

Case Number:	CM15-0060356		
Date Assigned:	04/06/2015	Date of Injury:	11/21/1999
Decision Date:	05/12/2015	UR Denial Date:	03/13/2015
Priority:	Standard	Application Received:	03/30/2015

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: California

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 (IW) is a 60-year-old male who sustained an industrial injury on 11/21/1999. Diagnoses include ankle pain, lumbago and encounter for long-term drug use (NEC). Treatment to date has included medications and bracing. Diagnostics performed to date included x-rays. According to the PR2 dated 12/23/14, the IW reported continued left ankle pain; he stated the topical cream and the brace are very helpful. He reported his pain as 6/10 with medication. A request was made for Flurbiprofen 25%/Capsaicin 0.0275% 30gm; Flurbiprofen 25%/Capsaicin 0.0275% 120gm and Tylenol-Codeine #4 300/60mg due to the efficacy of the medications for the IW.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 25%/Capsaicin 0.0275% 30 grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73. Capsaicin, topical Page 28-29.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Capsaicin topical is only an option in patients who have not responded or are intolerant to other treatments. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. All NSAIDs have the potential to raise blood pressure in susceptible patients. The primary treating physician's progress report dated 2/18/15 documented a diagnosis of hypertension and a blood pressure of 172/83. Per MTUS, NSAIDs are associated with the risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. MTUS guidelines warn against the use of NSAIDs with patients with hypertension. The use of the NSAID topical Flurbiprofen is not supported by MTUS guidelines. Per MTUS, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for topical Flurbiprofen and Capsaicin is not supported by MTUS guidelines. Therefore, the request for Flurbiprofen and Capsaicin cream is not medically necessary.

Flurbiprofen 25%/Capsaicin 0.0275% 120 grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73. Capsaicin, topical Page 28-29.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Capsaicin topical is only an option in patients who have not responded or are intolerant to other treatments. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain, as there is no evidence to support use. MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. All NSAIDs have the potential to raise blood pressure in susceptible patients. The primary treating physician's progress report dated 2/18/15 documented a diagnosis of hypertension and a blood pressure of 172/83. Per MTUS, NSAIDs are associated with the risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. MTUS guidelines warn against the use of NSAIDs with patients with hypertension. The use of the NSAID topical Flurbiprofen is not supported by MTUS guidelines. Per MTUS, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for topical Flurbiprofen and Capsaicin is not supported by MTUS guidelines. Therefore, the request for Flurbiprofen and Capsaicin cream is not medically necessary.

Tylenol-Codine #4 300/60mg, 240 count: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment, Chapter 14 Ankle and Foot Complaints Page(s): 47-48, 376-377, Chronic Pain Treatment Guidelines Opioids Page 74-96.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address opioids. The lowest possible dose should be prescribed to improve pain and function. Frequent evaluation of clinical history and frequent review of medications are recommended. Periodic review of the ongoing chronic pain treatment plan for the injured worker is essential. Patients with pain who are managed with controlled substances

should be seen regularly. Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the 4 A's (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). Immediate discontinuation has been suggested for evidence of illegal activity including diversion.

American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) Chapter 3 states that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal symptoms. Opioids should be used only if needed for severe pain and only for a short time. ACOEM guidelines state that the long-term use of opioids is not recommended for ankle and foot conditions. Medical records document the long-term use of opioids. ACOEM guidelines indicate that the long-term use of opioids is not recommended for ankle and foot conditions. Per MTUS, the lowest possible dose of opioid should be prescribed. The urine drug screen dated 8/27/14 was inconsistent. ACOEM guidelines indicate that opioids should be used only if needed for severe pain and only for a short time. The request for Tylenol with Codeine #4 300/60 mg quantity 240 tablets is not supported by MTUS & ACOEM guidelines. Therefore, the request for Tylenol with Codeine #4 300/60 mg quantity 240 tablets is not medically necessary.