

Case Number:	CM14-0004980		
Date Assigned:	01/24/2014	Date of Injury:	08/29/2003
Decision Date:	06/20/2014	UR Denial Date:	01/03/2014
Priority:	Standard	Application Received:	01/14/2014

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 Occupational Medicine and is licensed to practice in California. 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 patient is a 43-year-old female who has submitted a claim for left shoulder impingement syndrome with rotator cuff tendinitis and myofascial strain, lumbar spine sprain/strain, adjustment disorder with mixed anxiety and depression, and insomnia, associated with an industrial injury date of August 28, 2003. The medical records from 2012 to 2013 were reviewed. The patient complained of pain at left shoulder and low back area aggravated by lifting, carrying, pushing, pulling, overhead reaching, standing, sitting, reclining, walking, climbing stairs, bending, and kneeling. This resulted to difficulty performing household chores and basic self-care. Intake of medications only provided temporary relief of symptoms. Physical examination of the left shoulder revealed tenderness, positive impingement and cross-arm tests, limited range of motion, and weakness. Objective findings of the lumbar spine included tenderness, and limited range of motion. Leg raise test, both sitting and standing, resulted to increased low back pain without radicular component. Motor strength of bilateral lower extremities was normal. Reflexes and sensation were intact. Gait was normal. The treatment to date has included aquatic therapy, acupuncture, chiropractic care, home exercise program, left shoulder ultrasound-guided subacromial cortisone injection, and medications such as cyclobenzaprine, hydrocodone/ APAP, omeprazole, Tramadol, and topical medications. A utilization review from January 3, 2014 denied the requests for omeprazole 20 mg, #60 because the patient did not have gastrointestinal symptoms; cyclobenzaprine 7.5 mg, #60 because it is only recommended for short-term use; 240g Flurbiprofen 20%, lidocaine 10%, dexamethasone 4%; 240 grams capsaicin 0.0375%, diclofenac 20%, Tramadol 10%, Flurbiprofen 10% due to lack of efficacy of topical medications; Tramadol/L-carnitine 40/125 milligrams, #90; baclofen/Flurbiprofen/acetyl-carnitine 7/60/125 milligrams, #90 because there was no documentation that a compounded product is needed for this case. The request for Tramadol 50

mg, #100 was modified into quantity #60 because there were no measurable benefits from its use. The request for hydrocodone/APAP 10/325 milligrams, #60 was modified into quantity number 30 for weaning purposes.

IMR ISSUES, DECISIONS AND RATIONALES

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

OMEPRAZOLE 20 MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GASTROINTESTINAL SYMPTOMS & CARDIOVASCULAR RISK..

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

Decision rationale: As stated in the CA MTUS Chronic Pain Medical Treatment Guidelines, clinicians should weigh the indications for non-steroidal anti-inflammatory drugs (NSAIDs) against both gastrointestinal (GI) and cardiovascular risk factors: patient older than 65 years old, history of peptic ulcer, GI bleeding or perforation; concurrent use of acetylsalicylic acid (ASA), corticosteroids, or anticoagulant; or on high-dose/multiple NSAIDs. Patients with intermediate risk factors should be prescribed with proton pump inhibitors (PPI). In this case, the patient is on multiple medications including opioids, NSAIDs, and omeprazole since February 2013. However, there was no subjective report that she was experiencing heartburn, epigastric burning sensation or any other gastrointestinal symptoms that will corroborate the necessity of a PPI. Furthermore, the patient did not meet any of the aforementioned risk factors. The MTUS guidelines criteria were not met. Therefore, the request is not medically necessary.

TRAMADOL 50 MG #100: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78.

Decision rationale: As stated in the CA MTUS Chronic Pain Medical Treatment Guidelines, there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related behaviors. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. In this case, patient has been on opioids since February 2013. However, the medical records do not clearly reflect continued analgesia, continued functional benefit, or a lack of adverse side effects. The MTUS guidelines require clear and concise documentation for ongoing management. Therefore, the request is not medically necessary.

CYCLOBENZAPRINE 7.5 MG #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63.

Decision rationale: According to the CA MTUS Chronic Pain Medical Treatment Guidelines, non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In this case, the patient has been on cyclobenzaprine since May 2013. However, there are no documented functional improvements derived from its use. Furthermore, the most recent progress reports failed to provide evidence of muscle spasm necessitating its use. Long-term use is likewise not recommended. Therefore, the request is not medically necessary.

HYDROCODONE/APAP 10/325MG #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78.

Decision rationale: As stated in the CA MTUS Chronic Pain Medical Treatment Guidelines, there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related behaviors. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. In this case, the patient has been on opioids since February 2013. However, the medical records do not clearly reflect continued analgesia, continued functional benefit, or a lack of adverse side effects. The MTUS guidelines require clear and concise documentation for ongoing management. Therefore, the request is not medically necessary.

240GM FLURBIPROFEN 20%, LIDOCAINE 10%, DESAMETHASONE 4%: Upheld

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

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

Decision rationale: As noted in the CA MTUS Chronic Pain Medical Treatment Guidelines, there is little to no research as for the use of Flurbiprofen in compounded products. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Regarding the Lidocaine component, the CA MTUS Chronic Pain Medical Treatment Guidelines identify that topical formulations of lidocaine (whether creams, lotions or

gels) are not indicated for neuropathic or non-neuropathic pain complaints. Regarding topical dexamethasone, the CA MTUS does not cite specific provisions for use in chronic pain. In this case, there is no documented rationale concerning the need for multiple topical compounded products. There is no evidence that patient has intolerance to oral medications. Furthermore, the MTUS guidelines state that any compounded product with a drug class that is not recommended is not recommended. The requested drug has active ingredients that are not recommended for topical use. Therefore, the request is not medically necessary.

240GM CAPSAICIN 0.0375%, DICLOFENAC 20%, TRAMADOL 10%, FLURBIPROFEN 10%: Upheld

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

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

Decision rationale: As noted in the CA MTUS Chronic Pain Medical Treatment Guidelines, there is little to no research as for the use of Flurbiprofen in compounded products. The CA MTUS Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Regarding the capsaicin component, the MTUS states there is no current indication that an increase over a 0.025% formulation would provide any further efficacy. The MTUS guidelines also state that capsaicin in a 0.0375% formulation is not recommended for topical applications. Tramadol is indicated for moderate to severe pain. Diclofenac in topical formulation is recommended for osteoarthritis. In this case, there is no documented rationale concerning the need for multiple topical compounded products. There is no evidence that patient has intolerance to oral medications. Furthermore, the MTUS guidelines state that any compounded product with a drug class that is not recommended is not recommended. The requested drug has active ingredients that are not recommended for topical use. Therefore, the request is not medically necessary.

TRAMADOL/L CARNITINE 40/125MG, #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Compound Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Section, Medical Food and Compound Drugs.

Decision rationale: As stated in the CA MTUS Chronic Pain Medical Treatment Guidelines, there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related behaviors. The Official Disability Guidelines (ODG) states that L-carnitine is a medical food, which may be

used if there is distinctive nutritional requirement. In addition, the ODG states that compound drugs are not approved by the Food and Drug Administration (FDA). In this case, the patient is on Tramadol 50mg and hydrocodone/APAP 10/325mg. There is no discussion concerning the need to provide Tramadol with a compounded L-carnitine. Furthermore, there is no evidence that patient has a nutritional deficiency necessitating intake of medical food. There is no documented rationale for this request. The medical necessity has not been established. The quantity is likewise not specified. Therefore, the request is not medically necessary.

BACLOFEN 7MG/FLURBIPROFEN 60MG/ACETYL-CARNITINE 125MG, #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Compound Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 46,63. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Section, Medical Food and Compound Drugs

Decision rationale: As stated in the California MTUS Chronic Pain Medical Treatment guidelines, non-steroidal anti-inflammatory drugs (NSAIDs) are recommended at the lowest dose for the shortest period in patients with moderate to severe pain and that there is no evidence of long-term effectiveness for pain or function. The CA MTUS states that non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. The Official Disability Guidelines (ODG) states that acetyl-carnitine is a medical food, which may be used if there is distinctive nutritional requirement. In addition, the ODG states that compound drugs are not approved by the Food and Drug Administration (FDA). In this case, there is no evidence that patient has muscle spasm necessitating the use of a muscle relaxant. There is likewise no discussion that patient has a nutritional deficiency requiring prescription of medical food. There is no documented rationale for this request. The medical necessity has not been established. The quantity is likewise not specified. Therefore, the request is not medically necessary.