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Gauging the Impact of High-Impact Drugs in Workers' Comp

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Tom Kerr (TK): Welcome to part 4 of our [media series focusing on the Enlyte Drug Trends Report](#). Today, we'll highlight the so-called high-impact drug classes with Cameron Hannum, senior clinical account pharmacist. Cameron, thanks for joining us today.

Cameron Hannum (CH): It's a pleasure to be here today. Thanks for having me.

TK: So, let's start with the broad definitions of what is included in this report. What categories make up the high-impact drug classes?

CH: Sure. We define high-impact drug classes to include certain topical analgesic products, compound kits, combo or convenience packs, specialty medications, things of that nature. As a whole, these categories represent relatively low utilization but are associated with exponentially higher costs.

So, getting into the weeds a little bit, by definition, the class of compound kits contain two or more pre-measured drug ingredients that must be combined immediately prior to use based on a prescription order and are sold together as one product, generally under one National Drug Code, or NDC.

Combo packs consist of multiple commercially available products that are conveniently packaged together for sale with a common therapeutic purpose in mind. Per script in 2023, the exorbitantly priced combo packs, which contain components that are available separately or in different formulations at a much lower cost, average around \$1,200 per prescription, which can give you an idea of the impact they have on cost trends.

And this was a jump in cost per combo pack script of around 11% from the previous year. If the ingredients of co-packaged products such as these are sold separately, they represent a fraction of the price.

They contain things like over-the-counter topicals, gels, lotions, alcohol wipes, perhaps medical tape for, like I said, well over \$1,000 or more, when you can get the individual products just mentioned for an average wholesale price of a combined \$20 or less.

So, in 2023, for these compound kits and convenience packs we saw increases in cost per script across both. There were significant declines, however, in scripts per claim due, in no small part, to guardrails put in place by our program and the attention these meds are getting.

Further trending the compound kits, we see the cost per claim dropped in kind with the scripts per claim drop seen in that category. However, for the combo packs, while scripts per claim dropped a healthy 28%, the cost per claim there saw a rise greater than 40%, and that's substantial.

And this 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.

To round things out, you also have topicals, which have been a growing area of utilization and spend. And this category includes both prescription topical analgesics, as well as what we refer to as private-label topical analgesics, or PLTAs.

For the prescription topical analgesics for 2023, it was nice to see scripts per claim relatively flat year-over-year, with cost per script and cost per claim both down around 5%. And this is bucking the trend through last year, where we had been seeing increases in this category, which is a trend that was holding steady over the last five years. We've been carving the PLTA category out separately for analysis and trend tracking since going back to 2017.

So, prescription topicals primarily encompass non-sterile anti-inflammatories, NSAID. And it's drugs like diclofenac in varying strengths. These are products like Voltaren gel, Pennsaid solution, Flector patches and also anesthetic lidocaine products such as Lidoderm and ZTlido patches. They come in creams, ointments.

This category continues to be one of the avenues billers and dispensers are turning to, especially physician dispensers, as a money-making opportunity, and it stands out as a continuing area of focus within these drug classes.

The private-label topical analgesics are typically non-FDA approved or indicated medications that are not recommended as first-line therapy, and they really offer no greater clinical benefit over more cost-effective comparable over-the-counter (OTC) alternatives.

Fourteen of every 1,000 injured employees used a PLTA medication in 2023. And 26%-27% of all injured employee topical costs are PLTA. So, again, substantial, and that is an increase in cost of around 4% from the prior year.

Finally, similar to some of the other categories discussed already, is the specialty drug category, which includes medications that are typically used to treat complex chronic conditions and represent a major area of pharmaceutical development with significant costs.

These products do have evidence to support 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.

The category includes a number of injectable products, as well as biologic and biosimilar medications, which require unique considerations for appropriate use, and often special storage and handling requirements.

TK: A standout in this year's trends report, once again, are topicals, as they continue to be the No. 1 therapeutic class by spend in 2023 after displacing opioids for the first time in recent history last year.

Specifically looking at topicals, what are we targeting within the class, and what should be considered for appropriate management?

CH: Well, topicals are being prescribed in workers' compensation with a growing frequency and are a continued source of concern in the workers' compensation space, ranking in the top spot among the therapeutic classes at 18.4% of total drug cost in 2023, and that's an increase of 1% year-over-year.

And they're now displacing opioids, as you mentioned, with opioids moving to the No. 2 spot and representing 14.4% of total cost, which was a decrease of one percentage point comparatively.

Topicals made up 7.2% of total prescriptions, which was about a half percentage point increase over the previous year, and that gives you a sense of where things are trending proportionally. Topicals up, opioids down, year-over-year.

We target two categories within the topical and dermatological class for analysis and clinical and cost oversight, in particular. And, as we've discussed, those subcategories are prescription and private-label topical analgesics, which, again, primarily contain the NSAID diclofenac or the anesthetic lidocaine, carry specific yet limited FDA approval for use that should be considered along with appropriate place in therapy.

On the opposite end of things, PLTAs are not approved by the FDA and are not evaluated for compliance with applicable regulations and policies pertaining to safe and effective use. Topicals are also not recommended as first-line therapy in most instances, which is an important consideration.

So, if you take a look at the topical NSAIDs, you have diclofenac sodium solution, which comes in varying strengths of 1%, 1.5%, 2% and 3%. It represents the top-ranking medication category among prescription topicals at more than 32% of topical cost, and it's No. 2 by utilization at greater than 33% of topical scripts. And these topicals have limited FDA indications for use.

The 3% diclofenac is a point in case. That's one of the strengths within the diclofenac sodium solutions. It also goes by the name Solaraze Gel. It's only FDA-approved for use to treat actinic keratosis. It's kind of a mouthful.

It's also known as solar keratosis, which is a precancerous skin condition that appears as dry, scaly, or crusty patches. It has not been studied for nor is it approved for pain in that strength, yet it does get prescribed for it.

Topical lidocaine, the combined 4% and 5% strengths, ranks No.2 in spend at just south of 26% of total topical cost, and No.1 by utilization at 36.2% of topical scripts. That 5% strength in patch formulation, also referred to as Lidoderm, is prescription-grade strength and is only FDA-approved for use in the relief of pain associated with postherpetic neuralgia.

It's a very specific pain complaint that occurs following an infection of the varicella-zoster virus, which we all know more colloquially as chicken pox and shingles. And it leads to inflammation in the nerves under the skin and a burning pain sensation as a common complication of shingles.

Our industry evidence-based recommendations such as those from the Official Disability Guidelines, or ODG, only support Lidoderm to use for the FDA-approved indication here.

However, we see this drug commonly prescribed and used off-label for general low back pain and other types of deep tissue or joint pain complaints, which is not approved or rather supported by the evidence.

In addition, PLTAs in particular have not been shown to offer greater clinical benefit versus more cost-effective comparable over-the-counter alternatives and often contain the same ingredients.

And, to give you an example there, in New York, where the closed formulary does not specify the strength of the topical methyl salicylate, we are seeing 10% patches and 25% cream methyl salicylate promoted for the temporary relief of minor aches and pains of muscles and joints associated with anything from a simple backache, arthritis, strains, bruises, increasing in utilization. And this is one of the primary active ingredients available in over-the-counter products such as Bengay or Icy Hot, which many of us are familiar with.

And, if you take a look at Bengay Ultra Strength, for example, it contains camphor, menthol, and methyl salicylate. The methyl salicylate's at 30%. The other ingredients are at varying percentage, but Bengay Ultra Strength is at a fraction of the price.

It's available for just north of \$15 for a 4 oz. two-pack on Amazon without a prescription. The standalone methyl salicylate and the 10% strength, just mentioned is priced north of \$2,000 for a count of 60 over 30 days.

The 25% cream for 100-gram tube over 30 days, that's going for around \$500 per fill, both considerably more expensive than the over-the-counter alternatives. Creating further challenges, PLTAs are marketed directly to physicians' offices for dispensing.

That's creating pay-per-bill and out-of-network concerns regarding cost management and bypassing safety and clinical control, so something to keep an eye on. And topical medications can present several benefits and may be a viable option for select patients. You know, that's always a consideration, but they do require careful oversight.

And, in many cases, given their lack of demonstrated superiority and effectiveness, and given the potential price impacts, it really supports the argument for consideration of therapeutic ingredient, equivalence in products which produce lower costs with equally, if not at times, better clinical outcomes.

And that is what we push for and recommend in properly managing these specific opportunities.

TK: Great. And the specialty medication category contains some key drivers of spend in 2023. Can you explain how we define this category, and what particular therapeutic classes or disease management targets were of interest in our trend data?

CH: Well, there's no universal list of specialty drugs to easily identify this group of relatively low-volume, high-cost medications. Most entities 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 or complex conditions, considerations for special storage and handling requirements, cost, and various clinical applications for use, such as administration challenges, patient adherence, specific testing, and therapeutic monitoring requirements, and, of course, patient safety concerns.

Given this, the specialty category includes a broader definition of products that fall into this criterion set, as well as biologics and biosimilars defined by the FDA to include vaccines, viruses, therapeutic serums, toxins, blood or its derivatives, allergenic products.

For example, in workers' compensation, the specialty category often represents injectables used to manage inflammatory conditions or various types of joint pain, along with oral medications that benefit from added clinical oversight.

In 2023, the top five disease state categories ranked by specialty costs were, in descending order, blood clotting treatment and prevention, HIV/AIDS treatment, including post-exposure prophylaxis or needlestick injury protocol, antiviral meds. No. 3 osteoarthritis, followed by migraine, and then autoimmune and related disorders. To provide some perspective, the top five disease state categories represented 68.2% of all specialty usage and 60.5% of specialty cost, which is an increase of around 3% over the prior year.

Of note in 2023, the migraine category, which is the No. 4 spot by percentage of specialty category costs, experienced an increase of 14.2% in scripts per claim and 97.3% in cost per claim. And that is significant.

Migraine meds are a specialty category we very much have in focus presently and moving forward. The utilization and spend trends are driven primarily by the newer therapeutic class of migraine medications known as CGRPs, or calcitonin gene-related peptides. They're antagonists for the prevention and acute treatment of migraine medications in adults, such as Ajovy, Emgality, Aimovig, with average cost per script that are approaching \$1,000. Aimovig alone accounted for over 11% of the volume and about 12% of migraine medication cost in 2023, with an average cost per script of \$971.

And this isn't the full story with respect to drivers in spend for the migraine meds. Non-specialty oral CGRP therapies are gaining traction as a therapy of choice option for migraine sufferers as well as Nurtec Oral Disintegrating Tablets. That's now accounting for around 15% of volume, over a third of the spend that we're seeing within the migraine med category.

And the cost there is averaging an AWP per script of \$1,916. So, due to these new CGRP therapies, migraine meds as a category of utilization have experienced one of the largest script cost increases we've seen in recent years, and are very much in focus for us due to the specialty med makeup.

TK: Cameron, what things should the industry be targeting when it comes to better management within this class?

CH: 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.

The various distribution channels also pose additional concerns, with about half of these medications dispensed in doctor's offices, clinics, and hospitals, and not through traditional pharmacies, with many of these products billed using broader J-codes, the Healthcare Common Procedure Coding System protocols. Making them more challenging to really identify through systems and pharmacy that typically rely on NDCs or GPIs as

programming indicators within formularies that would allow for repricing to a specific drug or product.

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

It really comes down to the individual injured worker and the claim needs and then, of course, the input of a skilled clinician can be invaluable.

TK: What recommendations or strategies can be deployed to address the challenges with these high-impact drug class pharmaceuticals?

CH: The first thing that comes to mind for me, identification. If you can't measure or identify it, you can't manage it. So, most of these challenging low-volume, yet high-impact pharmaceutical categories are not readily recognizable on the surface within data sets, and it tends to take clinical eyes and interpretation to identify and target opportunities such as these within fill histories, leveraged program reports, and supportive workflows, etc.

So, a pharmacy program should include proactive solution options for post-dispense reporting and review plan edits, drug list control, formulary management, as well as medication prior authorization decision support that includes both clinical and regulatory state-specific rules that reinforce utilization management around quantities, and day supplies. And then, of course, you want to put in place billing controls.

Second, and this really goes hand in hand with identification, you have to follow the evidence within your specific patient population fill histories and then enforce clinical controls to target these categories and scenarios for intervention to promote first-line cost-effective alternatives.

This happens via formulary step therapy at point of sale and through clinical review, with timely recommendations, drug utilization assessments, and/or formal utilization review, depending on the situation and the juris.

You want all of this to be as dynamic and in-time as possible. And, you want to build these categories into predictive and demonstrative risk modeling to establish clinical solutions that address a patient's safety, align with evidence-based recommendations for treatment, and enforce the various treatment guidelines, such as the ODG, which is heavily leaned on in comp.

You follow all this up by promoting ongoing clinical engagement, oversight, education, and care coordination via roundtables and the like amongst the various teams internally and externally.

And then, reporting and data analytics. And these are the shoulders that the first two things mentioned here stand on. You can't say enough about the usefulness and the need of these tools in today's world of information available right at your fingertips. You want to use reporting tools and data analytics on set frequencies to continually assess and improve processes as well as collaborate with the various stakeholders over the course of a claim lifecycle.

And the reporting and insights gained will allow for more effective and timely communication, workflow adjustments, education, and supportive programs overall. And, ultimately, all of that in-time and ongoing analysis leads to deeper collaboration.

And when partnership reviews roll around, you are better able to speak to the trends to address areas of ongoing opportunity and potential impact from a program enhancement standpoint.

TK: Thanks, Cameron. In our next podcast, we'll be discussing current trends in specialty bill review. Until then, thanks for listening.



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