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# First Script Prescription Benefit News
## for Workers' Compensation

**February 2017**


## What is step therapy with regard to medications?

Step therapy is the concept of a patient trying a first-line recommended medication before taking a "step up" to a medication that costs more and/or has less supporting evidence of effectiveness. First-line medications are those that are usually maintained in various guidelines and prescribing recommendations as those that should be the first tried when treating a disease or condition, again based on evidence for use and cost considerations. Typically, a formulary (aka, drug list) determines where a particular medication falls with regard to a recommended place in therapy and what requirements need to be met prior to approval for payment. In general, the formulary represents "a list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits" (HealthCare.gov). When a particular medication falls outside of the formulary or involves a step therapy requirement, a "prior authorization" for coverage is typically initiated.

Formulary and drug list placement decisions are managed in a number of different ways, but the plan limitations are often administered by a pharmacy benefit manager (PBM), such as First Script. Many organizations incorporate the oversight of a Pharmacy & Therapeutics Committee (P & T Committee) for formulary system oversight and management, and the drug list is continually updated as new treatments become available or related information comes to light. In the case of workers' comp, many considerations may go into step therapy requirements and formulary placement, including work-relatedness, cost of the medication, place in therapy, treatment guidelines, availability of alternative agents, and evidence-based medicine (EBM) resources.

Several references are available with regard to treatment guidelines and medication recommendations, and these may be applied when determining formulary drug placement. The Official Disability Guidelines (ODG) from the Work Loss Data Institute and the Practice Guidelines from the American College of Occupational and Environmental Medicine (ACOEM) represent guidelines that are tailored to workers' compensation. These resources can be accessed online (subscription required) at www.odg-twc.com and www.acoem.org/PracticeGuidelines.aspx, respectively. In addition, general national guidelines that address a broader population (i.e., any individual being treated for an illness or injury and not those limited to workers' comp) are available through resources such as the National Guideline Clearinghouse and the Centers for Disease Control (CDC). An example of recently-published recommendations from the CDC that could have application for an injured worker population is the CDC's Guideline for Prescribing Opioids for Chronic Pain.

In addition to these resources, some states are developing their own workers' comp closed formulary drug lists and treatment recommendations. Several are in development, and one of the earliest examples of an established state-based formulary is found in Texas with their "N-List" that was created using the recommendations from ODG. New York is a state with its own medical treatment guidelines for injuries or illnesses involving the neck, back, shoulder, and knee.

Evidence-based medicine is also a driver of drug formulary decisions, medical guideline recommendations, and step therapy requirements. EBM generally refers to a grouping of data/results from high grade evidence trials (e.g., randomized controlled trials) and literature reviews along with patient considerations and clinical experience. This term typically points to best practices accepted by the clinical community and based heavily in fact and strong scientific evidence.

To better illustrate the concept of step therapy and formulary rules, it may be helpful to walk through a general example of how all of this works together when a patient attempts to fill a drug with such restrictions. On page 2 is an outline of an example of a step-by-step process that might occur using the brand-only medication Vivlodex® (meloxicam capsules). Please note, this example is strictly for illustrative purposes and is not necessarily based on an established drug list. Table 1 shows a basic cost comparison (using average wholesale price [AWP] accessed from Medispan) of Vivlodex® with alternative options within the same therapeutic class of nonsteroidal anti-inflammatory drugs (NSAIDs).

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An example monthly prescription cost comparison (based solely on AWP) for Vivlodex® 5 mg capsules taken once daily for 30 days (quantity 30) vs. generic meloxicam 7.5 mg tablets taken once daily for 30 days (quantity 30) would represent a monthly cost of $783.30 vs. $9.90, respectively, and a difference (or potential savings) of $773.40 per month. Based on the available evidence and treatment recommendations for this therapeutic class, generic NSAIDs and products such as Vivlodex® have similar efficacy and risks but a vast difference in cost. Thus, a formulary that applies current guidelines for use of medications would promote the alternative first-line therapy recommendations listed in Table 1 before recommending approval of the more costly Vivlodex®, and a patient presenting a prescription for Vivlodex® would encounter a requirement for prior authorization before being able to obtain the drug. In this case, step therapy prior authorization requirements might call for trial and failure of one or more of the alternative NSAIDs listed above before consideration of Vivlodex®.

Table 1

| Generic (Brand) | Cost/Unit | Cost Difference/Unit* |
|---|---|---|
| celecoxib 200 mg (Celebrex®) | $0.41 | $25.70 |
| etodolac 200 mg (Lodine®) | $0.73 | $25.38 |
| ibuprofen 800 mg (Motrin®) | $0.07 | $26.04 |
| nabumetone 500 mg (Relafen®) | $0.51 | $25.60 |
| naproxen 500 mg (Naprosyn®) | $0.10 | $26.01 |
| meloxicam 7.5 mg (Mobic®) | $0.33 | $25.78 |

**Compared to Vivlodex 5 mg, AWP $26.11/capsule*

While formularies and step therapy requirements may vary among and within administering bodies, the general purpose and structure is the same. These tools are intended to control costs and guide end users toward best practice pharmaceutical therapy with the incorporation of EBM and guideline consensus first-line therapies, thus enhancing savings and minimizing risks while promoting favorable patient outcomes. For more information, please contact your account manager. You can also send your client-specific questions to our team of clinical pharmacists at askthepharmacist@cvty.com.

## Drug of the Month

### Vantrela™ ER

The Food and Drug Administration (FDA) approved another abuse-deterrent formulation (ADF) of extended-release hydrocodone, Vantrela™ ER, on January 17, 2017 for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Vantrela™ ER joins FDA-approved ADF hydrocodone ER products already on the market: Hysingla® ER (approved 11/20/14) and Zohydro® ER (approved 10/25/13, reformulated version with abuse-deterrent BeadTek™ technology approved 1/30/15).

The intended dosing for Vantrela™ ER is for oral use on a scheduled basis every 12 hours in patients who are considered opioid tolerant (i.e., taking at least 60 mg oral morphine, or equivalent, per day for one week or longer). The tablets are to be swallowed whole and intact. Dosing should be individualized to the patient and initiated at the lowest effective dose for the shortest duration needed to minimize risk. Vantrela™ ER is available in five strengths (15 mg, 30 mg, 45 mg, 60 mg, 90 mg hydrocodone), with a maximum daily dose not to exceed 90 mg every 12 hours (180 mg/day).

Teva, the drug's manufacturer, indicates that the product's proprietary abuse-deterrent properties have been demonstrated in a handful of laboratory studies and clinical abuse potential (CAP) trials. Vantrela™ ER uses a physiochemical barrier formulation that helps to prevent abusers from manipulating the product to facilitate rapid opioid release into the body through intravenous, nasal, and oral (aka, by mouth) routes, and this can also prevent accidental crushing or chewing in compliant patients. However, this method does not deter the abuse of intact tablets such as the user taking more medication than prescribed during a single dose, and does not completely eliminate the possibility of abuse through any route. Some other examples of physiochemical barrier opioid products include Oxycontin®, Hysingla® ER, Zohydro® ER (reformulated), Opana® ER (crush-resistant formulation), and Exalgo®.

Vantrela™ ER is a Schedule II Controlled Substance, and although it possesses abuse-deterrent properties, abuse is still possible. Due to these risks along with the associated increased potential risk of overdose with extended-release products, providers are encouraged to assess the patient's risk of addiction, abuse, or misuse prior to prescribing Vantrela™ ER and regularly thereafter. It is also recommended to reserve use of Vantrela™ ER for individuals for whom alternative therapies such as non-opioid analgesics or short-acting opioids are not tolerated or are insufficient to provide adequate pain relief.

Today, the impact of abuse-deterrent formulations on prescription opioid abuse is difficult to validate as long-term post-marketing data are lacking. While these products represent a viable additional tool for the prevention of prescription drug abuse, they are not fool-proof, and provider vigilance and the application of evidence-based treatment best practices remain essential.

References:
www.accessdata.fda.gov/scripts/cder/drugsatfda/
www.tevapharm.com
www.vantrelaer.com