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| <b>Case Number:</b>   | CM15-0088376 |                              |            |
| <b>Date Assigned:</b> | 05/12/2015   | <b>Date of Injury:</b>       | 05/05/2008 |
| <b>Decision Date:</b> | 06/12/2015   | <b>UR Denial Date:</b>       | 04/01/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 05/07/2015 |

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: New Jersey

Certification(s)/Specialty: Family Practice

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 57 year old male, who sustained an industrial injury on 5/5/08. He reported mid and low back pain after falling from a truck. The injured worker was diagnosed as having lumbar disc protrusion, lumbar muscle spasm and lumbosacral sprain/strain. Treatment to date has included oral medications including opioids (only treatment documented). Currently, the injured worker complains of constant, dull, sharp, stabbing, throbbing low back pain with stiffness, heaviness and numbness of lumbar spine rated 7/10. Physical exam noted tenderness to palpation of L3-5 spinous processes and lumbar paravertebral muscles with diminished range of motion of lumbar spine. A request for authorization was submitted for compound: Gabapentin / Amitriptyline / Bupivacaine and Flurbiprofen / Baclofen / Dexamethasone / Menthol / Camphor / Capsaicin.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Compound medication - Gabapentin 10%/Amitriptyline 10%/ Bupivacaine 5% cream 210 grams:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 123-125.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

**Decision rationale:** The MTUS Chronic Pain Treatment Guidelines state that topical analgesics are mostly experimental, particularly the combination/compounded analgesic products, due to their limited supportive evidence. The Guidelines also state specifically that gabapentin is not recommended to be used in its topical form due to lack of supportive data. Any analgesic product which contains a non-recommended medication(s) or class is to be considered non-recommended. In the case of this worker, the provider recommended a compounded medication, which included gabapentin, amitriptyline, and bupivacaine. As this product contains a non-recommended ingredient (gabapentin), the request will not be considered medically necessary.

**Compound medications - Flurbiprofen 20%/Dexamethasone 2%/ Menthol 2%/ Camphor 2%/ Capsaicin 0.025% cream 210 grams:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 123-125. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Back Chapter, Steroid.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics and Capsaicin Page(s): 28-29, 111-113.

**Decision rationale:** The MTUS Chronic Pain Guidelines state that topical analgesics are generally considered experimental as they have few controlled trials to determine efficacy and safety currently. Topical NSAIDs, specifically, have some data to suggest it is helpful for osteoarthritis and tendinitis for at least short periods of time, but there are no long-term studies to help us know if they are appropriate for treating chronic musculoskeletal pain. Topical NSAIDs have not been evaluated for the treatment of the spine, hip, or shoulder. Although some topical analgesics may be appropriate for trial as a secondary agent for neuropathic pain after trials of oral therapies have been exhausted, topical NSAIDs are not recommended for neuropathic pain. The only FDA-approved topical NSAID currently is Voltaren gel (Diclofenac). Ketoprofen is not currently one of the topical NSAIDs available that is FDA approved, and it has a high incidence of photocontact dermatitis. All topical NSAID preparations can lead to blood concentrations and systemic effect comparable to those from oral forms and caution should be used for patients at risk, including those with renal failure and hypertension. The MTUS Chronic Pain Guidelines state that topical capsaicin is recommended for chronic pain only as an option in patients who have not responded or are intolerant to other treatments. High doses of capsaicin is considered experimental, and any dose of capsaicin has only moderate to poor efficacy, according to the studies. Doses over 0.025% capsaicin have no studies to prove more benefit than lesser strengths. In order to justify continuation of topical capsaicin, there needs to be evidence of functional improvement as well as measurable pain reduction. In the case of this worker, the topical NSAID in the requested topical combination product (Flurbiprofen 20% / Dexamethasone 2% / Menthol 2% / Camphor 2% / Capsaicin 0.025% cream) is not approved for use on the spine. Also, there was no explanation as to why topical formulations would be indicated over similar oral therapies. A full review of tried and failed therapies did not precede the consideration of capsaicin as well. Therefore, the request for Flurbiprofen 20% / Dexamethasone 2% / Menthol 2% / Camphor 2% / Capsaicin 0.025% cream will not be considered medically necessary.