

Case Number:	CM14-0030357		
Date Assigned:	06/20/2014	Date of Injury:	11/25/2008
Decision Date:	09/12/2014	UR Denial Date:	02/14/2014
Priority:	Standard	Application Received:	03/10/2014

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. The expert reviewer is Board Certified in Orthopedic Surgery and is licensed to practice in California and Washington. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 46-year-old female with a reported date of injury on 11/25/2008. The mechanism of injury was noted to be a pulling injury. Her diagnoses were noted to include bilateral knee sprain and strain, recurrent herniated nucleus pulposus to the left L5-S1, desiccation of the L4-5 with neural foramina L4-5 to the left, status post L5-S1 microdiscectomy, and gastrointestinal/gastroesophageal reflux disease secondary to medication usage. Her previous treatments were noted to include surgery, medications, and home exercise program. The progress note dated 03/10/2014 revealed the injured worker complained of intermittent low back pain rated 3/10 with associated numbness down the bilateral legs, left worse than right. The physical examination revealed restricted range of motion to the lumbar spine, positive straight leg raise and Braggard's on the left and negative on the right. The lower extremity motor strength testing was rated 5/5 bilaterally except for weakness in the left extensor hallucis longus at 4/5. The sensory examination revealed dull and diminished findings of the left L5 dermatomes with all remaining dermatomes intact. The progress note dated 06/02/2014 revealed the injured worker complained of constant low back pain rated 6/10 to 7/10 with radiation to the bilateral lower extremities, left worse than right, with associated numbness and tingling sensation in the bilateral feet and weakness in the bilateral lower extremities. She also complained of intermittent right knee pain with associated numbness and tingling sensation. The physical examination of the lumbar spine revealed restricted range of motion with a positive straight leg raise and Braggard's test. The lower extremity motor strength testing was rated 5/5 except for weakness in the left extensor hallucis longus at 4/5. The sensory examination revealed dull and diminished findings over the left L5 dermatomes with all remaining dermatomes intact. The Request for Authorization form was not submitted within the medical records. The request was for flurbiprofen 20% cream 120 g, Ketoprofen 20%/Ketamine 10% gel 120 g, and gabapentin

10%/cyclobenzaprine 10%/capsaicin 0.0375% 120 g; however, the provider's rationale was not submitted within the medical records.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 20% gel 20 grams: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: The request for Flurbiprofen 20% gel 20 g is not medically necessary. The injured worker has been utilizing this medication since at least 01/2013. The California Chronic Pain Medical Treatment Guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines primarily recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of any of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The guidelines state the efficacy in clinical trials for topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In the study, the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. The guideline indications for topical NSAIDs are osteoarthritis and tendonitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment for short-term use (4 to 12 weeks). The injured worker has been utilizing this medication for well over 6 months and there is a lack of documentation regarding efficacy of this medication. The guidelines recommend topical NSAIDs for the use of osteoarthritis; however, the injured worker does not have such a diagnosis. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request is not medically necessary.

Ketoprofen 20%/ Ketamine 10% gel 120 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines, Criteria for Compound Drugs.

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

Decision rationale: The request for Ketoprofen 20%/Ketamine 10% gel in 120 g is not medically necessary. The injured worker has been utilizing this medication since at least 01/2013. The California Chronic Pain Medical Treatment Guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines primarily recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of any of these agents. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The guidelines state the efficacy in clinical trials for topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In the study, the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. Ketoprofen is not FDA-approved for topical application. The guidelines state Ketamine is under study and only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatments have been exhausted. Topical Ketamine has only been studied for use in noncontrolled studies for complex regional pain syndrome 1 and postherpetic neuralgia, and both have shown encouraging results. The guidelines state any compounded product that contains at least 1 drug that is not recommended is not recommended, and Ketoprofen is not recommended for topical application and Ketamine is only recommended for treatment of neuropathic pain in refractory cases. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request is not medically necessary.

Gabapentin 10%, Cyclobenzaprine 10%, Capsaicin 0.0375% - 120 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113.

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

Decision rationale: The request for Gabapentin 10%/cyclobenzaprine 10%/capsaicin 0.0375% 120 g is not medically necessary. The injured worker has been utilizing this medication since at least 01/2013. The California Chronic Pain Medical Treatment Guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines primarily recommend topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of any of these agents. The guidelines state capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis), and a 0.075% formulation (primarily studied for postherpetic neuralgia, diabetic neuropathy, and post mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The guidelines state there is no evidence for use of a muscle relaxant as a topical

product. The guidelines do not recommend Gabapentin as a topical analgesic, as there is no peer-reviewed literature to support its use. The guidelines state any compounded product that contains at least 1 drug that is not recommended is not recommended, and Gabapentin and muscle relaxants are not recommended for topical use. The formulation of capsaicin 0.0375% exceeds guideline recommendations of 0.025%. Additionally, the request failed to provide the frequency at which this medication is to be utilized. Therefore, the request is not medically necessary.