Workers' Comp

Why High-Impact Drugs Are Taking a Bigger Piece of Pharm Spend

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Tom Kerr (TK): Welcome to the fourth and final installment of the Enlyte Drug Trends review. Today we'll be discussing aggregate trends and specifically highlighting so called high-impact drug classes.

Joining me, as always, is Nikki Wilson, Senior Director of Clinical Pharmacy Services. Nikki, good to talk with you again. Let's start with the broad definition of what is included in the report. What categories make up the high-impact drug classes?

Nikki Wilson (NW): We define high-impact drug classes to include certain topical analgesic products, compound kits, combo convenience packs, and specialty medication. So, as a whole, these categories represent relatively low utilization, but they're associated with exponentially higher costs.

For example, exorbitantly priced compound kits and combo packs, which contain components that are available separately or in different formulations at a much lower cost can average about $2,100 per prescription, which can give you an idea of the impact they have on cost trends.

So, I'll dive into the definitions of each of these in a little bit more detail and give you some ideas of where they sit and why they're driving price and cost, and why we've decided to highlight them the last several years.

So, by definition, compound kits contain two or more premeasured drug ingredients that must be combined immediately prior to use based on a prescription order. And they're sold together as one product generally under one National Drug Code Identifier (NDC).

The combo packs consist of multiple commercially available products that are conveniently packaged together for sale with a common therapeutic purpose. So, these are things that may be a bottle of powder that's premeasured and packaged, and then it is co-packaged with a bottle of liquid that's premeasured. And the pharmacist just has to take the tops off and combine them both, shake them up immediately prior to use. So, the work and compounding are kind of done for them and prepackaged, and the price is marked up under that one NDC, versus billing multiple lines of NDCs that we would typically see with a compound.

And rounding out our high-impact categories, similar to some of the other categories discussed, is the specialty drug category, which includes medications that are typically used to treat complex chronic conditions and represents a major area of pharmaceutical development with significant costs.

These products do have evidence to support their use, but place in therapy and proper patient selection are critical, along with work-relatedness considerations, as many are for conditions not often covered in the comp space. And the category includes a number of injectable products, as well as biologic and biosimilar medications, which require unique considerations for appropriate use, often along with special storage and handling requirements.

TK: OK, so let's dig a little deeper into the cost trends regarding this drug class. What are you seeing?

NW: The extreme price markup for combo or so-called convenience packs, is one we've seen enter the market recently that contains an over-the-counter topical gel combined with a 100-count box of alcohol wipes packaged together as one product and build under one NDC.

When dispensed separately, the individual products carry an average wholesale price or AWP of about $15 combined or total for the product. However, as a combo pack product co?packaged under one NDC, the price for these same products now represents an AWP around $3,400, which is over a 22,000 percent increase in price.

You can start to see how especially the combo packs or those convenience packs can really get the attention of those who are monitoring pharmacy spend. And again, both those products would be commercially available on their own for sale as well at a much lower price.

In 2022, we saw increases in scripts per claim, cost per script, and cost per claim across these categories with declines and scripts per claim within the combo pack trends being offset by almost a 90 percent increase in cost per script in that category. Which further drives home the need for vigilance, given the inflated costs associated with these products with little to no added therapeutic benefit and the importance of a continued focus on this area and the impacts it can have.

Also of note, topicals have been a growing area of utilization and spend, and this category includes both prescription topical analgesics as well as private label topical analgesics or PLTAs. The topical category

experienced increases across the board in 2022, which is a trend that has been holding steady over the last five years, where we've been carving the category out separately for analysis and trend tracking starting back in 2017.

Prescription topicals typically encompass non?steroidal anti?inflammatory drug or NSAID, particularly those containing diclofenac and the anesthetic lidocaine products, primarily including products like Voltaren gel, Pensaid solution, Flector patch, Lidoderm, and ZTlido patches, and lidocaine creams and ointments.

And the category seems to be really the next horizon for billers and dispensers, especially physician dispensers to turn as a money-making opportunity. And it stands out as a continuing trend.

TK: So, one thing that stood out in this year's report was the jump in the topical class to No. 1 for spend in 2022, displacing opioids for the first time in recent history. Specifically looking at topicals, what are we targeting within this class and what should we be considered for appropriate management?

NW: Yeah, so topicals are being prescribed in workers' comp with growing frequency. We've definitely seen that over the last several years. And, like you said, they now represent a leader in spend and a growing source of concern in the workers' compensation space.

They're ranking in that top spot among the therapeutic classes at 18.5 percent of total drug cost in 2022 and displacing opioids, as you mentioned, with opioids moving to the No. 2 spot and representing 15.4 percent of total cost comparatively.

By utilization, topicals ranked fifth by volume of scripts among the top therapeutic classes at 7.2 percent of total prescriptions. So again, there's that cost-to-use disparity where if they're much higher in spend, well, they're only fifth as far as the volume of scripts goes.

So, we do target two categories in the trend reports that we put out. There's a lot of topicals on the market, including ophthalmic or otic. So, for the ear, the eye, other types of antibiotics, but we're targeting two categories specifically when we talk about this trend data within that topical and dermatological class for analysis and clinical and cost oversight in particular.

And, as I mentioned a little bit earlier, those subcategories are prescription and private label topical analgesics (PLTAs). So, I'm going to talk a little bit about each one and give a couple examples to hopefully color in what exactly we're targeting.

So, prescription topical products which, again, primarily contain the NSAID, diclofenac, or the anesthetic lidocaine, carry specific limited FDA approval for use that should be considered along with the appropriate place in therapy.

Conversely, PLTAs are not approved by the FDA and they're not evaluated for compliance with applicable regulations and policies pertaining to safe and effective use. Topicals are also not typically recommended as first-line therapy in most cases. So, other things should be tried in most cases before we prescribe a topical agent.

For example, topical NSAID Pensaid solution, which is available in a 2 percent solution, represents the top ranking drug within the category at 22.9 percent of prescription topical costs, and it's No. 3 by utilization at 6.6 percent of topical scripts. And it's only FDA approved for use on the knee for treatment of osteoarthritis pain and has not been studied in other joints.

Topical lidocaine 5 percent patches, which is a generic version of Lidoderm, ranks No. 2 at 15.1 percent of topical costs and No. 2 by utilization as well at 24 percent of topical scripts. And it's only FDA approved for use in the relief of pain associated with postherpetic neuralgia, which is - a very specific pain complaint that occurs following infection of the varicella zoster virus, which people would be familiar with that it causes chicken pox and shingles. And so, after shingles, it can lead to inflammation in the nerves under the skin and this burning pain sensation, which is really the most common complication of shingles. It's what people remember when they have that virus sort of flare back up after an original chickenpox infection.

So, our industry evidence?based recommendations, such as those from the official disability guidelines or ODG, only support that form of Lidoderm or lidocaine topical patches used for the FDA-approved indication. However, we see that particular drug product commonly prescribed and used off label for general low-back pain and other types of deep tissue or joint pain complaints, which is not supported by the evidence.

In addition, PLTAs, in particular, have not been shown to offer greater clinical benefit versus more cost-effective, comparable OTC alternatives. And they often contain the same ingredients. As an example, newer to the market Mencylate cream. It's a new one that we've been tracking in our book. It's a pain-relieving cream containing 2 percent menthol along with 10 percent methyl salicylate. And it's promoted for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

And it contains the same active ingredients available in OTC products such as Bengay, BioFreeze, and IcyHot that you can get at a fraction of the price, which are all available for easily under $10 without a prescription. But the PLTA product is priced at almost $1,500 per 2 oz. package.

So, again, there's really nothing special about it. And creating further challenges, these PLTAs are marketed directly to physicians' offices for dispensing, which creates paper bill and out-of-network concerns regarding cost management. And they're bypassing safety and clinical controls that we have in place for things that are coming through in-network or at the retail space. In 2022, both categories experienced increases in both scripts, and about a 10 percent increase in cost per claim, so their impact continues to inch upward.

And while topical medications can present several benefits and may be a viable option for select patients, they really require careful oversight and, in many cases, their lack of demonstrated superiority, effectiveness, and their price impacts support the argument for consideration of therapeutic ingredient equivalents, and products which produce much lower costs and or clinically efficacious outcomes.

TK: OK, so moving on to the special medication category, um, it contains some key drivers to spend for 2022. Can you explain how we define this category and what particular therapeutic classes or disease management targets were of interest in our trend data?

NW: Sure. So, challenging about this class, there really is no universal list of specialty drugs that allows anyone to easily identify this group. It's again made up of relatively low-volume, high-cost medications, and most entities out there will establish their own definition of what should be included within the category. Which generally comprises some combination of criteria involving drugs used to treat rare complex conditions, considerations for any special storage and handling requirements, like refrigeration or temperature controls, cost, various clinical applications for use (such as administration challenges), patient adherence, specific testing and therapeutic monitoring requirements, and patient safety and immunogenicity concerns.

So, given this, the specialty category includes a broader definition of products that fall into this criterion set for us, as well as biologics and biosimilars. So, those are also included in this bucket defined by the FDA to include vaccines, viruses, therapeutic serums, everything to toxins, blood or its derivatives, allergenic products.

So, for example, in workers' compensation, the specialty category often represents injectables used to manage inflammatory conditions, or various types of joint pain, along with a number of additional oral meds that benefit from added clinical oversight. So, in 2022, we report on the top five disease state categories primarily by the disease state that they're managing, and then we carve these particular drugs that are meeting that criteria underneath that bucket.

So, the top five disease state categories in 2022 ranked by specialty costs were, in descending order, blood-clotting treatment and prevention, HIV and AIDS treatment (including post-exposure prophylaxis, or needlestick injury protocol), antiviral meds, osteoarthritis, migraine, and autoimmune and related disorders.

So, to provide some perspective, the top five disease state categories with the medications rolled up underneath them represented 75.9 percent of all specialty usage and 57 percent of specialty cost. Of note in 2022, the migraine category jumped 18.4 percent to the No. 4 spot by percent of specialty category costs, driven primarily by the newer therapeutic class of migraine medications known as CGRPs or calcitonin gene-related peptide.

And I know we talked about that a little bit in the second series of drug trends reports . I went into a little bit more detail about how those work, but it's really a novel mechanism of action in that class, and a lot of those are available as an injection. There's one that's an oral. But those are the CGRP antagonist for the prevention and acute treatment of migraine headaches in adults, and includes drugs such as Ajovy, Emgality, Aimovig, with an average cost per script of just under $800.

In addition, for workers' compensation, specialty drugs can be especially challenging as they're prescribed to treat conditions that may either directly, or even indirectly, be related to workplace injuries or illnesses.

So, the various distribution channels also pose additional concerns with about half of these medications being dispensed or administered in doctor's offices, clinics and hospitals and not through traditional pharmacies with many of these products being billed under broader J codes or the health care common procedure coding system or hicks picks. This makes them a little bit more challenging to readily identify through systems and pharmacy that typically rely on NDCs, or GPIs, or other codes that we're more familiar with as programming indicators that would allow for repricing to a specific drug or product.

While high costs and other challenges remain a concern, specialty drugs, including biologics and biosimilars should be continually evaluated for the potential benefits to injured employees as they may provide relief that our traditional therapies cannot, which could potentially result in better quality of life and even advantageous overall claim outcomes, as well as fewer hospital admissions, emergency room visits and laboratory tests.

However, in other cases, less expensive, but equally effective alternative therapies might offer a better choice. So, it really comes down to the individual ill or injured employee and the claim needs. And the input of a skilled clinician can be invaluable in this space.

TK: And then what recommendations or strategies can be deployed to address the challenges with these high-impact pharmaceuticals?

NW: When it comes to addressing these high-impact pharmaceutical challenges, the best approach is to deploy targeted clinical solutions that leverage three basic strategies to drive pharmacy program optimization.

So first, identification of these challenging high-impact pharmaceutical categories is key. So, they're not readily identifiable within the data. I think I've said a couple different ways. In addition, a pharmacy program should include proactive solution options for post-dispense review, plan edits, drugless control or formulary management, as well as medication prior authorization decision support that includes both clinical and

regulatory or juris rules that reinforce utilization management and billing controls.

Second, follow the evidence. So, enforcing those clinical controls that target these categories and scenarios for interventions to promote first-line more cost-effective alternatives through clinical review and timely recommendations, drug utilization assessments, and/or formal utilization review.

I’m building these categories into predictive and demonstrative risk-modeling to establish clinical solutions that address patient safety, align with evidence?based recommendations for treatment, and enforce various treatment guidelines, such as the ODG, and then following this up by promoting ongoing clinician engagement, oversight, education and coordination can really be a strong approach.

And finally, I think this could be one of the most important pieces, is being able to use reporting tools and data analytics to continually assess and improve processes and collaboration with the various stakeholders on the claim. This includes communication, any workflow adjustments that are needed, education, support, and partnership review to address areas of ongoing opportunity and impact.

TK: Thanks, Nikki. This concludes our Enlyte drug trends review series. We hope you enjoyed it as much as we enjoyed sharing it with you. However, Nikki and I will be offering a free webinar on Wednesday Sept. 27 on Evaluating an Ever-Changing Pharmacy Landscape in Workers’ Compensation . Click here to register.



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