publication on June 5, 2019.

Description of the Formulary

New York's formulary, developed in collaboration with the Reed Group, is a product of established medical treatment guidelines.

Implementation Process

Per NYS regulatory process, regulations were released for public comment. On 4/17/19 the third version was released for public comment. The regulation was adopted 5/21/19 with a 6/5/19 effective date.

New vs. Legacy Claims

Regulations require the use of the formulary:

- New Rx – six months from the effective date
- Refill/Renewal – 12 months from the effective date

Stakeholder Engagement

New York engaged stakeholders in a series of educational seminars, online training materials, society and individual practitioner outreach.

Prior-Authorization Process

The process is a fully electronic three (3) level prescriber-initiated process.

Enforcement

Via the point of sale adjudication process

Treatment Guidelines

New York currently uses treatment guidelines and medications are outlined within the guidelines.

Outcomes

New York's formulary became effectives on 6/5/19. No outcomes are available yet.

NORTH DAKOTA

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

Background

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

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

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

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

Description of the Formulary

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

Any new FDA approved drug is considered N/F until it is reviewed by the P&T Committee.

For example:

> *Celecoxib cap 200 mg is labeled "PA" and "MDD", which requires pre-authorization and has a maximum daily dose of 2x daily.*
> *Diciofenac Sodium Solution 1.5% is labeled "N/F" and is a non-formulary drug.*

WSI's PBM publishes the formulary, which can be downloaded at: https://www.usscript.com/Media/Default/docs/FORMULARY-WSI.pdf [1]

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

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

Implementation

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

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

Prior-Authorization Process

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

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

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

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

[1] WSI relies on their PBM to develop the document posted online. There are minor differences in the legend included in the publication and the status given to each drug by the WSI P&T Committee.

Enforcement

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

New vs. Legacy Claims

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

Dispute Resolution

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

There is no expedited dispute resolution process in place.

Outcomes

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

Recommendations

Lessons Learned

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

Hindsight

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

OHIO

Updated June 2019

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

Revisions in drug coverage have been made to the formulary since September 1, 2011. The most recent update took effect on June 1, 2019 and impacts 3 medications: Lyrica, Oxycontin, and Xtampza ER.

History of the BWC Pharmacy Department

2005

The prescription benefit for injured workers of State Fund employers was controlled through a Preferred Drug List, a Non-Preferred Drug List, and a Relatedness Drug List. The Pharmacy Benefit Manager (PBM) electronically applied the lists at the point-of-sale. The relatedness drug list looks for a link between the allowed conditions in a claim and the common indications for a drug prior to allowing the medication to pay.
All limitations on drug coverage were subject to a Prior Authorization (PA) process. PA requests were approved for use by a BWC claims staff member or sent for physician review. By Rule, only an independent physician peer reviewer could deny a PA request. In practice, most requested drugs were approved by BWC staff and not referred for independent physician peer review. Oversight and control of pharmacy related activities was disseminated across multiple areas of BWC. There was no pharmacy director or defined pharmacy department.

2009

A pharmacy program was established at BWC and staffed.

2010

Work began on the development of the tools necessary to properly oversee drug utilization. The Pharmacy & Therapeutics (P&T) Committee functioned as a sub-committee of a Quality Assurance Committee and had no defined authority or responsibilities. A rule was introduced into the Ohio Administrative Code (OAC 4123-6-21.2) giving structure, authority, and responsibility to the P&T Committee. Among other duties, it made the committee responsible for the development and maintenance of a drug formulary.

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

2011

The P&T rule (OAC 4123-6-21.2) was adopted in January 2011.

With a committee administratively responsible for the development of a formulary, work began on creating the final document. Early in 2011, multiple stakeholders were engaged (i.e. medical organizations, health care organizations, and legal organizations), the formulary was given definition, and how it would be utilized was explained. It was determined the formulary would be driven by the clinical, not claims or fiscal, data.

Description of Formulary

The Rule appendix lists all drugs covered as well as any coverage restrictions. Since implementation, there have been twelve formulary revisions, the most recent took effect on June 1st, 2019. At this time Oxycontin was deleted from the medication formulary, Xtampza ER was added as a tier 2 opioid, and Lyrica was moved to a tier 2 requiring a trial of gabapentin prior to approval.

In January BWC also eliminated coverage of duplicate benzodiazepine therapy and required prior authorization for antipsychotics except in cases of bipolar disorder or schizophrenia.

If a drug is not listed in the appendix to the rule (OAC 4123-6-21.3) it can only be covered under two scenarios:

I. Pursuant to an administrative hearing, the Industrial Commission (IC) of Ohio orders the BWC cover a specific drug in a specific claim.
II. The rule allows for coverage of a non-formulary drug under specific clinical situations for a 6-month period while the drug is reviewed by the P&T Committee.

Implementation

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

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

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

Description of P&T Committee

The Committee is made up of 6 pharmacists and 6 physicians from various areas of practice. The Pharmacy Director is the chair of the committee and the Chief Medical Director is a non-voting member. Meetings are held quarterly. Enrolled BWC physicians may use a MEDCO-35 form to request that a medication be considered for formulary addition.

Drug Utilization

Drug utilization is managed primarily with relatedness, prior authorization requirements, and drug utilization physician peer review.

Relatedness

Relatedness is enforced at the point-of-sale (POS) in the pharmacy by edits in the PBM software. Medications are related to certain diagnosis codes. For example, lisinopril would be related to hypertension and ICD codes for hypertension. Prior to approval of many medications on the BWC formulary the POS will validate that there is a condition allowed in the claim that is related to the medication being filled. If a related condition is not allowed the bill denies and will require prior authorization. This is how our relatedness editing functions.

Relatedness simultaneously prevents unrelated medications being filled in a claim, while bypassing the prior authorization process and saving time when a there is a clear indication for the medication. Examples of drug classes relatedness applies to include: antihypertensives, antidiabetics, impotence agents, and antihyperlipidemics.

Prior-Authorization Process

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

Many medications on the BWC formulary require prior authorization. Some examples of these medications include:

- Antipsychotics in claims that are not allowed for bipolar disorder or schizophrenia
- Benzodiazepines over 30 days of use
- Skeletal muscle relaxants over 90 days of use
- Lyrica
- Oral disintegrating dosage forms
- Dronabinol
- Movantik, Amitiza, and Symproic
- Tier 2 and 3 long acting opioids

BWC has pulled the prior authorization process in house and it is managed solely by the pharmacy department and not the PBM.

Physician Peer Review (DUR)

Prior authorization requests will be approved or denied according to the formulary restrictions or sent for a physician review. If there is question as to the appropriateness of the medication request, BWC may request a review by a physician to approve or deny the medication.

Dispute Resolution

In Ohio, the Industrial Commission (IC) oversees the administrative decisions of the BWC. An injured worker can appeal the non-coverage of a medication to the IC and request coverage. Hearings are formal, with both parties represented by counsel.

Outcomes

Outcomes of the BWC formulary are displayed below for nine classes of medications that have restrictions. The result has been a decrease in utilization. Utilization across all classes of medication has declined more quickly than the number of active claims has declined. Two 5-year periods are included below for comparison.

Table 1: Ohio Formulary Outcomes

	2014 vs 2010						2018 vs 2014					
	Total Rx's	**Total Doses**	**Rx's per IW**	**Doses per IW**	**Total Paid (%)**		**Total Rx's**	**Total Doses**	**Rx's per IW**	**Doses per IW**	**Total Paid (%)**	
Opioid Analgesics	-35%	-34%	-7%	-5%	-38%		-49%	-52%	3%	-2%	-32%	
Anti-Anxiety Agents	-25%	-25%	1%	2%	-31%		-53%	-53%	-5%	-6%	-23%	
Antipsychotics	-12%	-15%	4%	0%	20%		-28%	-29%	6%	4%	-57%	
Sedative Hypnotics	-38%	-37%	4%	6%	-39%		-59%	-59%	-1%	0%	-77%	
Muscle Relaxants	-70%	-72%	-45%	-48%	-77%		-43%	-40%	23%	29%	-8%	
Analgesics	-60%	-60%	-31%	-32%	-53%		-18%	-22%	-13%	-17%	59%	
Anticonvulsants	-7%	-5%	2%	5%	31%		-28%	-28%	4%	4%	11%	
Antidepressants	-11%	-12%	5%	5%	0%		-30%	-30%	6%	6%	-62%	
NSAIDs	-26%	-28%	1%	-2%	47%		-45%	-46%	6%	4%	-77%	

Recommendations

- Formulary decisions should not be based solely on cost savings. There should always be a sound clinical argument for your decisions in this area.
- It is not uncommon to have pushback from injured workers who are resistant to the change.
- Communicate with your agency staff. Make sure everyone in your agency understands why changes are made to the formulary, and why they are necessary.
- The P&T Committee is crucial to success. Recruit the best members possible
- Try to consider every injured worker the change may impact, how it will impact them, and what options will be available to them.

TENNESSEE

Updated June 2019

Quick Facts: Discussion of a formulary as part of the comprehensive treatment guidelines began in 2014 and it was adopted in January 2016. Described in regulation 0800-02-25 Workers' Compensation Medical Treatment Guidelines, it took effect on February 28, 2016. The process involved many stakeholders including medical associations, plaintiffs' bar, unions, and employer associations. There were numerous meetings with professional groups (plaintiffs' bar and medical associations), presentations by various guideline vendors, input from prescribers and pharmacies, and articles/announcements in stakeholder publications.

Background

The implementation of the formulary was designed to address several challenges with inappropriate use and increasing cost of prescription use. Discussion with system stakeholders identified the following goals for formulary adoption:

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

Tennessee adopted treatment guidelines at the same time as they adopted the formulary. Tennessee adopts the current edition, and any future published updates, of the Work Loss Data Institute ODG Guidelines as published by the Work Loss Data Institute, The Chronic Pain Guidelines of the State of Tennessee, Department of Health, and any other related appendices to the above references guidelines adopted by the Administrator. Adoption of treatment guidelines and the formulary are part of the mandate from the legislature to be comprehensive.

Description of Formulary

Tennessee adopted the ODG Drug Formulary as found in Drug Appendix A published and updated by the Work Loss Data Institute. The rule incorporates future updates and is published on the Bureau website and is updated monthly or when ODG makes changes. Any drug identified with the status "N" in the current edition of the ODG/Appendix A shall require prior approval. Prescription of "N" drugs should only be approved when supported by documentation using evidence-based medicine. The rule specifically notes that compound medications and topical applications are "N" and require prior approval.

Implementation

The first step in implementation was adoption of enabling legislation, TAC 50-6-124, which went into effect in 2013. The formulary was vetted through the Tennessee Medical Advisory Committee (MAC) made up of various providers, insurers, labor, case managers, and employers. All meetings of the MAC were open to the public. Rules for the process were developed following a public hearing, had public comment and modifications were made in response to some issues raised. The final rules were then sent to the Attorney General for approval, approved by the Government Operations Committee and became effective February 28, 2016.

Prior-Authorization Process

The prior-approval process is through the insurer and/or pharmacy benefit manager where review determines the appropriateness for the injury, the drugs' formulary status and possible generic substitution. This process is quicker that full utilization review-the process to determine medical necessity.

Enforcement

The formulary is enforced through the pharmacy point of sale process; drugs that are not approved are not dispensed by the pharmacist.

New vs. Legacy Claims

The drug formulary is in effect for all prescriptions written after February 28, 2016. New prescriptions were given six months after the effective date to comply with the formulary with legacy claims having a full year.

Dispute Resolution

A request for reconsideration of a denied medication can be made to the Tennessee Bureau of Workers' Compensation Medical Director within30 days. The appeal is governed by the utilization review appeal process, described in Rule 0800-02-06.

An expedited determination, for those denials which may pose a risk of a medical emergency, may also be requested from the Bureau's Medical Director. In this instance, the Medical Director has 3 business days to render a decision and the Medical Director's determination shall prevail over the employer, carrier, or utilization review agent.

Outcomes

Significant improvement has been documented particularly with compounds and topicals. The availability of the formulary on the website has improved its penetration and use.

Recommendations

Lessons Learned

- Gain the support of insurers and PBMs.
- Provide sufficient early information to patients and prescribers.
- Learn from the experiences of other states and use that learning in the development of your jurisdiction's program.
- Explain the process clearly and as often as you can.
- Think through retrospective denials thoroughly.
- "First fill" timeframes and criteria should be clearly delineated.
- Include compounds and topicals in the rules.
- Clearly differentiate prior approval or prior authorization criteria from utilization review.
- Be aware of the complexity of the PBM/insurer interactions. Each contract is different.

Would Do Differently

- Be prepared for more questions.
- Focus on more education of the prescribers.

TEXAS

Updated June 2019

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

Background

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

The adoption of a formulary was part of a comprehensive reform package and thus preliminary activity for the closed formulary did not begin until 2008, after DWC had enacted other major components of the HB 7 reforms, including evidence-based treatment guidelines.

ODG Treatment in Workers' Comp published by MCG/Hearst Health is the Texas treatment guideline and became applicable on May 1, 2007. Appendix A of the ODG treatment guidelines is the basis for the Texas closed formulary. As a result, treatment recommendations and the closed formulary are consistent with each other. DWC adopted an amendment to the closed formulary rules in 2018 to exclude all compounded drugs prescribed and dispensed on or after July 1, 2018 from the closed formulary.

Description of the Formulary

The Texas closed formulary is defined in Texas Administrative Code §134.500, Definitions, amended April 22, 2018.

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

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

(B) any prescription drug created through compounding prescribed before July 1, 2018 that contains a drug identified with a status of "N" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates;

(C) any prescription drug created through compounding prescribed and dispensed on or after July 1, 2018; and

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

MCG/Hearst Health maintains ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary with updates published monthly. A list of drugs excluded from the formulary is available on the DWC website and is updated monthly to reflect changes in Appendix A.

There is no blanket policy regarding "off-label" use in the formulary. In some instances drugs that have been identified with common "off label" uses are individually addressed by the formulary.

Implementation

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

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

After adoption of the rules, DWC had eight months to inform and educate system participant about the impending enactment of the closed formulary. DWC hosted over 30 events including

seminars, webinars, education session and group practice presentations throughout the state to help system participants prepare for the implementation of the closed formulary.

DWC also has detailed information concerning the development, implementation and current operation of the closed formulary posted on the DWC's website at http://www.tdi.texas.gov/wc/pharmacy/index.html

Additionally, DWC provides support through its annual conference, seminars, field office educational sessions and its ongoing provider outreach activities. DWC also engages stakeholders through quarterly meetings directed to insurance carriers and health care providers. The Comp Connection for Health Care Providers, 1-800-252-7031, provides one-on-one assistance to the health care provider community who serve injured employees.

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

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

Preauthorization Process

Preauthorization requirements for the Texas workers' compensation system are set out in Texas Administrative Code §134.600 and Chapter 19, Subchapter U. In Texas, utilization review is considered the practice of medicine and all utilization review must be performed by an insurance carrier that is registered with, or a utilization review agent that is certified by, the Texas Department of Insurance to perform utilization review.

DWC's adopted treatment guidelines, which include the closed formulary, must be considered when a utilization review decision regarding medical necessity is made.

Enforcement

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

New vs. Legacy Claims

There was a bifurcated applicability process for the implementation of the closed formulary after the closed formulary rules were adopted in December of 2010. Beginning September 1, 2011, the closed formulary applied to claims with a date of injury (DOI) on or after September 1, 2011. Claims with a DOI prior to September 1, 2011, were designated as legacy claims. The closed

formulary became applicable to legacy claims on September 1, 2013. The closed formulary does not apply to “old law” claims i.e. claims with a DOI prior to January 1, 1991.

Dispute Resolution

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

Flow Chart: Workers Compensation Non Network (WC) IRO

If the dispute persists, the parties may pursue a contested case hearing at DWC and ultimately file suit in district court.

In an instance when a drug excluded from the closed formulary has previously been prescribed and dispensed, preauthorization of the drug has been denied, and an unreasonable risk of medical emergency exists, the prescribing physician or pharmacy may pursue a medical interlocutory order (MIO) as described in Texas Administrative Code §134.550. This process shortens or eliminates some timeframes in the dispute process and allows for continued use of the drug through the duration of the dispute process. Since the initial implementation of the closed formulary DWC has received 163 MIO requests. As of February 2019, 66 requests were approved while the remainder were either withdrawn or rescinded, or the request was for a drug that did not require preauthorization.

Outcomes

Results for one year of new claims after 24 months of activity

- The number of injured employees receiving N-drugs fell by 67 percent.
- N-drug costs fell by 78 percent, and N-drug costs as a percentage of all drug costs decreased by 74 percent (from 20 percent of total to 5 percent of total).
- The number of injured employees receiving other drugs fell by 1 percent.
- The share of N-drug claims among all claims fell from 23 percent to 8 percent.
- The total number of prescriptions for N-drugs fell by 74 percent while it fell by 3 percent for other drugs.
- The average number of N-drug prescriptions per claim fell by 42 percent.
- The generic substitution rate for N-drugs increased from 58 percent in 2010 to 73 percent in 2011.
- The number of N-drug prescriptions fell by 70+ percent across all drug groups.
- The number of prescriptions for the 10 most-prescribed N-drugs decreased by 82 percent.
- Source: https://www.tdi.texas.gov//reports/wcreg/documents/formulary16.pdf.

Results for legacy claims 12 months after applicability of the closed formulary

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

Recommendations

Lesson Learned

- Allow sufficient time to actively engage stakeholders prior to the adoption and implementation of the closed formulary.
- The adoption of a closed formulary is more easily explained if the focus is on medical necessity and appropriateness rather than cost.
- Transition to the closed formulary for individual claims works best when there are peer-to–peer discussions regarding treatment decisions.
- Communication is a shared responsibility. Encourage insurance carriers and prescribing doctors to communicate with each other and with injured employees about the transition to the closed formulary and the impact the formulary will have on employees' claims.
- Other facets of the workers compensation system such as treatment guidelines, utilization review requirements and a medical dispute resolution process should be in place to support the effective implementation of the closed formulary.
- Devise a plan to track the progress and impact of the closed formulary in your state before the formulary is implemented.

WASHINGTON

Updated June 2019

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

Background

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

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

A contractor reviewed evidence on effectiveness and safety of the 12 most costly and highly prescribed classes of drugs. These drug classes were then used to establish Washington's PDL. The PDL was implemented by all three agencies on May 1, 2004. The number of included drug classes has since expanded to approximately 53 drug classes.

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

Description of the Formulary

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

The PDL

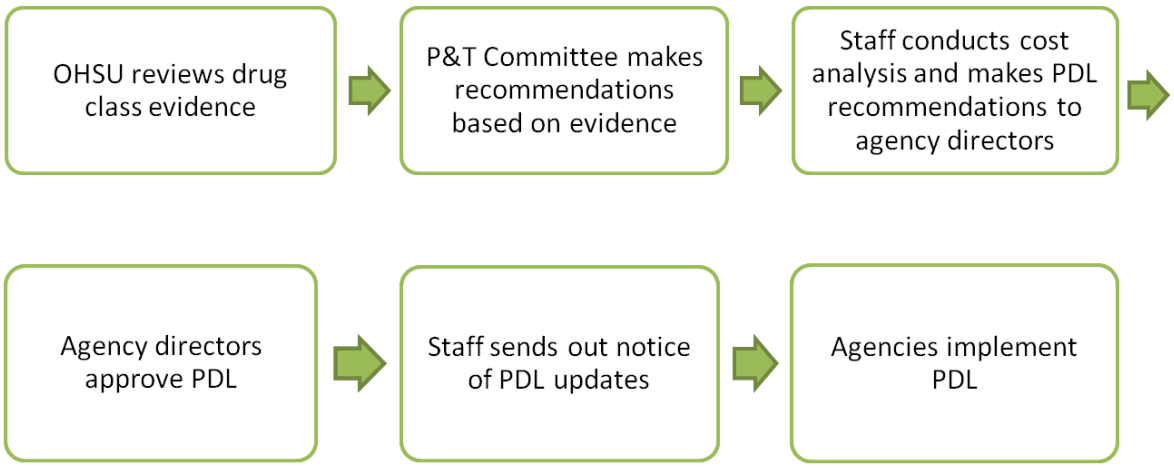
The PDL is an evidence-based list of drugs used by participating state agencies as the basis to purchase drugs within the state-purchased health care program. Drugs are given a status of:

Preferred drug: A drug selected by state agencies as recommended by the P& T Committee or based on cost.
Non-preferred drug: A drug that wasn't selected due to inferior safety or efficacy or due to cost and may require prior authorization for coverage or placed on a higher cost copay tier.

Of the 53 PDL drug classes, L&I participates in 23 which are applicable to workers' compensation (e.g. non-steroidal anti-inflammatory drugs, muscle relaxants, and antidepressants). The L&I PDL can be downloaded at: http://www.lni.wa.gov/ClaimsIns/Files/Providers/SelectedPDLforworkers.pdf.

The PDL is developed according to the following process:

Figure 3: The PDL Process



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

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

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

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

The Directors (designees) of each of the agencies makes the final decision as to which drugs will be included on the PDL. The State then notifies all stakeholders and implements PDL changes. Newly available drugs in PDL classes require prior authorization or are non-covered until reviewed by the P&T Committee.

Each drug class is re-reviewed on a yearly basis to summarize new evidence and identify new drugs and indications since the last review. The P&T Committee may request a single drug addendum which reviews drugs not included in the existing class. Another cost analysis is conducted with each review.

Endorsing Practitioner & Therapeutic Interchange Program (TIP)

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

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

Wrap-around Formulary

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

Prior Authorization for Non-preferred or Non-formulary drugs

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

Dispute Resolution

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

Outcomes

The use of generics is very high in Washington. A 2011 WCRI Study showed only 6% of all prescriptions in WA were brand, compared to the 17-state median of 16% (WCRI Study). In the same study, the prescription cost per claim was among the lowest at just above $400 for claims with more than 7 days of lost time. This was 40% lower than the median. In 2008, prescription drugs represented only 5.7% of the ultimate medical costs compared to a national average of 13.5% (NCCI 2010 Prescription Drug Study).