



## COMPOUNDED AND PRE-MANUFACTURED TOPICAL MEDICATIONS

Prepared for: Florida Division of Workers' Compensation

## Overview

Utilization and cost of compounded medications have been an industry issue for many years. To help curb and control usage, programs, including those from Optum, state regulations, and those from the Florida Division of Workers' Compensation (the Division), were enacted.

The focus on controlling compounded medications by Optum and the DWC made an impact. The Division of Workers' Compensation, 2019 Results & Accomplishments Report showcases a **decrease in cost and utilization of compounded medications** – thanks to the regulatory changes enacted.

**However, while compounded medications decreased in the same time period, topical medications increased and sparked additional concerns about their use, cost and effectiveness.**

So, let's take a closer look at topical medications, including private label topicals (PLTs), and find out how they compare to compounded medications, how they can impact overall costs and what can be done to control utilization.



## The difference and the definition

COMPOUNDED MEDICATIONS	TOPICAL MEDICATIONS (INCLUDING PRIVATE LABEL TOPICALS)
Produced on demand by a pharmacist pursuant to an individual prescription	Produced at scale through mass manufacturing processes
Intended to meet specific and unique needs of an individual patient	Mass produced and do not account for individual patient needs
Products or formulations are not commercially available	Commercially available products
No unique manufacturer NDC	Unique manufacturer NDC
Prescription required	Prescription often not required
Created and dispensed by pharmacists	Often dispensed by physicians, clinics or over-the-counter (OTC)



## Compounded Medications

The U.S. Pharmacopeia Convention (USP) defines compounding as “the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice.”

The Florida Board of Pharmacy defines compounding as “the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner’s agent; and shall specifically include the professional act of preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S.”

**Generally, compounds do not have a unique manufacturer’s NDC as they are a composite of multiple drugs (with their own NDCs). When billed for a workers’ compensation claim in Florida, each drug ingredient utilized in the compound must be billed by individual NDC and quantity of that NDC.**



## Topical Medications

Pre-Manufactured Topical medications (PMTs) – which are inclusive of Private Label Topical medications (PLTs) – are manufactured in the mass production of drug products for temporary relief of minor pain associated with injury, including back and shoulder pain.

- PLTs are frequently dispensed by physicians and come in various formulations such as creams, gels, lotions and patches
- PMTs, in general, are dispensed either with a prescription or as an over-the-counter (OTC) from a pharmacy.

**Though PMTs are often marketed as superior alternatives to prescription and OTC medications, they offer virtually no clinical advantages and are much more expensive.**


The position of Official Disability Guidelines (ODG by MCG) on PMTs is they are “independently manufactured products that are not recommended. They are generally prescribed for minor pain conditions. Common ingredients are those found in commercially available over-the-counter products (menthol, methyl salicylate, and capsaicin). They are not clinically tested for safety or efficacy. Safety issues include reports of serious skin burns in products containing high doses of menthol and methyl salicylate.”

Generally, prescription topical medications including prescription PLTs have a singular and unique NDC from the manufacturer of the product. When billed for a workers’ comp claim in Florida, the single unique NDC is provided on the billing form.

**According to the ODG, PMTs are independently manufactured products that are not recommended.**

## Utilization and cost on the rise

Optum data, as shown in the tables below, illustrates the rising utilization and overall cost of topical medications in Florida’s workers’ compensation system. Additionally, the DWC reports that Lidocaine – a topical medication – is the tenth most frequently utilized drug in Florida, to the tune of \$509 (paid charge) per treatment. The fact is that most of the topical medications listed below have a less expensive and more clinically accepted alternative.

In 2020  
**26%**   
 increase in utilization  
 of Lidoderm patches at  
**\$361.33 per treatment**

### Optum Top five dermatological pre-manufactured topical medications by utilization

BRAND NAME	GENERIC NAME	INCREASE IN UTILIZATION SINCE 2016	COST PER PACKAGE/ TREATMENT
Voltaren Gel	diclofenac	32.5%	\$65.83
Lidoderm Patch	lidocaine	26.3%	\$361.33
Lidocaine Ointment	lidocaine	5.7%	\$644.64
Flector Patch	diclofenac epolamine	5.1%	\$677.49
Bactroban Ointment	mupirocin	5.1%	\$30.15

### Optum Top five dermatological pre-manufactured topical medications by cost

BRAND NAME	GENERIC NAME	INCREASE IN UTILIZATION SINCE 2016	COST PER PACKAGE/ TREATMENT
Lidoderm Patch	lidocaine	29.5%	\$361.33
Pennsaid Solution	diclofenac	20.6%	\$2,053.29
Lidocaine Ointment	lidocaine	11.5%	\$644.64
Flector Patch	diclofenac epolamine	10.8%	\$677.49
Solaraze Gel	diclofenac	7.1%	\$1,561.71

The continued use of **Pennsaid Solution** at \$2,053 per treatment is impacting overall pharmacy costs for employers

## Optum recommendations

Optum strongly supported legislative changes, which capped reimbursement for physician dispensed medications, and strongly supported the regulatory change adopted by the Division to impart a prior authorization requirement on compounds. Now, we believe it's time to control utilization of topical medications. This is the clinically appropriate and financially responsible next step for the industry and the state of Florida.

While efforts of the Division to control utilization of compounds is paying dividends, the marketplace reality is that topical medications have not come under the same scrutiny. Stakeholders do not see topical medications – having a single unique manufacturer NDC – as a compound and thus they are not defined as “specialty services” by Florida Statutes 440.13(3)(i). To remedy this we would respectfully offer the following possible recommendations to the Division.

- Continue to monitor the cost and utilization of topical medications
- Consider modifying existing data collection and analysis of NDCs associated with topical medications to provide greater insight on cost and utilization.
- Modify existing language in the Florida Workers' Compensation Health Care Provider Reimbursement Manual (Chapter 2: subsection Medication) to identify the dispensing of topical medications as a specialty service covered under existing statute.

As an industry steward acting on behalf of our insurer and employer clients, we look forward to continued discussion on this topic. We offer any and all assistance to the Division to quickly and properly address this issue.



For more information, contact us at **1-833-4U-OPTUM** or email us at **[OWCApolicymatters@optum.com](mailto:OWCApolicymatters@optum.com)**



### About Optum Workers' Comp and Auto No-Fault Solutions

Optum Workers' Comp and Auto No-Fault Solutions collaborates with clients to lower costs while improving health outcomes for the claimants we serve. Our comprehensive pharmacy, ancillary, medical services, and settlement solutions, combine data, analytics, and extensive clinical expertise with innovative technology to ensure claimants receive safe, efficacious and cost-effective care throughout the lifecycle of a claim. For more information, email us at [expectmore@optum.com](mailto:expectmore@optum.com).

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