American Arbitration Association
New York No-Fault Arbitration Tribunal

In the Matter of the Arbitration between:

JMD Pharmacy Inc.
(Applicant)

- and -

Allstate Insurance Company
(Respondent)

AAA Case No.	17-18-1093-5213
Applicant's File No.	GS-617062
Insurer's Claim File No.	0468248471
NAIC No.	19232

ARBITRATION AWARD

I, Charles Blattberg, the undersigned arbitrator, designated by the American Arbitration Association pursuant to the Rules for New York State No-Fault Arbitration, adopted pursuant to regulations promulgated by the Superintendent of Insurance, having been duly sworn, and having heard the proofs and allegations of the parties make the following **AWARD:**

Injured Person(s) hereinafter referred to as: Eligible injured person

1. Hearing(s) held on 12/13/2019, 02/12/2020
   Declared closed by the arbitrator on 02/18/2020

   Nicole Montrony, Esq. from Law Offices Of Gabriel & Shapiro, LLC. participated in person for the Applicant

   Peter Graziosi, Esq. from Law Offices Of Karen L Lawrence participated in person for the Respondent

2. The amount claimed in the Arbitration Request, **$ 4,306.82**, was NOT AMENDED at the oral hearing.
   Stipulations WERE NOT made by the parties regarding the issues to be determined.

3. Summary of Issues in Dispute

   The claimant was a 47 year-old female bicyclist who was involved in an accident with a motor vehicle on 7/25/17. Following the accident the claimant sought treatment. At issue is the medical necessity of a compounded pain cream dispensed by Applicant on 8/29/17 that Respondent timely denied reimbursement for based on an 11/1/17 peer review by Jay M. Weiss, M.D.

4. Findings, Conclusions, and Basis Therefor

Based on a review of the documentary evidence, this claim is decided as follows:

An applicant establishes a prima facie case of entitlement to reimbursement of its claim by the submission of a completed NF-3 form or similar document documenting the facts and amounts of the losses sustained and by submitting evidentiary proof that the prescribed statutory billing forms [setting forth the fact and the amount of the loss sustained] had been mailed and received and that payment of no-fault benefits were overdue. See, *Mary Immaculate Hospital v. Allstate Insurance Company*, 5 A.D.3d 742, 774 N.Y.S.2d 564 (2nd Dept. 2004). I find that Applicant established a prima facie case for reimbursement.

The 12/13/19 hearing was continued to allow Applicant "to upload a peer rebuttal" and Respondent "to upload peer addendum by Jay M. Weiss, M.D., if necessary." Applicant uploaded a peer rebuttal and Respondent's request to have interest stayed for the period 12/13/19-2/12/20 was granted.

The claimant was a 47 year-old female bicyclist who was involved in an accident with a motor vehicle on 7/25/17. The claimant reportedly injured her neck, low back, and right knee. There was a reported loss of consciousness. There were no reported lacerations or fractures. Following the accident the claimant was transported by her husband later that day to New York Community Hospital where she was evaluated, treated, and released. On 8/2/17 the claimant presented to Shaung-Jin Xu, L.Ac. of New Long Life Acupuncture, PLLC with complaints of pain in her shoulder, wrist, mid back, low back, hip, and knee. The claimant's tongue had a white/yellow coating. The claimant's pulse was normal and floating. The claimant was initiated on acupuncture. On 8/14/17 the claimant presented to Kathy Aligene, M.D. of Pain Medicine of NY, P.C. with complaints of daily headaches that radiate from the posterior left side of the head anteriorly rated 7/10 (on scale of 0 to 10), neck pain associated with intermittent pain shooting to both shoulders rated 5-7/10, low back pain localized to the midline and radiates across the low back rated 5/10, and anterior right knee pain rated 8/10. Cervical spine examination revealed decreased active range of motion anterior flexion 25/45°, extension 20/40°, lateral rotation to the left 50/80° and right 40/80°. Palpation revealed significant and diffuse tenderness and muscle spasm. Spurling test was negative on the left and right. Thoracic spine examination revealed symmetrical and no gross deformities. On palpation, no significant tenderness to thoracic spine midline or thoracic paraspinal muscle. Right knee examination revealed no gross deformities and mild/moderate swelling present. On palpation there was tenderness to the quadriceps tendon, medial and lateral joint line and patellofemoral joint. There was full active range of motion in all planes, except knee extension lacking by 5-7° due to pain. No ligamentous laxity valgus and varus maneuver. McMurray test was positive. Lachman's test was negative. Lumbar spine examination revealed decreased range of motion anterior flexion 75/90°, extension 20/30°, lateral bend 15/20°. Palpation revealed tenderness to lumbar midline, severe lumbar paraspinal muscle and over the lumbar facet joints; mild tenderness to sacroiliac joints and greater trochanteric bursae. Straight leg raise test was negative on the right and left. Motor examination revealed muscle strength 5/5 with normal muscle tone throughout the muscle groups in the upper and lower extremities; except for right knee extension 4+/5 limited secondary to pain.

Sensory examination revealed intact sensation to light touch and pin-prick in all dermatomes in upper and lower extremities; except hyperesthesia to right dorsum. Reflex examination 2+ and symmetric to the biceps, triceps, brachioradialis, patella and Achilles. Dr. Aligene's treatment plan included MRI of right knee to rule out internal derangement, referral to Orthopedics surgery for further evaluation of the right knee, consider right knee hinged brace to off load right knee, synergistic use of **Tylenol 2 tablets and Advil 2 tabs** three times a day for 7-10 days, and physical therapy 3 times a week for the next 4-6 weeks. Dr. Aligene also prescribed a topical compound cream containing Gabapentin, Cyclobenzaprine, Lidocaine HCl, Flurbiprofen, Baclofen, and Menthol in a transdermal cream base; that was dispensed by JMD Pharmacy, Inc, (Applicant) on 8/29/17; which is at issue here.

The burden has shifted to the Respondent as they have raised a medical necessity defense. In order to support a lack of medical necessity defense Respondent must "set forth a factual basis and medical rationale for the peer reviewer's determination that there was a lack of medical necessity for the services rendered." See, *Provvedere, Inc. v. Republic Western Ins. Co.*, 2014 NY Slip Op. 50219(U) (App. Term 2nd, 11th and 13th Jud. Dists. 20140. Respondent bears the burden of production in support of its lack of medical necessity defense, which if established shifts the burden of persuasion to Applicant. See generally, *Bronx Expert Radiology, P.C. v. Travelers Ins. Co.*, 2006 NY Slip Op. 52116 (App. Term 1st Dept. 2006). As a general rule, reliance on rebuttal documentation will be weighed in light of the documentary proofs and the arguments presented at the arbitration. Moreover, the case law is clear that a provider must rebut the conclusions and determinations of the IME/peer doctor with his own facts. *Park Slope Medical and Surgical Supply, Inc. v. Travelers*, 37 Misc.3d 19 (2012).

Respondent timely denied (in light of verification that was requested and received) the subject compounded cream based on an 11/1/17 peer review by Jay M. Weiss, M.D. After reviewing the claimant's history, treatment, and medical records, Dr. Weiss opines "based on the records reviewed here, the topical compounded medication ordered on 8/14/17 and furnished over two weeks later was not medically necessary. This medication consists primarily of oral medications such as flurbiprofen, baclofen, cyclobenzaprine and gabapentin. It also includes menthol and lidocaine. Menthol and lidocaine are ingredients in topical over-the-counter drugs, however, the other medications are oral medications without significant efficacy when placed on the skin. Some oral anti-inflammatories such as diclofenac have some limited topical use, however, flurbiprofen was used in this case. There is no medical basis for these medications being used topically. Furthermore the quantities and ratio of medication utilized also has no scientific basis or medical rationale or evidence of efficacy." Dr. Weiss continues "I am aware of no evidence based medical literature that would show that topical compounded medications of any type are more effective than oral anti-inflammatories and a prudent physician would not try these types of medications in lieu of an adequate trial oral ant-inflammatories without specific contraindications to the oral anti-inflammatories. There is no evidence that these compounded medications would be any more beneficial than over-the-counter commercially available preparations such as Bengay or Salonpas or other topical medications that employ topical lidocaine, capsaicin or menthol and the literature has not shown the compounded medications such as the ones utilized here to be any more efficacious than commercially available

over-the-counter products which are available at a small fraction of the price of medications furnished here. Furthermore, the New York Mid and Low Back Injury Medical Treatment Guidelines concluded that topical, oral and/or systemic compound medications are not recommended. New York Mid and Low Back Injury Medical Treatment Guidelines, (NYS Workers Compensation Board, Third Edition, Sept 15, 2014 D.7.e.i). According to the FDA website: "Are compound drugs approved by the FDA? Compounded drugs are not FDA-approved. This means that FDA does not verify the safety, or effectiveness of compounded drugs. Consumers and health professionals rely on the drug approval process to ensure that drugs are safe and effective and made in accordance with Federal quality standards. Compounded drugs also lack an FDA finding of manufacturing quality before such drugs are marketed. Generally, state boards of pharmacy will continue to have primary responsibility for the day-to-day oversight of state-licensed pharmacies that compound drugs in accordance with the conditions of section 503A of the FDCA, although FDA retains some authority over their operations. However, outsourcing facilities that register under section 503B are regulated by FDA and must comply with CGMP requirements and will be inspected by FDA according to a risk-based schedule." FDA. Gov." Dr. Weiss asserts "a prudent physician would not order the ingredients in the compound to be placed on the skin when there are unknown and variable absorption rates. Oral absorption rates and doses are established. Without significant contraindications to oral medications there would be no reason to place these oral medications on the skin when they can more reliably and effectively be administered orally. According to the Official Disability Guidelines 2013, Formulary and Pain Chapter: "Topical analgesics may be recommended as an option (but are) largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004). These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006). Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, a-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006). There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required." Dr. Weiss concludes "in this case, no medical rationale is given for this topical preparation. Many of the components have no recognized topical value. I would note topical preparations without any specific indication or without any evidence of efficacy that cost in excess of $1,000.00 would not be appropriate or medically necessary. [*Dr. Weiss recites the AMA definition of medical necessity without specifically indicating how it was contravened here.*] The standard of care as noted above is that oral medications should not be furnished topically and cannot be expected to have the same effect when furnished topically. The standard of care as noted above is also that a medication that has components which are not indicated for topical use is not recommended. Furthermore, this compound that was furnished is a non-approved compound."

Where the Defendant insurer presents sufficient evidence to establish a defense based on lack of medical necessity, the burden shifts to the Plaintiff which must then present its own evidence of medical necessity (see Prince on Evidence section 3-104, 3-202).*West Tremont Medical Diagnostic PC v. Geico*, 13 Misc.3d 131, 824 N.Y.S. 2d 759.

Applicant submitted an 11/29/19 peer rebuttal by Ella Leers, M.D. After reviewing the claimant's history, treatment, and medical records, Dr. Leers opines "based upon a review of the aforementioned documents, taking into consideration the patient's history, the history of the injury, the patient's complaints, the clinical findings and a review of the medical history, and in accordance with the generally accepted standards of care in the relevant medical community, the topical compound cream (Gabapentin powder, Cyclobenzaprine powder, Lidocaine HCl powder, Flurbiprofen powder, baclofen powder, Menthol, and Transdermal cream base) provided on 08/29/2017 was medically necessary, within a reasonable degree of medical certainty." Dr. Leers asserts "it should be noted as per an article Topical preparations for pain relief: efficacy and patient adherence published on 2010 Dec 20 "As the understanding of pain pathophysiology and treatment increases, new routes of drug delivery are being discovered with the objective of attempting to block pain at peripheral sites, with maximum active drug and minimal systemic effects. Topical preparations are the result of such exploration. Evidence based on empirical practice has suggested that topically applied medications can be almost as effective as those taken orally, with a good safety profile in terms of adverse effects. The ultimate goal that motivates the development of topical preparations is the improvement of patient compliance to medical treatment, by providing efficient pain relief with less central nervous system effects and minimal drug regimen burden. Topical preparations can potentially benefit the pediatric population, whose chronic pain management is just as challenging as in adults. Topical analgesics or anesthetics are defined as liquids, gels, powders, creams, semisolids, emulsions, patches, foams, or aerosols containing an analgesic or anesthetic agent applied on or around the painful site. Most topical preparations are available as patches, ointments, or creams and this review will focus on cutaneous applications for adult patients, although some studies in children are also mentioned…[*citation omitted*]… first-line pain treatment options are typically oral pain medications; however, concerns regarding side effects, prescription drug abuse, risk of overdose, patient non-adherence to treatment regimens, and lack of efficacy in certain conditions provide a number of challenges for both healthcare providers and patients. As a result, healthcare providers have become increasingly interested in new ways to manage pain and develop customized treatment plans for their patients. Compounded transdermal pain medication may offer benefits such as customizable dosages and formulations, the ability to combine multiple drugs with various mechanisms of action, the likelihood of lower systemic absorption with minimization of side effects, more convenience and consequent improved adherence to treatment regimens, and minimization of risk of abuse and addiction. BENEFITS OF TRANSDERMAL PAIN MEDICATION: Utilizing transdermal compounds for pain management presents opportunities to customize regimens to meet the challenges of treating pain. Potential benefits include side effect minimization, combination of multiple active ingredients in a single formulation (thereby providing greater convenience and potentially better efficacy than single-ingredient products), application of the medication directly to the site of pain, easy titration to meet individual patient needs, lower systemic absorption, and improvement of patient adherence to treatment

regimens [*Citation omitted*]. Dr. Leers continues "furthermore, as per the article Effectiveness and safety of topical versus oral nonsteroidal anti inflammatory drugs: a comprehensive review. Published on 2013 May; authored by Klinge SA, Sawyer GA-INTRODUCTION: Topical nonsteroidal anti-inflammatory drugs (NSAIDs) represent a relatively recent alternative to oral NSAIDs. Topical NSAIDs are designed to target their therapeutic effect locally to damaged tissue while minimizing systemic exposure. To better inform patients considering topical NSAIDs as an alternative to oral NSAIDs, this is the first comprehensive review to present all available evidence comparing topical NSAIDs with oral NSAIDs in the treatment of both acute and chronic musculoskeletal injury. METHODS: Six studies, including 600 subjects, compared the use of topical versus oral NSAIDs in the treatment of a variety of acute injuries. Nine trials, including 2403 subjects, studied topical versus oral NSAIDs for chronic injury treatment, almost exclusively for osteoarthritis (OA) of the knee. This review included all available comparative studies, the majority of which were well-designed, double-dummy, placebo-controlled trials. Relevant meta-analyses were also reviewed. RESULTS: Topical and oral NSAIDs performed statistically better than placebo for chronic injury treatment. Limited evidence comparing topical NSAIDs with placebo for acute injury treatment was available in the included studies, but supported greater effectiveness for topical NSAIDs. In all head-to-head comparisons, topical and oral NSAIDs demonstrated similar efficacy for treatment of both acute and chronic injuries. There were more gastrointestinal side effects in patients receiving oral NSAIDs, while local skin reactions occurred more frequently in patients treated with topical NSAIDs. CONCLUSION: Overall, topical NSAIDs may be considered as comparable alternatives to oral NSAIDs and are associated with fewer serious adverse events (specifically GI reactions) when compared with oral NSAIDs. Caution should be exercised with the use of both topical and oral NSAIDs, including close adherence to dosing regimens and monitoring, particularly for patients with previous adverse reactions to NSAIDs [*citation omitted*]. There are many side effects of oral analgesics (NSAIDs) as per article; Effectiveness and Safety of Topical versus Oral Nonsteroidal Anti-inflammatory Drugs: A Comprehensive Review Topical nonsteroidal anti-inflammatory drugs (NSAIDs) represent a relatively recent alternative to oral NSAIDs. Topical NSAIDs are designed to target their therapeutic effect locally to damaged tissue while minimizing systemic exposure. This is the first comprehensive review to present all available evidence comparing topical NSAIDs with oral NSAIDs in the treatment of both acute and chronic musculoskeletal injury. Methods: Six studies, including 600 subjects, compared the use of topical versus oral NSAIDs in the treatment of a variety of acute injuries. There were more gastrointestinal side effects in patients receiving oral NSAIDs. Conclusion: Overall, topical NSAIDs may be considered as comparable alternatives to oral NSAIDs [*Citation omitted*]. Side effects of oral medications: Common oral medications prescribed for the management of acute or chronic pain include NSAIDs, acetaminophen, narcotics, muscle relaxants, tricyclic antidepressants, and anticonvulsants, such as gabapentin. While these oral medications may be effective in treating pain, there are challenges associated with long-term use of these medications for both the prescriber and patient. For example: Non-Steroidal Anti-Inflammatory Drugs (NSAIDS): Oral NSAID use presents the risk of a number of potential side effects, particularly with chronic use. While some less serious side effects, such as nausea, are common, of particular concern are the potentially severe side effects in the gastrointestinal (GI) tract, including GI bleeding, perforation, and intestinal toxicity.

Long-term exposure to oral NSAIDs has been associated with ulcer rates of 10 to 30%, serious ulcer-related complications in 1 to 2% of patients, and an increased risk of lower GI bleeding. An estimated 100,000 patients are hospitalized annually in the US as a result of NSAID-related GI complications, with mortality rates of up to 5%. To reduce the risk of GI toxicity from NSAIDs, the addition of gastroprotective agents such as H2 receptor antagonists and proton pump inhibitors (PPIs) are suggested, but PPIs have been shown to fail to protect against lower GI complications and have their own potential for adverse events. In addition, over 30% of patients prescribed PPIs in addition to pain medication are non-compliant with their treatment regimens. Further, it should be noted that at the time these topical compound medication was prescribed, the patient here was experiencing pain post the MVA… Due to the patient's clinical symptoms, this topical medication was prescribed for relief of pain to these specific areas. Such compound cream was prescribed to avoid systemic exposure, avoid sedation, avoid high serum levels of drug, reduce risk of side effects and drug interactions compared to oral ingestion and the compound medication prescribed will work well with other therapies. In summary, the peer reviewer has not provided an established medical standard to provide a basis for the claim. The peer doctor's claim is simply an opinion, unsupported by any kind of medical guideline. It is by no means a description of inconsistency with standards of care or guideline. Thus, the peer reviewer fails to prove that the prescribing physician has deviated from the generally accepted guidelines and standards of medical practice in this case." Dr. Leers concludes "acute pain easily can evolve into chronic pain, which can become difficult to treat. Many commonly prescribed, commercially available pain relief medications help the symptoms associated with nerve and muscle pain as well as other conditions but they can also result in unwanted side effects such as drowsiness, dizziness or stomach irritation. Topical pain and anti-inflammatory creams or gels reduce inflammation, pain, swelling and discomfort in localized areas without the typical side effects associated with non-steroidal therapy when taken by mouth. Topical medications are preferred to minimize side effects or problems like stomach upset and drug interactions. Below find a description of all the ingredients in the topical medications and how they are effective. [*This portion is omitted as, in part, Dr. Leers fails to sufficiently distinguish between systemic and topical application*]. Thus, based on the aforementioned documents, recommendation of the Topical Compound Medication (Gabapentin powder, Cyclobenzaprine powder, Lidocaine HCl powder, Flurbiprofen powder, baclofen powder, Menthol, and Transdermal cream base) was required as a result of the patient's injuries and was medically necessary. In conclusion, the provided topical compound medication was not only medically necessary but the standard of care."

In Dr. Weiss' opinion topical medication should not be used unless there is a specific contraindication to oral medication. Dr. Leers extols the benefits of topical medication over the use of oral NSAIDs. Here, the claimant was prescribed Tylenol x 2 and Advil x 2 to take three times a day for 7-10 days at the same time the compound cream at issue was prescribed. The fact that the prescriber's treatment plan included simultaneous use of oral medication tends to undermine some of Dr. Leers' arguments. Overall, I find Dr. Weiss' arguments more persuasive than Dr. Leers. Upon careful review of the evidence I find that Applicant has failed to rebut Respondent's finding that the claim was not medically necessary and has failed by a preponderance of the evidence to establish the necessity of the claim. Accordingly, Applicant's claim is denied in its entirety.

5. Optional imposition of administrative costs on Applicant.
   Applicable for arbitration requests filed on and after March 1, 2002.

   I do NOT impose the administrative costs of arbitration to the applicant, in the amount established for the current calendar year by the Designated Organization.

6. **I find as follows with regard to the policy issues before me:**
   - ☐ The policy was not in force on the date of the accident
   - ☐ The applicant was excluded under policy conditions or exclusions
   - ☐ The applicant violated policy conditions, resulting in exclusion from coverage
   - ☐ The applicant was not an "eligible injured person"
   - ☐ The conditions for MVAIC eligibility were not met
   - ☐ The injured person was not a "qualified person" (under the MVAIC)
   - ☐ The applicant's injuries didn't arise out of the "use or operation" of a motor vehicle
   - ☐ The respondent is not subject to the jurisdiction of the New York No-Fault arbitration forum

Accordingly, the claim is DENIED in its entirety

This award is in full settlement of all no-fault benefit claims submitted to this arbitrator.

State of New York
SS :
County of Nassau

I, Charles Blattberg, do hereby affirm upon my oath as arbitrator that I am the individual described in and who executed this instrument, which is my award.

03/14/2020
(Dated)

Charles Blattberg

IMPORTANT NOTICE

This award is payable within 30 calendar days of the date of transmittal of award to parties.

This award is final and binding unless modified or vacated by a master arbitrator. Insurance Department Regulation No. 68 (11 NYCRR 65-4.10) contains time limits and grounds upon which this award may be appealed to a master arbitrator. An appeal to a master arbitrator must be made within 21 days after the mailing of this award. All insurers have copies of the regulation. Applicants may obtain a copy from the Insurance Department.

ELECTRONIC SIGNATURE

Document Name: Final Award Form
Unique Modria Document ID:
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Electronically Signed

Your name: Charles Blattberg
Signed on: 03/14/2020