A black and white photograph showing a hand holding a white tube of cream, applying a dollop to the back of another hand. The background is dark.

## Understanding topical medications in workers' compensations and auto no-fault

June 17, 2020

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# Presenters



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# Topical medications

WHAT ARE THEY?

WHEN AND WHY ARE THEY USED?

WHAT ARE THEY MADE FROM?



TOPICALS ARE MEDICATIONS APPLIED TO THE SKIN OR MUCOUS MEMBRANES OFTEN TREATING PAIN OR OTHER CONDITIONS TO THE AFFECTED AREAS OF THE BODY.

# What are and Why use topical medications?

- May be prescription or over-the-counter medications
- Could be commercially available or compounded by a pharmacy
- Often contain more than one active ingredient, but not always
- Used when an alternative to the oral delivery of medications is needed
- Might have a decreased potential for adverse effects associated with an oral therapy for a certain injured party or population of patients
- Potentially play an increased role in treatments for a catastrophically injured claimant or in one with co-morbidities that cause dysphagia (difficulty swallowing) thus the topical route offers ease of administration
- Are more common in pediatric or geriatric medicine

## Topical medication use in injuries

- Generally considered second- or third-line treatments in nationally recognized guidelines and state-based formularies or medical treatment protocols
- Could be helpful as Industry shift away from the use of opioid analgesics for pain associated with non-terminal, yet chronic in nature
- Use may be complicated depending on how the medication is used by the body to illicit its actions
- Often include the use of compounded medications, individualized for the injured worker
- May wish to look for an OTC alternative especially for the commercially available products
- Care should be given to look for duplications of therapy with oral or injectable medications



## Some potential concern with topical medications

- In certain states of jurisdiction, prescribers and smaller pharmacies have identified a niche based on workers' compensation rules
- May be very high in cost
- Efficacy may not be established for some injured parties
- Compounding practice guidelines are typically overseen by state boards of pharmacy
- May have limited shelf life/use life that drives refills
- Limited state and federal guidance to address compounding regulations. This is changing in recent years and many of the state formularies are not allowing compounded medications, such as:



Tennessee



Texas (07/01/2018 ODG drug list changes)

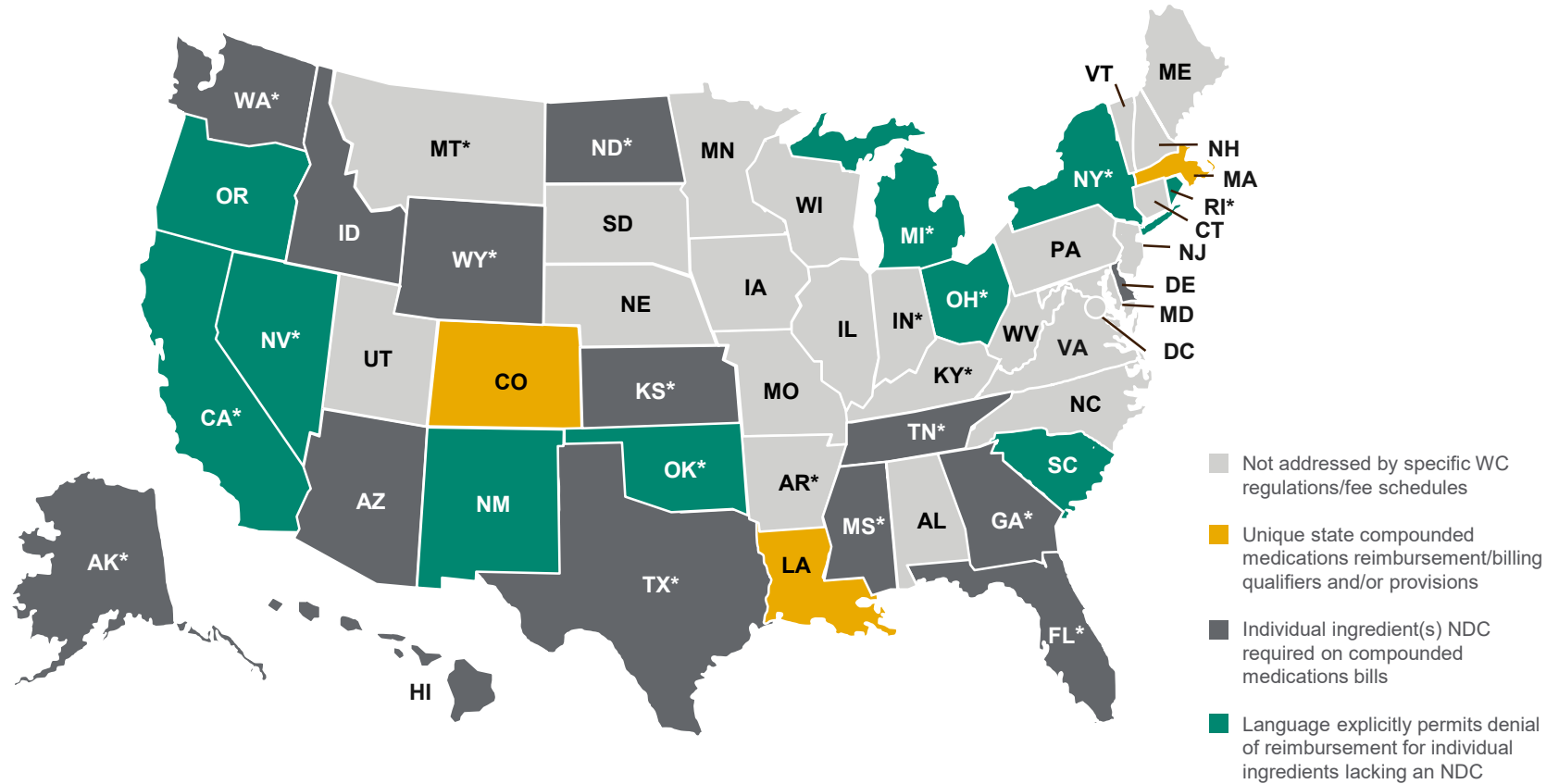


California (01/01/2018)



New York (12/05/2019)

# Compounded medication regulations



\*Additional state regulatory/statutory billing and payment requirements which may include prior authorization. Data – Reflects published statutes/regulations/fee schedules related to workers' compensation compounded medication billing/reimbursement. Current as of **January 2020**.



# Compounded medications

TYPES

THERAPEUTIC CONCERNS

CONSIDERATIONS

# Types of compounded medications

## STERILE PRODUCTS

- Intended to be delivered by injection or used in the eye/ear
- Must be manufactured under strict sterility and compounding guidelines
- Governed by state and local entities and industry groups
- Examples:
  - Injectable formulations (e.g., highly concentrated morphine) for infusion pumps or epidural steroid injections

## NON-STERILE PRODUCTS

- Generally topical, suppositories or oral formulations
- Not required to be produced in a sterile environment
- Examples:
  - Topical formulations applied to the skin, often to treat nerve, muscle or joint pain (e.g., muscle relaxants, analgesics, anticonvulsants)
  - Oral compounded formulations used for local or systemic absorption (e.g., capsules, solutions, suspension, lozenges)
  - Suppositories used for local or systemic absorption (e.g., rectal application)

## **Compounded medications are personalized for patients and include ingredients in the exact strength and dosage form to their specific needs**

- Require a prescription. The active ingredients in compounded medications are usually prescription medications combined together.
- The compound products themselves are not FDA approved; however, the individual ingredients typically are FDA approved.
- Are largely experimental in use with few randomized controlled trials to determine efficacy or safety.
- Are not commercially available and are typically much more expensive than their oral formulation counterparts.
  - Recent regulatory changes by states are aimed at controlling the costs of compounded medications and ensuring patient safety.

## Common topical ingredients

On average there are four to five individual ingredients in compounded medications

<b>THERAPEUTIC CLASSES</b>	<b>COMMONLY USED AGENTS</b>
NSAIDs	Ibuprofen, diclofenac, ketoprofen, flurbiprofen
Opioid analgesics	Tramadol, loperamide
Local anesthetics	Lidocaine, benzocaine, ketamine
Antidepressants	Amitriptyline, nortriptyline
Anticonvulsants	Gabapentin, Lyrica®
Skeletal muscle relaxants	Cyclobenzaprine, baclofen
Other topical analgesics	Clonidine

# Safety of topical compounded medications

- The unique nature of how medication is absorbed through the skin presents concerns about the actual dose received during each application
- Topical compounded medications are promoted as being safer due to less absorption than oral medications, but there is little evidence to back this claim
- Potential for drug-drug interactions if the injured party is taking other medications and within the compound itself
- Adverse effects from a compounded medication are difficult to tie back to a specific ingredient



## Compounded medications may be appropriate in therapy when...

- A commercial product is unavailable from the manufacturer
  - <https://www.accessdata.fda.gov/scripts/drugshortages/>
- The treatment of the injury requires a specialty mix of medications
- Typical administration of the drug therapy is unsuitable or ineffective
  - Side effects
  - Allergies
  - Difficulty swallowing
  - Absorption issues
- Other therapies have documented failures

# Efficacy of compounded medications

THERAPEUTIC CLASS	ODG RECOMMENDATION FOR TOPICAL USE
<b>NON-STEROIDAL ANTI-INFLAMMATORY DRUG (NSAID)</b>	<p>Recommended after a trial of oral NSAIDs for short-term use 1-2 weeks for acute pain from soft tissue injuries (strain/sprain) or prolonged use in osteoarthritis</p> <ul style="list-style-type: none"> <li>• Compound not recommended</li> <li>• First line: Diclofenac (Diclofenac 1% gel)</li> </ul>
<b>LOCAL ANESTHETICS</b>	<p>Lidocaine recommended after trial for localized neuropathic pain after two trials of anticonvulsant/antidepressant have failed</p> <ul style="list-style-type: none"> <li>• Compound not recommended</li> <li>• First line: lidocaine 5% ointment or patch</li> </ul>
<b>TRICYCLIC ANTIDEPRESSANTS (TCAS)</b>	<p>Not recommended-inconsistent results</p>
<b>SKELETAL MUSCLE RELAXANTS</b>	<p>Not recommended, no peer reviewed literature</p>

# Official Disability Guidelines recommendations

INGREDIENT	RECOMMENDATION
<b>GABAPENTIN AND OTHER AC</b>	Not recommended as there is no peer-reviewed literature to support use
<b>KETOPROFEN</b>	Not recommended, this has a high incidence of photo contact dermatitis and topical treatments can result in systemic effects comparable to oral forms
<b>CAPSAICIN</b>	Option for claimants who have not responded to or are intolerant of other treatments
<b>CYCLOBENZAPRINE</b>	Not addressed in topical application. Cyclobenzaprine as an oral form is recommended as an option, using a short course of therapy, however, the addition of cyclobenzaprine to other agents is not recommended
<b>PIROXICAM</b>	Not recommended, this is known to produce drug-induced photo contact dermatitis
<b>KETAMINE</b>	Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatments have been exhausted
<b>FLURBIPROFEN</b>	Not addressed in guidelines
<b>BACLOFEN</b>	Not recommended, there is no peer-reviewed literature to support use

# Compounded pain creams case study

Feb. 2019

A randomized controlled trial of **399 patients** with neuropathic (n=133), nociceptive (n=133), or mixed pain (n=133)

- Patients randomized to pain creams compounded for neuropathic pain (ketamine, gabapentin, clonidine, and lidocaine), nociceptive pain (ketoprofen, baclofen, cyclobenzaprine, and lidocaine), or mixed pain (ketamine, gabapentin, diclofenac, baclofen, cyclobenzaprine, and lidocaine), or placebo
- Measured pain score at baseline and one month post treatment

## RESULTS:

- No differences found in pain reduction between placebo and treatment groups
- At one month, 72 participants (36%) in the treatment groups and 54 (28%) in the control group had a positive outcome

Source: <https://annals.org/aim/article-abstract/2724041/compounded-topical-pain-creams-treat-localized-chronic-pain-randomized-controlled>

# Private label topicals and topical compounded medication kits



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## Private label topicals

- Topical (ointment, cream, gel, patch) that is premade with a single NDC and therefore not considered compounded medications
- Commercially available and often physician dispensed
- Ingredients include a combination of over-the-counter ingredients
- Not FDA-approved or clinically tested for safety and efficacy
- Not recommended by evidence-based guidelines such as Official Disability Guidelines and American College of Occupational and Environmental Medicine

## Examples of private label topicals

Brand names	Menthol	Methyl Salidcylate	Capsaicin	Camphor	Lidocaine	AWP† per 4oz or 5-15 patches (note: multiple bottles or boxes are often dispensed at a time)
Terocin Lotion	10%	25%	0.03%	-	2.50%	\$398.50
New Terocin Lotion	10%	25%	0.03%	-	-	\$487.00
Terocin Patch	4%	-	-	-	4%	\$485.00 (10/box)
Dendracin Neurodendraxcin Lotion	10%	30%	0.03%	-	-	\$464.40
Menthocin Patch	5%	20%	0.04%	-	0.50%	\$454.50 (15/box)
Medrox-Rx Ointment	7%	20%	0.05%	-	-	\$375.00
Avalin Patch	4%	-	-	-	4%	\$462.64 (15/box)
Limencin Lotion	10%	25%	0.03%	-	-	\$487.42
Medi-Derm Cream	5%	20%	0.04%	-	-	\$389.00
Medi-Derm/L; Medi-Derm/L-Rx Cream	5%	20%	0.04%	-	2%	\$398.69
Menthoderm Ointment	10%	15%	-	-	-	\$488.26
Medi-Patch/Lidocaine or Medi-Patch	5%	20%	0.04%	-	0.50%	\$220.00 (5/box)
LenzaPro Patch	4%	-	-	-	4%	\$753.49 (15/box)
Lidopro Ointment	10%	27.50%	0.03%	-	4%	\$485.88
Lidopro Patch	5%	4%	-	-	4%	\$720.00 (15/box)
Lidothol Pad	5%	-	-	-	4.50%	\$745.00 (15/box)
Nulido Gel	1%	-	-	-	4%	\$499.82
Ultracin Lotion	10%	28%	0.03%	-	-	\$492.00
Exoten-C Lotion	10%	20%	0.00%	-	-	\$394.34
Xoten-C Lotion	10%	20%	0.00%	-	-	\$382.85
Renovo Patch	5%	-	0.04%	-	-	\$573.60 (15/box)
1st Medx-Patch with Lidocaine	5%	20%	0.04%	-	4%	\$450.00 (10/box)

†Average Wholesale Price, July 2019; per 4 oz. or 5–15 patches as package sizes vary

NOTE: Multiple bottles or boxes are often dispensed at one time

Disclaimer: Not all commercially available topical analgesics are represented in this chart. Additionally, not all products have registered trademarks.



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# Examples of private label topicals and their alternatives

## Private label topicals

Brand names	Menthol	Methyl Salicylate	Capsaicin	Camphor	Lidocaine	AWP†
<b>Terocin Lotion</b>	10%	25%	0.03%	-	2.50%	\$398.50
<b>Terocin Patch</b>	4%	-	-	-	4%	\$485.00 (10/box)
<b>Nulido Gel</b>	1%	-	-	-	4%	\$499.82

## Alternative medications

Brand name (manufacturer)	Menthol	Methyl salicylate	Capsaicin	Camphor	Lidocaine	AWP†
Aspercreme® with Lidocaine cream (Chattem, Inc.)					4.0%	\$6.30 (2 oz.)
Aspercreme® with Lidocaine patch (Chattem, Inc.)					4.0%	\$7.08 (5/box)
Greaseless BENGAY® Cream (Johnson & Johnson)	10.0%	15.0%				\$3.95 (2 oz.)
Icy Hot® Cream (Chattem, Inc.)	10.0%	30.0%				\$4.91 (3 oz.)
Icy Hot® Patch (Chattem, Inc.)	5.0%					\$5.48 (5/box)
Icy Hot® with Lidocaine Cream (Chattem, Inc.)	1.0%				4.0%	\$6.60 (3 oz.)
Ultra Strength BENGAY® Cream (Johnson & Johnson)	10.0%	30.0%		4.0%		\$6.97 (4 oz.)
Muscle Rub Ultra Strength Cream (AmerisourceBergen)	10.0%	30.0%		4.0%		\$7.99 (4 oz.)
ZIKS Arthritis Pain Relief Cream (Nnodum Corp)	1.0%	12.0%	0.025%			\$25.99 (2 oz.)
Salonpas® Pain Relief Patch (Hisamitsu America, Inc.)	3.0%	10.0%				\$10.36 (10/box)
Salonpas® Lidocaine 4% Patch					4.0%	\$9.98 (6/box)
Capsaicin Cream (Ferndale Laboratories, Inc.)			0.025%			\$9.95 (2 oz.)
Capsaicin Hot Patch (Rite Aid Corp)			0.025%			\$2.39 (3/box)

†Average Wholesale Price, July 2019; per 4 oz. or 5–15 patches as package sizes vary

NOTE: Multiple bottles or boxes are often dispensed at one time

Disclaimer: Not all commercially available topical analgesics are represented in this chart. Additionally, not all products have registered trademarks.



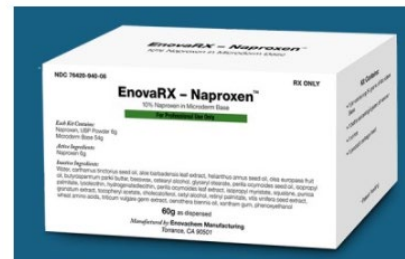
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# Topical compounded medication kits

- Combined kits for topical, oral and injectable medications with single NDC
- May be difficult to identify in medical records
- Often listed as EnovaRx, Active Kit, Active Prep Kit or just an ingredient without a dose or dosage form
- Most commercial plans are not covering these items
- Prescribing information supplied with these kits is for the oral formulations
- Compounded medication kits are considered **investigational** as they do not have a confirmed FDA approval of use



## Topical compound medication kit examples

These are not recommended as many of the contained ingredients are not supported for topical use.

Enova-Rx lidocaine HCL 5% (60 grams)	EnovaRx-amitriptyline 2% Kit (120 grams)	Lorvatus PharmaPak Combination Kit 800
<ul style="list-style-type: none"> <li>• Base cream plus lidocaine</li> <li>• Single NDC</li> <li>• AWP* = \$298</li> </ul>	<ul style="list-style-type: none"> <li>• Base cream plus amitriptyline</li> <li>• Single NDC</li> <li>• AWP* = \$513</li> </ul>	<ul style="list-style-type: none"> <li>• Metaxalone 800 mg #60 oral tabs and diclofenac 1.5% 150 ml topical solution</li> <li>• Single NDC with two products</li> <li>• AWP* = \$6,488</li> </ul>

\*AWP Current as of January 1, 2020

# NSAIDs case study

Oct. 2013

Randomized, double-blind, Phase III trial of **555 patients** with American College of Rheumatology-defined Osteoarthritis of the knee and moderate pain comparing topical ketoprofen gel with ketoprofen-free gel

- Patients were randomized to receive either of the following topical medications, twice daily, for 12 weeks
  - 100 mg ketoprofen in 4.4 g Transfersome gel (IDEA-033)
  - 4.4 g ketoprofen-free vehicle (TDT 064)
- The primary endpoint was mean change in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale score from baseline to week 12
- IDEA-033 was inferior to the drug-free gel in relieving moderate OA knee pain and improving joint function

## RESULTS:

- No difference in adverse effects

Source: <http://www.jrheum.org/content/40/10/1742.long>

# Systemic review of topical agents

May 2017

A systemic review conducted on the efficacy of topical therapy in acute and chronic pain, primary outcome was  $\geq$  50% pain reduction

**206 studies and 30,700 patients** evaluated comparing topical analgesic (NSAID, lidocaine, clonidine, capsaicin and salicylate to placebo or a comparable oral agent)

- Of all the NSAIDS studied, only two showed greater efficacy in acute nociceptive pain relief, diclofenac and ketoprofen compared to placebo
- When comparing oral NSAIDS to topical NSAIDS, no difference in efficacy was found
- Lidocaine was found to provide superior efficacy to placebo for neuropathic pain
- Evidence for other agents was of very low quality

Source: <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008609.pub2/full>  
<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD007400.pub3/full>



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# Summary

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## Monitoring medical necessity

- Did you confirm with prescriber that the topical medication is medically necessary
- Have you reviewed available medical records and/or prescription history
- Are there patient-specific issues that make use of the commercially prepared agents harmful?
- Have you consulted with a clinical pharmacist?



## Questions to ask while managing your claims

- Did you confirm with prescriber that the topical medication is medically necessary?
- Have you reviewed available medical records and/or prescription history?
- Are there patient-specific issues that make use of the commercially prepared agents harmful? Unable to take oral medications?
- Have you consulted with a clinical pharmacist?
- Has the injured person tried and failed with commercially available medications?
- Have first-line oral agents been tried, failed or unavailable?
- Is there a comorbid condition that prevents oral therapy from being tried first?
- Does the injured party have a documented allergy to commercially available products?
- Have other non-compounded topical medications been tried?

## Questions to ask while managing your claims

- Have the individual ingredients within the compound been compared to ensure there is not duplicate therapy? Consider escalating to a clinical resource or a pharmacist for review.
- Is the condition being treated compensable?
- If compensable, are the ingredients appropriate for the condition being treated?
- Are the individual ingredients within the compound recommended by evidence-based guidelines such as Official Disability Guidelines (ODG) and American College of Occupational and Environmental Medicine (ACOEM)?



# Thank you!

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