Healthesystems™

RxInformer

Topics and issues impacting workers' compensation, today

medication watch | recalls & alerts | evidance-based guidelines | new standards | compliance & legislative issues >>

In an industry as niche as workers' compensation pharmacy and ancillary benefits management, change comes in many forms ... and with change comes complexity.

new medications. shifting prescribing patterns. legislative changes. advances in technology. safety issues.

The *Rx Informer* industry journal is published by Healthesystems to address these timely and complex issues, so payers are aware of emerging topics in order to plan for the future.

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More about the propoxyphene product withdrawal: In November 2010, due to risks exceeding benefit, the Food and Drug Administration requested all manufacturers to remove propoxyphene-containing products from the U.S. market. Xanodyne Pharmaceuticals Inc., a maker of Darvon® and Darvocet® brands, has voluntarily agreed to the withdrawal. [1] Other generic manufacturers have also received notice to remove their products and have begun to follow suit.

Propoxyphene is a weak analgesic with adverse effects that outweigh its benefits. Its long half-life, cardiotoxic metabolite (norpropoxyphene), and narrow therapeutic index (i.e., a toxic dose that is not much higher than the therapeutic dose) put patients at a high risk for serious adverse events.[2] The basis for the withdrawal request is new clinical data that indicates even standard therapeutic doses of propoxyphene can increase the risk for serious abnormal heart rhythms, including those that can result in sudden death. Fortunately, the effects on the electrical activity of the heart are not cumulative and are expected to be eliminated when propoxyphene is discontinued.

It is the recommendation of Healthesystems clinicians that patients be directed to their prescribing physician to discuss an alternative treatment to propoxyphene.

More about the acetaminophen dose reduction: In January 2011, the Food and Drug Administration (FDA) issued a recommendation to manufacturers that all prescription acetaminophen-containing products be limited to no more than 325mg of acetaminophen per dosage unit. In addition, a *Boxed Warning* noting the potential for severe liver damage and a Warning concerning the potential for severe allergic reactions will be added to the labeling of all prescription acetaminophen-containing products.[3]

Acetaminophen is used in hundreds of over-the-counter and prescription medications including some of the most commonly prescribed medications for workers' compensation patients, such ashydrocodone with acetaminophen (e.g., Vicodin®, Lortab®) and oxycodone with acetaminophen (e.g., Tylox®, Percocet®). For example, according to Healthesystems data, in 2010 three hydrocodone with acetaminophen products containing more than 325mg of acetaminophen per tablet were included in the top 20 drugs dispensed and represented nearly 14 percent of the total transactions among the top 50 medications. This includes hydrocodone with acetaminophen 5mg/500mg (Vicodin), which was the most frequently dispensed medication to Healthesystems claimants. In many medications, as with Vicodin, the amount of acetaminophen in each tablet is greater than 325mg and can be up to 750mg per tablet. The manufacturers of prescription medications were given three years to limit the amount of acetaminophen in their products. The deadline is January 14, 2014[4] , so they will either have to pull their product from the market or reformulate it before this date.

Since this is a phased withdrawal, a shortage of acetaminophen-containing prescription medications is not expected and there should be minimal impact to patient care when transitioning to a product containing a lower dose of acetaminophen. However, the withdrawal may pose a significant increase in costs for workers' compensation prescriptions because the cost of the reformulated tablets may be increased due to increased costs for manufacturers. Additionally, the average wholesale price (AWP) for products currently on the market is generally higher for formulations containing 325mg.

More about the Embeda withdrawal: In March 2011, King Pharmaceuticals issued a voluntary recall of all dosage forms of Embeda (morphine sulfate with naltrexone extended release capsules).[5] The company's recall noted that pre-specified stability requirements were not met during routine testing, but the issue is unlikely to pose a safety risk to patients taking the medication as prescribed. Embeda is extended-release morphine formulated with naltrexone as an abuse deterrent for

treating moderate to severe chronic pain when a continuous, around-the-clock opioid is needed.[6] This medication is appropriate for workers' compensation patients with chronic pain who have been identified by the prescriber to be at risk for opioid misuse. Patients should be advised to take action regarding this recall by notifying their prescriber as soon as possible to determine options for continued treatment with opioids.

Claims professionals should be aware of this recall since it may affect the ability for some workers' compensation patients to obtain their medication. It is recommended that patients be advised to contact their prescriber as soon as possible (before running out of medication) to discuss other treatment options, since Embeda may not be available for some time. If patients have experienced an adverse reaction or other problem, they are urged to contact the manufacturer (800.776.3637) or the FDA (http://www.fda.gov/medwatch/report.htm).

The value in having a proactive PBM: Instead of waiting to see what happens as a result of actions on the part of the FDA or a drug manufacturer, a watchful pharmacy professional will mitigate the potential dangers associated with a product withdrawal, formulary change or other concern, anticipate the financial impact and keep a client informed on how its business will be affected by these and other issues.

The integration of this type of proactive clinical service with a comprehensive pharmacy benefit management (PBM) program has proven to be the most effective way to ensure that claimants receive the best quality of prescription care while the total cost of that care is kept under control for the payer.

A judicious case for using evidence-based guidelines for worker's comp prescription care

Any payer can tell you that prescription drugs constitute a significant and growing portion of their total workers' compensation medical costs.

By Dr. Ralph Kendall, PharmD

That's certainly not new news or particularly surprising for any of us. What payers may not be aware of is that "there is increasing evidence that many injured workers are receiving inappropriate prescriptions that may not be the best choices in helping them recover from the injury or illness." That discouraging statement was issued by Phil Denniston, president of the Work Loss Data Institute (WLDI) and editor-in-chief of the Official Disability Guidelines (ODG).[7]

But we can be encouraged by the current trend toward the use of evidence-based standards, including ODG, in determining appropriate prescription drug treatments for workers' comp claimants. This can be seen as a positive step toward arresting and reversing the potentially dangerous and often costly practices that have led to the situation that Mr. Denniston described.

There are currently a few popular approaches for managing medication use for workers' comp claimants. These plans aim to control cost and/or ensure that the patient is getting medications related to the injury:

>>A general drug plan that described the therapeutic classes of medications that would "fit" with a work-related injury. This method was applied to the treatment of the injury no matter where the patient was in the course of recovery and return to work.

>>A more refined technique is the acuity of care guide that allowed those medications that were expected to be used in treating a traumatic injury in the beginning (e.g., antibiotics, analgesics, corticosteroid dose packs). This plan usually migrated toward a more targeted list of medications that would be used after the acute phase of injury.

>>And, an injury-based drug plan or list that used either body parts, ICD9 codes (provided in the World Health Organization's International Statistical Classification of Diseases and Related Health Problems) or various forms of National Council on Compensation Insurance (NCCI) codes to restrict access. While very appealing, this approach is very difficult to maintain and usually only covers a few of the "most popular" injury codes and generally gives a false sense of security.

Many plans were developed to isolate specific agents, such as controlled release opioids or extremely high cost narcotic agents, as were edits to control quantities dispensed, raw costs, authorized prescribers and more.

Each of these had the same objective: to allow patient access to needed pharmaceutical agents without giving away control of relationship to injury, cost or clinical appropriateness of therapeutic agents. Each also had its short comings. With the emergence of ODG and the knowledge gained from past attempts to manage workers' comp prescription costs, a new model incorporating both approaches may allow workers' comp payers to get closer than ever to achieving their goals, including those for returning to work and cost-efficiency.

When it comes to prescription drugs, evidence-based means that the best available evidence gained from scientific methods is applied to clinical decision making. What that boils down to for a workers' comp payer and pharmacy benefit manager (PBM) is that rather than developing a medication plan based strictly on rigid criteria such as therapeutic drug classifications or injury codes, they can assess the strength of proven evidence in identifying the risks and benefits of individual prescription drug treatments.

For example, a commonly used muscle relaxant, carisoprodol, lacks evidence and presents a number of patient safety risks. In the past, it would have been common to include this medication in a drug plan, but now it may require authorization for use since other agents are safer and equally or more effective. Another example can be found in determining the appropriate use of antidepressants or anticonvulsants for treating neuropathic pain. Guidelines can help make the distinction between those agents that are and those that are not effective. When these distinctions are made clear, a more informed evaluation can be made in determining whether or not a prescribed medication is appropriate for a claimant's injury.

A notable source for such evidence-based guidelines is the ODG developed by the WLDI. Its stated purpose for treatment in our interest area is "to improve outcomes for any claim that might be seen in a jurisdictional

workers' compensation system." The studies for this guide are focused on one primary outcome — what is best for the injured worker.[8] And, as we have seen time after time, what's best for the injured worker usually turns out to be what's best for the payer in their attempts to control costs.

Interestingly, the most recent version now provides a separate appendix — the ODG Drug Formulary — that deals specifically with the medical literature evidence supporting specific medications that are often used for work-related injuries and the appropriate use for each. Just as important, it also indicates when there is NOT any evidence-based justification for use.

As described, ODG is a valuable resource to PBMs. As a PBM, the focus of our clinical programs at Healthesystems is centered on the application of evidence-based medical treatment guidelines from sources such as ODG.

And it seems that Healthesystems is not alone in our support of evidence-based guidelines. In recent years, high medical costs and poor patient outcomes have become such a growing concern for state policymakers nationwide, that it has led to the passage of legislation adopting evidence-based treatment guidelines as the standard against which medical therapies, including prescription drug therapies, should be measured. A recent market survey showed that every one of the top 30 workers' comp and disability carriers has a major multi-user ODG license, as does each of the leading 20 TPAs and managed care vendors.

In Texas, for example, which adopted the ODG several years ago as part of the reform of its workers' comp system, legislators concluded that "If health care providers are utilizing the treatment guidelines in their provision of services, there will be identifiable changes in the way injured workers are treated." And, they were just as straightforward in their anticipation of cost improvements: "If excessive or inappropriate services are avoided, this will result in the absence of bills for such services."[9]

That being said, we must take into consideration that ODG does not address every issue or complexity related to administering drug benefits to workers' comp patients. For example, ODG remains silent on some therapeutic classes (e.g., antibiotics) which are needed to treat a number of work related injuries and does not adequately address the abuse of compounded medications for which alternative FDA approved products are available. It does comment on the role of urine drug screening among opioid users and the application of step therapy. As in all managed care settings, there is still a need for the insurer to determine the true nature and complexity of the injury when administering benefits for certain individuals.

So, what can we conclude from all of this? It is unknown how many states will adopt ODG and how it will evolve. What's been done so far is an important step in trying to apply evidence-based medicine to thwart the drug costs experienced by workers' comp payers while providing safe and effective care to patients. Also, that the most effective approach to prescription care is where you apply the best that each resource has to offer – the objectivity and accuracy of proven scientific data combined with real-world, practical experience and knowledge.

NCPDP Version D.0: A new standard means new opportunities

Plans are underway for the National Council for Prescription Drug Programs (NCPDP) Telecommunications Standard Version D.0 to become the standard for billing not only for drugs, but also for medical supplies and services.

Version D.0 is an update to NCPDP's Health Insurance Portability and Accountability Act (HIPAA) compliant standard for pharmacy claims transactions.

The transition from Version 5.1 to Version D.0 is underway, with regulatory compliance required on January 1, 2012.

During much of 2010 and all through 2011, Healthesystems has been in the process of business planning and development to address the changes that will affect those who provide medical cost management solutions for the workers' compensation industry.

How does this impact the PBM business? There are several areas of focus for Healthesystems:

>>Increase in RX Number field (increase to 13)
>>Increase in Member ID field (increase to 20)
>>Increase in NCPDP Reject Code field (increase to 3)
>>Compound ingredient level billing requirements

Of all the changes mandated by Version D.0, those related to compound drugs represent the biggest impact on the retail pharmacist's daily workflow and our workers' compensation market challenges. In previous versions of the NCPDP telecommunication standard, there were three methods for billing compounded prescriptions:

1. Report multi-ingredients using the claim and compound segments
2. Bill most expensive legend drug in compound
3. Use generic billing codes

These methodologies posed problems for pharmacies and pharmacy benefit managers (PBMs) for retail and mail order transactions processed online as there was no mandated or, in many instances, automated processing that required ingredient level capture, validation and adjudication to contracted rates. Compounds would typically pay in full or the PBM would have to deny processing online and force billing to occur manually through paper submission, a process which negates the efficiencies for all involved.

In Version D.0, the only way to bill for compounded prescriptions is to bill for multiple ingredients using the claim and compound segments. All ingredients of a compound should be billed in the compound segment within a single transaction and a single transmission. It does not matter what order the compound ingredients are entered. This change will result in more accurate and transparent reimbursement for valid ingredients making up compounded prescriptions.

PBMs, software providers and pharmacies that have not already begun development for Version D.0 could face significant challenges in meeting the implementation timeline because the new standard will require upgrades to existing pharmacy software.

To learn more about NCPDP and Telecommunications Standard Version D.0, visit http://www.ncpdp.org or contact Healthesystems at info@healthesystems.com.

Unintended consequences of polypharmacy

According to a recently published study, adverse reactions from prescription medications kill or injure more than 700,000 people each year and are a leading cause of emergency department (ED) admissions.[10]

ED visits involving adverse reactions to prescription medications taken as prescribed increased 83 percent between 2005 and 2009.[11] An estimated 7 percent of all hospital admissions are related to adverse drug events.[12] Polypharmacy, or use of multiple, often duplicative medications, has been implicated in increasing the potential for serious medication-related misadventure.

Polypharmacy has largely negative connotations, indicative of sometimes inappropriate or irrational therapy on the part of prescribing physicians. Though there are situations in which polypharmacy is appropriate or necessary, in many cases the increased risk is often not tempered by increased effectiveness. Workers' compensation claimants are often prescribed complicated medication regimens that can lead to unintended consequences, and such regimens very often exhibit polypharmacy. There are two types of polypharmacy:

>>Same-class – the use of two or more agents from a single therapeutic class (for example, two short-acting opioids, two antidepressants, two NSAIDs or two muscle relaxants)

>>Multi-class – the use of two or more agents from different therapeutic classes (for example, an anticonvulsant plus an antidepressant for neuropathic pain)

Both same-class and multi-class polypharmacy have the potential for therapeutic duplication. When two or more agents with identical or very similar mechanisms of action are taken together, it can lead to potentially life threatening consequences. For instance, taking an antidepressant with certain migraine medications may cause serotonin syndrome—a condition whereby the body produces an overabundance of the chemical serotonin, which, in severe cases, can cause muscle rigidity, fever and seizures and can be fatal if not treated.

Conversely, some medications may confound the effects of other medications the patient is taking simultaneously, making it difficult to determine which of the therapies are beneficial and which are not.

Another common practice in the workers' comp population is adjunctive polypharmacy — the use of one medication to treat the side effects of another prescribed medication. An example of adjunctive polypharmacy is the prescription of a sedative, such as zolpidem, to treat insomnia, along with a stimulant medication, such as modafinil, to promote wakefulness for daytime use. Use of multiple prescribers further exacerbates the problem and increases the risk of overlapping therapies and prescription of interacting medications.

Patient perception is often overlooked when considering the pros and cons of polypharmacy.[13] A feeling of overmedication — or of taking too many medications —can play a significant role in the benefit of therapy. "Pill burden," coupled with complicated scheduling of multiple medications has been shown to directly correlate to poor patient compliance, an increase in adverse events and a decreased health-related quality of life.[14]

In group health, a natural barrier to widespread polypharmacy is likely the out-of-pocket cost to patients. When patients assume responsibility for a portion of the per-prescription cost, they are more likely to ask their prescribers not to add medications to their prescription regimen. However, the unique nature of workers' comp rules removes this barrier, decreasing or, in most cases, eliminating any cost to the patient. As cost is not a consideration for patients and prescribers, there may be a tendency towards adding rather than switching medications. And, when cost is not a concern for patients and prescribers, it becomes an even greater concern for payers, not only for the costs of the initial polypharmacy, but for additional treatments to address any resulting adverse effects.

Simplification of a claimant's medication regimen can lead to better patient compliance, decrease the chance for adverse drug reactions and help control costs. Pharmacy benefit management (PBM) programs, especially those that offer clinical review services, can be instrumental in this effort. A PBM program is most effective when it provides clinical oversight and collaboration between PharmD professionals and prescribers through drug use evaluation, coordination of multiple prescribers and monitoring for use of duplicative or interacting medications.

Managing the challenges posed by the unintended health and monetary consequences of polypharmacy can be complex, but it is a solvable problem.

The impact of the propoxyphene product withdrawal

In order to evaluate the potential impact of the recent withdrawal of all propoxyphene-containing products, the Healthesystems clinical services group conducted a sampling of transactions for patients who had taken one of these products within 90 days of the recall.

A random sampling of more than 125 profiles was taken across Healthesystems clients for the purpose of evaluating the financial impact of withdrawing propoxyphene-containing products from the market. The average cost of a propoxyphene prescription was calculated (brand and generic) at $57.34. The same average was calculated for all replacement prescriptions one and two months after the propoxyphene withdrawal. Respectively, those costs were $63.60 (+9.84 percent) and $59.94 (+4.34 percent). Patients were most often switched to tramadol, oxycodone with APAP or acetaminophen with codeine. In a small number of cases, the initial drug switch was to a stronger agent and subsequently discontinued, while in other cases the drug switch was to a weaker agent that was later replaced with a stronger one. An immediate and direct increase was seen in prescription drug cost related to the withdrawal.

Over the long-term, a slow increase in prescription drug costs should also be expected. This is due to 51 percent of those patients being switched to a stronger opioid analgesic. It is reasonable to assume that in a subpopulation, opioid tolerance will develop quicker, the severity of hyperalgesia will increase and the need for laxative medications will increase.

According to the 2009 Annual Report of the American Association of Poison Control Centers' National Poison Data System, 4627 propoxyphene with acetaminophen (APAP) exposures were reported.[15] Of those, 1168 were treated in hospitals. Outcomes were:

- >>509 — no clinical problem
- >>404 — minor clinical problem
- >>209 — moderate clinical outcome
- >>39 — major episode
- >>8 — fatal outcome

A further analysis suggested that six of the eight fatalities were more likely due to other causes. In comparison, in Florida alone, seven deaths every day are attributed to the abuse of oxycodone and hydrocodone (both in combination with APAP).[16] Coincidentally, these are the same agents to which 31 percent of the patients in the sample population were switched. Without question, this product withdrawal will lead to increased opioid use and possible abuse, addiction, hospitalization or even death for some of these patients. While the propoxyphene withdrawal was appropriate, from a clinical standpoint, the implications of the FDA's action are unknown at this point. The continued growth in use of opioids in the workers' compensation population is concerning, and that may be compounded by propoxyphene's exit from the market.

Hold for chart

Compliance updates

Georgia's Board of Workers' Compensation has adopted changes to the Pharmaceutical section of the Medical Fee Schedule, effective on April 1, 2011. Dispense fees were increased slightly and new language was adopted which addresses the reimbursement of repackaged drugs at the original packager's NDC reimbursement rate.

Oregon's Workers' Compensation Division (WCD) completed its fee schedule review process, publishing updated reimbursement rates which became effective on April 1, 2011. One of the notable changes is a new Pharmaceutical Clinical Justification Form 4909 which is intended to reduce the prevalence of physicians prescribing some of the highest cost brand name medications. The Division will now require the prescribing physician to complete this new form for any first-time prescription greater than a five-day supply for Celebrex®, Cymbalta®, Fentora®, Kadian®, Lidoderm®, Lyrica®, and OxyContin®.

California's State Assembly is working on a bill to address the prevalence of California physicians who prescribe compound medications which, according to a CWCI study published in 2010, is a growing cost driver in the workers' compensation system. Assembly Bill 378 (D-Solorio) proposes to amend Section 139.3 of the Labor Code to address this issue. Existing law prohibits a physician from referring a patient for medical goods or services when the physician or their family has a financial interest in the entity that receives the referral. The amendment explicitly includes pharmacy services among the list of services and goods which are applicable in this section of the Labor Code.

Medications to watch

Every year, a number of new medications are approved and introduced into the marketplace with the potential to impact costs to workers' compensation payers.

In 2010 alone the Food and Drug Administration (FDA) approved four new generics formulations and 13 new drugs that are likely to be seen as players in workers' compensation drug spend. Notably, there were three new opioid products including Exalgo™ (hydromorphone extended-release), the reformulated, abuse-deterrent Oxycontin® (oxycodone extended-release), and a generic version of Opana IR® (oxymorphone immediate-release) that warrant close monitoring.

In the first three months of 2011, five new medications were approved that will likely be used for treating workers' compensation patients. Three of these, Gralise™ (gabapentin extended-release), Viibryd™ (vilazodone), and Abstral® (fentanyl sublingual tablet) are certainly drugs to watch as they emerge in the marketplace.

>>Viibryd is an antidepressant that was approved for the treatment of major depressive disorder and is expected to be launched in the second quarter of 2011.[17] The labeling contains a boxed warning concerning suicidality as well as caution concerning serotonin syndrome. Its efficacy was evaluated in two 8-week randomized, double-blind, placebo-controlled clinical trials. It is a selective serotonin reuptake inhibitor (SSRI) that also effects 5HT1A receptors as a partial agonist.

>>Gralise is an extended-release version of Neurontin® (gabapentin) and was approved for the treatment of post-herpetic neuralgia.[18] There is no launch date currently scheduled for this medication, but, expected in late 2011, it will likely be extensively used off-label for the treatment of neuropathic pain as an alternative to gabapentin and Lyrica®.

>>Abstral is an oral fentanyl product that falls into the same category as Actiq®, Fentora®, and Onsolis®. Like these other oral fentanyl products, though Abstral is only approved for treating pain in cancer patients, it may be seen used off-label in workers' compensation cases. But, it is not recommend for use in workers' compensation cases and it is recommended that in every case the physician be asked to select a different immediate-release opioid (e.g., morphine IR, oxycodone IR).[19]

Additionally, in early February 2011, Zolpimist™ (zolpidem oral spray) was released to the marketplace after being approved by the FDA at the end of 2008. Zolpimist is a sleep aid with the same active ingredient as Ambien® (zolpidem) or Ambien CR® (zolpidem controlled-release).[20] It is an oral spray formulation that is absorbed through the mouth and GI tract, allowing for a faster onset. As with other forms of zolpidem, complex sleep-related behaviors such as sleep driving—that is, driving while not fully awake after ingestion of a sedative-hypnotic, with no memory of the event—are possible. There is some concern that these behaviors

may increase with the delivery system and rapid onset of this formulation. Accidental use by children if not stored properly is also a serious concern. Due to the nature of this medication and its delivery form, it is recommended that other sleep aids be used whenever possible.

It is certain that 2011 will bring more new drug approvals that will require action by workers' compensation payers. FDA review of two new abuse-resistant oxycodone formulations, Remoxy® and Acurox®, are expected by the end of June 2011. Watching the drug spend and utilization of opioid analgesics continues to be important as new drugs are introduced in this therapeutic class. The clinical staff at Healthesystems monitors the pharmaceutical marketplace continuously for new drugs and new information in order to evaluate the potential for adverse reactions, inappropriate use and effects on drug spend for the workers' compensation patient population. Proactive oversight allows us to keep our clients informed and prepared for whatever impact a new drug may have for patient and payer alike.

Assessing new drugs in workers' comp drug plans

An important responsibility of a pharmacy benefit manager is to monitor the pharmaceutical pipeline for new and interesting agents that may have application in the workers' compensation pain management arena.

As each new agent is approved by the Food and Drug Administration (FDA), it is important for a PBM's clinical services group to proactively evaluate the likelihood of the new drug replacing an old and trusted agent, perhaps a generic, and its potential financial impact.

There are several very logical and, heretofore, seldom asked questions that can be applied when conducting such an evaluation. A paper published in *American Family Physician* in 2010 titled "Evaluating the Safety and Effectiveness of New Drugs" has organized some thoughts concerning this essential activity.[21] The article proposes these five "STEPS" that should be followed when a new drug is assessed.

1. Safety
2. Tolerability
3. Effectiveness
4. Price
5. Simplicity

S.T.E.P.S

Ideally, applying these STEPS, or taking a similar approach, would promote use of appropriate, safe and cost-effective medications in workers' compensation cases and could also be used in developing injury related treatment guidelines, such as the Official Disability Guidelines (ODG).

Safety

Safety is, of course, a primary concern regarding any drug. The authors found that 10 percent of the new drugs introduced between 1975 and 1999 had very serious adverse effects that were not discovered until after the drugs were introduced into the market.[22] What many lay persons and health care workers alike may not realize is just how few patients are involved in the clinical studies conducted to evaluate new drugs. Typically, only about 1,500 patients participate in such evaluations.[23] Additionally, the studies usually last a very short period of time — perhaps as little as two or three weeks — while the drugs are frequently intended for long-term use in the treatment of chronic conditions.

Tolerability

Can the patient tolerate the new agent? While it may be safe, if the new agent makes the patient nauseated or dizzy, will they be motivated to take the medication for an extended period? Some drugs cause visual disturbance for the first several weeks, others may alter the sense of smell or taste. The most ineffective drug is the one the patient can't or won't take. Therefore, it is important to consider tolerability, especially in workers' compensation cases where a patient may be dealing with a painful injury.

Effectiveness

How well does the drug produce the intended result? If it is intended to moderate the perception of pain, how well does it accomplish its task? In other words, is the drug effective? For clinicians, one of the most positive features of the Patient Protection and Affordable Care Act — the federal statute signed into United States law in March 2010 — is the provision that establishes a Patient-Centered Outcomes Research Institute to undertake "comparative effectiveness" research. This provision mandates the comparison of a new drug to those it is intended to replace. In current studies, a new drug is typically compared only to a placebo, or "sugar pill," to determine its effectiveness in moderating the clinical end point. If it is no more effective than the old drug, has more side effects or is more costly, then the new drug should probably not be used as a first-line treatment for a claimant.

Price

How costly is the new drug? Pharmaceutical companies are expert at assessing what the market will bear. If the new drug is more effective, has fewer side effects or can be taken fewer times per day, then the price is likely to be higher than an older agent. If it is intended to replace two medications in a drug regimen, again the price increases. If a drug has a better "cure-rate" than a predecessor, its price will reflect that advantage. It is important for prescribers, payers, and PBMs to weigh the cost versus benefit of a new drug when evaluating whether it should be included in the medication plan.

Simplicity

How complicated is it to take the drug? Is the regimen simple enough to promote adherence? When Gralise™ (gabapentin extended release) is introduced to the market, it will provide an alternative to gabapentin, which currently requires multiple daily doses to be effective in treating neuropathic pain. If this medication meets the requirements in the other four STEPS, it's an example of one medication that might be a good alternative for workers' compensation patients.

It is estimated that 30-50 percent of prescribed medications are not taken as intended.[24] Patients forget to take their medication, skip doses to save money or don't take them with or without food, or as otherwise directed. For example, a reasonably popular medication to strengthen bones and sometimes used to treat patients with chronic regional pain syndrome (CRPS) must be consumed with large amounts of water and the patient must remain upright for at least a half-hour after taking the medication. For some patients, those restrictions are too complex or too bothersome to follow.

To be effective, medications must be taken according to prescribed directions, so if the new drug has simpler directions that make adherence easier, and as long as the new agent is tolerable, any added expense may be worthwhile.

For each new agent that arrives on the health care scene, these basic questions should be answered before the agent is added to a medication plan. While some of the STEPS might be difficult to apply to certain medications or circumstances in workers' compensation cases, it is still important for new medications to be reviewed and analyzed by a PBM and information proactively passed on to the payer. And, if a medication plan requires that a drug have prior authorization, that should, at minimum, trigger the claims professional to carefully review the drug for its relatedness to the injury. Ultimately, further consideration should be given to the safety, tolerability, effectiveness, price and simplicity of medications requiring prior authorization in order for the claimant to obtain approval. A PBM and its clinical services group are key players in applying these considerations to a medication plan and in answering drug-related questions for its clients.

About Healthesystems

Healthesystems is a specialty provider of innovative medical cost management solutions for the workers' compensation industry. Our comprehensive products include a leading Pharmacy Benefit Management Program, expert Clinical Review Services and a revolutionary Ancillary Benefits Management solution for prospectively managing ancillary medical services.

Our Verticē Claims Information Portal delivers real-time pharmacy and ancillary benefit management program information, reports and tools. This intuitive web portal allows claims professionals to access tools for quickly and efficiently processing provider transactions, running reports, retrieving relevant clinical information and many other functions.

By leveraging powerful technology, clinical expertise and enhanced workflow automation tools, we provide clients with flexible programs that reduce the total cost of medical care and manage drug utilization, including the overuse of narcotics and other problematic drugs, all while increasing the quality of care for injured workers.

Data referenced in this document was produced using Healthesystems' proprietary pharmacy database information.

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