

Case Number:	CM15-0130912		
Date Assigned:	07/17/2015	Date of Injury:	06/14/2007
Decision Date:	09/10/2015	UR Denial Date:	06/17/2015
Priority:	Standard	Application Received:	07/07/2015

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 York

Certification(s)/Specialty: Internal Medicine

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 70-year-old male who sustained an industrial injury on 06/14/2007. The injured body part and mechanism of injury were not mentioned. Treatment provided to date has included physical therapy; medications (duloxetine, hydrocodone, naproxen, pantoprazole, Cyclobenzaprine, antiepileptic and antidepressants); and conservative therapies/care. No diagnostic test results were available for review or discussed. There were no noted comorbidities or other dates of injury noted. On 04/30/2015, physician progress report noted complaints of ongoing low back pain with intermittent lower extremity symptoms. The pain was rated 6/10 in severity. The report indicates that there had been a previous trial of topical analgesics, which resulted in a 4-point diminution in neuropathic/radicular pain in lower extremities with improved tolerance to standing and walking by 30%. It was also reported that there had been failed trials of oral antiepileptic and antidepressant medications due to nausea and lethargy. The injured worker reported that current medication regimen allows improved ability to complete activities of daily living (ADLs) and stay compliant with home exercise program. Current medications include duloxetine, hydrocodone, naproxen, Cyclobenzaprine and pantoprazole. There was discussion of further tapering of medications during this exam. The physical exam revealed tenderness to palpation of the lumbar spine, restricted range of motion in the lumbar spine, positive facet compression test, pain with lumbar extension and rotation, and point tenderness over the lower lumbar facets. The provider noted diagnoses of facet osteoarthopathy at L5-S1, rule out facet mediated low back pain. Plan of care includes topical Gabapentin, continuation of home exercise program, continuation of current medications, urine drug screening, and follow-up

in 4 weeks. The injured worker's work status remained permanent and stationary. The request for authorization and IMR (independent medical review) includes: Retrospective topical Gabapentin 300g (ketoprofen 10%, Gabapentin 6%, bupivacaine HCL 5%, baclofen 2%, Cyclobenzaprine HCL 2%, clonidine HCL 0.2%, sodium hyaluronate 0.2%) applied 3 times daily Refills: 3 (dispensed 04/30/2015).

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective topical Gabapentin 300g (Ketoprofen 10%, Gabapentin 6%, Bupivacaine HCL 5%, Baclofen 2%, Cyclobenzaprine HCL 2%, Clonidine HCL 0.2%, Sodium Hyaluronate 0.2%) Refills: 3 (dispensed 04/30/2015): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Gabapentin (Neurontin); NSAIDs, specific drug list & adverse effects; Cyclobenzaprine (Flexeril) Page(s): 111-113, 49, 70-72, 41-42. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Chapter: Gabapentin (Neurontin) and Clonidine, intrathecal.

Decision rationale: According to the MTUS guidelines: Topical Analgesic 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. 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 MTUS goes on to specify that gabapentin is "not" recommended, as there is no peer-reviewed literature to support its use. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photo-contact dermatitis and absorption of the drug depends on the base it is delivered in. Bupivacaine is a local anesthetic that causes numbness or loss of feeling in an area of your body. According to the MTUS, bupivacaine is approved for use in some intrathecal delivery methods and injections; however, there is no recommendation for topical use. Baclofen is not recommended as there is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. Otherwise, there is no peer-reviewed literature to support the use of topical baclofen. Cyclobenzaprine (brand names: Amrix, Flexeril and Fexmid; generic form: tabradol) is a centrally acting skeletal muscle relaxant and is not recommended for topical application. Catapres (Clonidine) is an anti-hypertensive medication and a Central alpha-2 Adrenergic Agonist. According to the MTUS, clonidine is recommended for treatment in cancer patients only after a short-term trial indicates pain relief in patient's refractory to opioid monotherapy or opioids with local anesthetic. There is no recommendation for topical use. Hyaluronate sodium is a hyaluronic acid derivative, that when injected, works by increasing the effectiveness of the fluid within the knee joint to act as a lubricant and shock absorber. The FDA has also approved this medication for the use in certain eye surgeries. There is no recommendation for topical use. After reviewing the available documentation and the MTUS

and ODG guidelines, as well as FDA criteria, it was determined that the MTUS states Gabapentin, Cyclobenzaprine, baclofen and ketoprofen are not recommended for topical use. As such, the request for topical Gabapentin 300g (ketoprofen 10%, Gabapentin 6%, bupivacaine HCL 5%, baclofen 2%, Cyclobenzaprine HCL 2%, clonidine HCL 0.2%, sodium hyaluronate 0.2%) is not medically necessary.