

<b>Case Number:</b>	CM15-0119336		
<b>Date Assigned:</b>	06/29/2015	<b>Date of Injury:</b>	06/03/2013
<b>Decision Date:</b>	07/29/2015	<b>UR Denial Date:</b>	05/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/19/2015

### 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: Massachusetts

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

### 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 54 year old male, who sustained an industrial injury on 6/3/13. Initial complaints were low back and left hip pain that shot toward the ankle. The injured worker was diagnosed as having lumbar sprain/strain; lumbar radiculopathy. Treatment to date has included physical therapy; TENS unit; LSO back brace; medications. Currently, the PR-2 notes dated 4/2/15 indicated the injured worker complains of low back pain rated at 7/10 with lower extremity symptoms. The injured worker complains of deconditioning. He recalls a successful trial of topical antiepileptic drugs facilitating up to 50% diminution of the radicular component. He has failed other medications in this regard as well as oral antiepileptic drugs that resulted in nausea and lethargy. The injured worker notes he is unable to do recommended exercise regime without medications on board due to pain. On objective findings, there is tenderness in the lumbar spine with range of motion normal. He has positive leg raise of the left for pain to the foot and right notes pain to the distal calf at 30 degrees. He has spasms in the lumboparaspinal musculature less pronounced. The provider's treatment plan included Compounded cream: Ketoprofen 10%, Gabapentin 6%, Bupivacaine 5%, Fluticasone 1%, Baclofen 2%, Cyclobenzaprine 2%, Clonidine 0.2%, Hyaluronic acid 0.2% Qty: 300gm with 3 refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Compounded cream: Ketoprofen 10%, Gabapentin 6%, Bupivacaine 5%, Fluticasone 1%, Baclofen 2%, Cyclobenzaprine 2%, Clonidine 0.2%, Hyaluronic acid 0.2% Qty: 300gm with 3 refills: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (1) Medications for chronic pain, p60 (2) Topical Analgesics, p111-113 Page(s): 60, 111-113.

**Decision rationale:** The claimant sustained a work-related injury in June 2013 and continues to be treated for radiating low back pain. When seen, pain was rated at 7/10. There was decreased lumbar spine range of motion with tenderness. Left straight leg raising was positive. Tramadol ER, hydrocodone / acetaminophen, naproxen, pantoprazole, cyclobenzaprine, and topical compounded medication was prescribed. In terms of topical treatments, Baclofen and cyclobenzaprine are muscle relaxants and there is no evidence for the use of any muscle relaxant as a topical product. Oral Gabapentin has been shown to be effective in the treatment of painful diabetic neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. However, its use as a topical product is not recommended. Compounded topical preparations of ketoprofen are used off-label (non-FDA approved) and have not been shown to be superior to commercially available topical medications such as diclofenac. Many other agents are compounded as monotherapy or in combination for pain control such as opioids antidepressants, glutamate receptor antagonists, alpha-adrenergic receptor agonists, adenosine, cannabinoids, cholinergic receptor agonists, GABA agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor. There is little to no research to support the use of many these agents, including clonidine and hyaluronic acid. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. By prescribing a compounded medication, in addition to increased risk of adverse side effects, it is not possible to determine whether any derived benefit is due to a particular component. Additionally, in this case, oral cyclobenzaprine and oral naproxen are also being prescribed with is duplicative. The requested medication is not medically necessary.