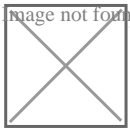




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Examining High-Impact Drug Class Trends

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9 MIN READ

As part of our supplemental podcast series to [Mitchell's Drug Trends Report](#), we've brought back Nikki Wilson, PharmD, MBA, Senior Director, Mitchell Clinical Pharmacy Solutions, to discuss aggregate trends, specifically highlighting so-called high-impact drug classes.

Tom Kerr (TK): For today's conversation we've categorized high-impact classes to include topicals, compound kits, combo packs, and specialty medications that represent relatively low utilization, however, they can be

associated with exponentially higher costs. So, with that in mind, let's focus on the topical category to start. Why is this area included?

Nikki Wilson (NW): Over the last several years, the industry has seen category spend in utilization for topicals climb as our compound spend and utilization has declined. So topicals are actually now a leading spend and source of concern in the workers' comp space and the category is part of the makeup of a whole that seems to be the next horizon that billers and dispensers, especially physician dispensers, are turning to. So sometimes, purely, that's a money-making play, which is essentially what we've carved out in our fourth drug trends installment with our high-impact classes. And we'll continue to watch as we see this trend continue.

The topical category is of particular interest as topicals are being prescribed in workers' comp with growing frequency — ranking third among the top therapeutic classes at 12.4 percent of total drug cost and representing 5.7 percent of total prescriptions in 2021.

And, within that class, we have some cost drivers, including prescription and private-label topical analgesics or PLTAs. And those are associated with limited clinical efficacy and exorbitant pricing that often eliminates them as a favorable first-line therapy option.

While topical meds can present several benefits, such as lower systemic absorption, meaning less gets into the circulatory system and goes through the body, thus leading to a potentially lower side effect profile and less drug-to-drug interactions. They might be a viable option for select patients, especially those with confounding comorbid conditions or with a contraindication to the oral alternatives.

But there's still very much need for oversight, where possible, given, in many cases, their lack of demonstrated superiority and effectiveness, along with considerations for therapeutic similarity ingredient equivalents, price impacts, essentially looking for opportunities for a lower cost or equally as clinically efficacious alternative.

TK: So, what's the difference between prescription and private-label topical analgesics or PLTAs?

NW: Prescription topical medications, including non-steroidal anti-inflammatory products containing diclofenac, such as common ones we see are Flector patch and Pennsaid, as well as some topical anesthetics containing lidocaine, such as Lidoderm patches or ZTlido is a newer one.

Those carry a specific, limited FDA-approved uses that should be considered along with appropriate place and therapy for select patients. So-called private-label topical analgesics or PLTAs, on the other hand, they're not approved by the FDA. And the FDA does not evaluate PLTA compliance with applicable regulations and policies pertaining to safe and effective use.

So, examples of these types of products include Velma, LidoPro, and New Terocin. And they're not recommended as first-line therapy, nor have they been shown to offer greater clinical benefit to the injured employee versus more cost-effective, comparable over-the-counter or OTC alternatives. Often, they contain the same ingredients.

Creating further challenges, most of these products are marketed directly to physicians' offices for dispensing, creating paper bill and out-of-network concerns regarding cost management. Breaking out our data from 2021 a little further, the top five topical medications in our book by cost were represented by four prescription topicals and one PLTA.

Brand name ZTlido, which is the brand name product containing lidocaine 1.8 percent in prescription topical patch form, held the No. 1 spot, followed by two different prescription topical diclofenac products, Pennsaid

solution and Voltaren Gel. ZTlido and Voltaren Gel also had the highest utilization at over about 1/3 each of the prescription volume within the category.

Interestingly, Voltaren Gel is available both as a generic and as an over-the-counter product, following the FDA's approval for the OTC product launch in February 2020, which makes it available now without a prescription. So, in this case, the cost ranking for Voltaren is primarily driven by its utilization. We see a lot of that, which is good.

Velma, a brand-name-only, private top-, private-label topical patch containing analgesics, methyl salicylate 16 percent, menthol 2 percent, and lidocaine 4 percent, rounded out the top, the No. 5 spot in the 2021 data.

As a point of reference, the top five topicals on this list accounted for 75.3 percent of all usage and 71.2 percent of all costs associated with this therapeutic class. So, in other words, we're really talking about the products that represent the majority of use and spend for topicals in 2021.

TK: Great. And let's discuss compound kits and combo packs in more detail. What are they and why are they under scrutiny?

NW: 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. Combo packs consist of multiple commercially available products that are conveniently packaged together for sale with a common therapeutic purpose.

So, in either case, those fixed combination and co-packaged drugs and non-drug items, they're primarily coming through out-of-network channels. And often, the individual components are available separately or in different formulations at a much lower cost.

So, one example I like to give to illustrate the extreme price markup for the combo pack products, in particular, involves a topical cream combined with silicone gel sheets in one package which, when they're dispensed separately, they carry an average wholesale price or AWP of about \$59 altogether.

However, a combo pack product exists today that co-packages these under one National Drug Code and marks up the price for the same products to AWP north of \$5,000. In our recently published fourth drug trends infographic, we highlighted declining trends in both scripts and costs within the combo pack category, fortunately. Following implementation of various programs and controls we've used to address them.

However, the inflated cost associated with such products averaging about \$2,100 per script in 2021 speaks to the importance for continued focus on this area and the impacts it can have. It's certainly a category that gets attention based on that large markup.

TK: Thanks. And how do we define the specialty drug category? And what's important to understand here?

NW: Similar to some of the other categories we've discussed so far, there is no universal list per se of specialty drugs out there that we can use to address this group of medications. And most entities will establish their own definition of what is included. And generally, that involves some combination of criteria that may look at low-volume, high-cost medications. Those used to treat rare complex conditions, consideration of special storage and handling requirements, and various clinical applications for use, such as administration concerns, patient adherence, specific testing and monitoring requirements, and sometimes patient safety and immunogenicity concerns.

Our specialty category includes a broader definition of products that may fall into this criteria set, as well as biologics and biosimilars. Biologic products are defined by the FDA to include vaccines, viruses, therapeutic serums, toxins, blood or its derivatives, allergenic products and others. And they're similar to chemical drugs, but typically represent larger, more complex molecules that are derived from living cells and organisms. This category is often represented by injectables used to manage inflammatory conditions or various types of joint pain, for example.

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. And the various distribution channels can pose additional concerns, with about half of these medications dispensed in doctors' offices, clinics, and hospitals, and not through traditional pharmacies. And, on top of that, many are billed with the J codes.

TK: OK, so I understand that many of these types of drugs are prescribed to manage complex, often chronic conditions. What are the top disease states we see trending in the workers' comp space today for specialty drug management?

NW: The top five specialty conditions actually represented over 60 percent of all specialty usage and cost in our data in 2021, with the majority represented by blood clotting treatment and prevention medications, including top meds that prevent and treat deep vein thrombosis and pulmonary embolism such as brand-only Xarelto and Eliquis, as well as the injectable Lovenox or generic enoxaparin.

The category accounted for 20.9 percent of all specialty costs. Other disease state categories in the top five were driven by medications used to treat HIV or AIDS, primarily antiviral drugs, Truvada and Isentress HD, which are currently used for post-exposure prophylaxis following needlestick injury in workers' comp.

Cancer drugs, autoimmune-related disorders, and migraine medications, including newer injectables within the therapeutic class, such as brand-only Ajoovy and Emgality, were the other disease state categories in the top five.

While costs and other challenges are likely to remain a concern, specialty drugs including biologics and biosimilars continue to be researched for these and other conditions. And they may provide relief that so-called traditional therapies cannot, which could potentially result in better quality of life, as well as fewer hospital admissions, emergency room visits, and laboratory tests.

In other cases, less expensive but equally effective alternative, alternative therapies might offer a better choice. So, these are things that we really look for as far as appropriateness to try to control appropriate use.

TK: And lastly, what are some tips of the trade as far as strategies that can be deployed to address the challenges with these high-impact pharmaceuticals?

NW: The best approach is to deploy targeted clinical solutions that leverage what I've divided into three general buckets that can help drive pharmacy program optimization. First, somewhat unsurprisingly, identification of these challenging categories of high-impact pharmaceuticals is key. They're not readily identifiable in the data, you have to know how to look for them, know how to define them.

You have to set that for your program and set your program up for success with, ideally, a proactive solution, but include options for post-dispense review, including approaches such as plan edits and drugless control or formulary management, and medication prior authorization decision support, whether that's clinical or regulatory, or both, to apply utilization, management, and billing controls.

Second, do what I like to call follow the evidence. Enforce clinical controls and target categories and scenarios for intervention that promote first?line, more cost?effective alternatives through clinical review and timely recommendations, drug utilization assessments, and/or formal utilization review where that's available.

You can build those categories into your predictive and demonstrative risk modeling. You can establish clinical solutions that address patient safety, and align with evidence?based recommendations for treatment, as well as enforce various treatment guidelines that are out there, including in our own space with the official disability guidelines and others. And then promote ongoing clinician engagement, oversight, education, and coordination where needed.

And finally, once that's all in place, look for ways to continually improve in collaboration with clients along the way through education and support and stewardship or partnership reviews, use reporting tools, and through data analytics to address areas of opportunity.

And you can catch up on all the Mitchell's Pharmacy Solutions Trends Report at [Enlyte.com/drug-trends](https://enlyte.com/drug-trends).

Want Additional Insights Into This Report and Work Comp Drug Trends?

Register for our webinar, "[Drug Trends Analysis: Navigating the Changing Pharmacy Landscape in Workers' Compensation](#)," taking place October 25 at 11:00 am PT.



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