

Case Number:	CM14-0030243		
Date Assigned:	06/20/2014	Date of Injury:	07/13/2010
Decision Date:	07/17/2014	UR Denial Date:	02/19/2014
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 Physical Medicine and Rehabilitation and is licensed to practice in Texas and New York. 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 60-year-old male who reported an injury on 07/13/2010. The injury reportedly occurred when the injured worker was adjusting a block and was struck in the bilateral knees by a guardrail. His previous treatments were noted to include surgery, medications, and physical therapy. His diagnoses were noted to include knee joint prosthesis and synovitis/tenosynovitis. The progress note dated 05/29/2014 reported the injured worker complained of pain in the right knee rated 5/10 and hurt with prolonged walking. The injured worker reported he was using a brace for support. The physical examination showed range of motion to the right knee for extension was 170 degrees and flexion was 100 degrees. The range of motion to the left knee was 180 degrees and flexion was 120 degrees. The provider reported there was no effusion, ligamentous instability, and the grinding test was negative. There was no joint line tenderness but there was tenderness in the medial and lateral knee. There was no motor deficit but there was hypoesthesia to light touch along the anterolateral knee. His medication list was noted to include Menthoderm and Norco. The Request for Authorization Form dated 02/11/2014 was for flurgabalido and Norco 5/325 mg due to osteoarthritis to the right knee.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurgabalido (Flurbiprofen 10%/Gabapentin 10%/Lidocaine 6%) 20gms (dispensed in Office 01/30/14) QTY:1.00: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESIC Page(s): 111, 113.

Decision rationale: The injured worker has been taking this medication since at least 01/2014. California Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines state topical analgesics are 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 1 drug (or drug class) that is not recommended is not recommended. The guidelines state that 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 this 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. Topical NSAIDS are indicated for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment. The guidelines recommend topical NSAIDS for short term use (4 to 12 weeks). The guidelines recommend Lidoderm patch for neuropathic pain. Topical lidocaine, in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. But guidelines state gabapentin is not recommended as a topical modality because there is no peer reviewed literature to support use. Therefore, due to the guidelines recommendation that any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended; and gabapentin, is not recommended for use. The formulation of lidocaine in a gel or cream is also not recommended by the guidelines. Additionally, the request failed to provide the frequency and location to which this medication is to be utilized. As such, the request is not medically necessary and appropriate.

Flurgabalido (Flurbiprofen 10%/Gabapentin 10%/Lidocaine 6%) 240gm QTY:1.00:
Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESIC Page(s): 111, 113.

Decision rationale: The request for flurgabalido (flurbiprofen 10%/gabapentin 10%/lidocaine 6%) 240 gm is non-certified. The injured worker has been taking this medication since at least 01/2014. California Chronic Pain Medical Treatment Guidelines state that topical analgesics are

largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines state topical analgesics are 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 1 drug (or drug class) that is not recommended is not recommended. The guidelines state that 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 this 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. Topical NSAIDS are indicated for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment. The guidelines recommend topical NSAIDS for short term use (4 to 12 weeks). The guidelines recommend Lidoderm patch for neuropathic pain. Topical lidocaine, in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. But guidelines state gabapentin is not recommended as a topical modality because there is no peer reviewed literature to support use. Therefore, due to the guidelines recommendation that any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended; and gabapentin, is not recommended for use. The formulation of lidocaine in a gel or cream is also not recommended by the guidelines. Additionally, the request failed to provide the frequency and location to which this medication is to be utilized. As such, the request is non-certified.

Norco 5/325 (dispensed in offices 01/30/14) QTY: 60.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 89.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS, ON-GOING MANAGEMENT Page(s): 78.

Decision rationale: The injured worker has been taking this medication since at least 01/2014. According to the California Chronic Pain Medical Treatment Guidelines, the ongoing use of opioid medications may be supported with detailed documentation of pain relief, functional status, appropriate medication use, and side effects. The guidelines also state the 4A's for ongoing monitoring including analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors, should be addressed. There is a lack of evidence of decreased pain on a numerical scale with the use of medications. There is a lack of documentation regarding improved functional status such as with activities of daily living as well as a lack of side effects reported or aberrant drug taking behavior. There is a lack of documentation regarding a previous consistent urine drug screen and when the last test was performed. Therefore, due to the lack of evidence regarding significant pain relief, increased function, adverse effects, and without details regarding urine drug testing to verify appropriate medication

use and the absence of aberrant behavior, the ongoing use of opioid medications is not supported by the guidelines. As such, the requested service is not medically necessary and appropriate.