

Case Number:	CM15-0001481		
Date Assigned:	01/12/2015	Date of Injury:	05/23/2012
Decision Date:	03/13/2015	UR Denial Date:	12/22/2014
Priority:	Standard	Application Received:	01/05/2015

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: Physical Medicine & Rehabilitation

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 51 year old female with an injury date on 05/23/2012. Based on the 12/04/2014 progress report provided by the treating physician, the diagnosis is: 1. Left lower leg severe crush injury. According to this report, the patient complains of left leg pain with history of fracture of the left tibia, fibula. Range of motion of the left lower extremity is decreased. Motor strength of the left lower extremity is decreased by 15% when compared to the opposite side. The 12/13/2014 report indicates the patient's work status is to remain off work. There were no other significant findings noted on this report. The utilization review denied the request for compound creams, Omeprazole #60, Tramadol #60, Theramine #90, Sentra PM #60, Gabadone, and Sentra AM on 12/22/2104 based on the MTUS/ODG guidelines. The requesting physician provided treatment reports from 06/21/2013 to 12/13/2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen / Capsaicin/Camphor 10/0.025%/2%/1% 120gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesic Page(s): 111-112.

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

Decision rationale: According to the 12/04/2014 report, this patient presents with left leg pain with history of fracture of the left tibia, fibula. The current request is for Flurbiprofen/Capsaicin/Camphor 10/0.025%/2%/1% 120gm. Regarding topical compounds, MTUS states that if one of the compounded products is not recommended then the entire compound is not recommended. The MTUS guidelines do not support the usage of Flurbiprofen (NSAID) for the treatment of spine, hip, shoulder or neuropathic pain. NSAID topical analgesics are indicated for osteoarthritis and tendinitis of the knee and elbow or other joints that are amenable to topical treatment. In reviewing the medical reports provided, the treating physician does not indicate that the patient presents osteoarthritis and tendinitis of the joints that are amenable to topical treatment. This patient presents with leg pain which topical NSAID is not indicated. The current request IS NOT medically necessary.

Ketoprofen/Cyclobenzaprine/Lidocaine 10%/3%/5% 120gm: 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 Page(s): 111-113.

Decision rationale: According to the 12/04/2014 report, this patient presents with left leg pain with history of fracture of the left tibia, fibula. The current request is for Ketoprofen/Cyclobenzaprine/Lidocaine 10%/3%/5% 120gm. MTUS specifically states ketoprofen is not FDA approved for topical applications. Any compounded topical product containing ketoprofen would not be recommended. Regarding Cyclobenzaprine topical, MTUS states Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. MTUS further states Lidocaine is only allowed in a patch form and not allowed in cream, lotion or gel forms. The guidelines indicate any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, all 3 compounds are not recommended for topical formulation. The current request IS NOT medically necessary.

Omeprazole QTY #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms, & cardiovascular risk .

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 69.

Decision rationale: According to the 12/04/2014 report, this patient presents with left leg pain with history of fracture of the left tibia, fibula. The current request is for Omeprazole #60. The MTUS page 69 states under NSAIDs prophylaxis to discuss; GI symptoms & cardiovascular risk

and recommendations are with precautions as indicated below. Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). MTUS further states Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI. In reviewing the provided reports, there is no mention of this medication usage; it is unknown exactly when the patient initially started taking this medication. The patient is currently not on NSAID. The patient is not over 65 years old; no other risk factors are present. The treating physician does not mention if the patient is struggling with GI complaints and why the medication was prescribed. There is no discussion regarding GI assessment as required by MTUS. MTUS does not recommend routine use of GI prophylaxis without documentation of GI risk. In addition, the treater does not mention symptoms of gastritis, reflux or other condition that would require a PPI. Therefore, the request IS NOT medically necessary.

Tramadol, unspecified dosage QTY #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 93-94.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CRITERIA FOR USE OF OPIOIDS Medications for chronic pain Page(s): 60-61, 76-78, 88-89.

Decision rationale: According to the 12/04/2014 report, this patient presents with left leg pain with history of fracture of the left tibia, fibula. The current request is for Tramadol, unspecified dosage, # 60. In reviewing the medical reports provided, there is no mention of this medication usage; it is unknown exactly when the patient initially started taking this medication. For chronic opiate use, MTUS Guidelines pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4A's; analgesia, ADLs, adverse side effects, and aberrant behavior, as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. In this case, the documentation provided by the treating physician does not show any pain assessment and no numerical scale is used describing the patient's function. No specific ADL's or return to work is discussed. No aberrant drug seeking behavior is discussed, and no discussion regarding side effects is found in the records provided. The treating physician has failed to clearly document the 4 A's as required by MTUS. Therefore, the request IS NOT medically necessary and the patient should be slowly weaned per MTUS.

Theramine QTY#90: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS.
Decision based on Non-MTUS Citation ODG pain chapter: Theramine

Decision rationale: According to the 12/04/2014 report, this patient presents with left leg pain with history of fracture of the left tibia, fibula. The current request is for Theramine # 90, a medical food. The MTUS and ACOEM guidelines are silent with regards to this product. However, the ODG guidelines state that Theramine is a proprietary medication of [REDACTED] based in [REDACTED]. Its intended use is in the management of pain syndromes including acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. ODG further states for each ingredient, there is no high quality peer-reviewed literature that suggests that GABA is indicated; for Choline, There is no known medical need for choline supplementation; L-Arginine, This medication is not indicated in current references for pain or inflammation; & L-Serine, There is no indication for the use of this product. It does not appear that there is any guideline support for this product in the management of chronic pain. Therefore, the current request IS NOT medically necessary.

Sentra PM QTY#60: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS.
Decision based on Non-MTUS Citation ODG Pain Chapter: Medical food

Decision rationale: According to the 12/04/2014 report, this patient presents with left leg pain with history of fracture of the left tibia, fibula. The current request is for Sentra PM # 60. The ODG guidelines states that, Sentra PM is a medical food from [REDACTED], [REDACTED], intended for use in management of sleep disorders associated with depression, that is a proprietary blend of Choline Bitartrate, Glutamate, and 5-hydroxytryptophan. ODG further states that for each ingredient: for choline, there is no known medical need for choline supplementation; for Glutamic Acid, This supplement is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine; for 5-hydroxytryptophan, this supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. It has been found to be effective for depression. In this case, choline, and ingredient in Sentra PM is not supported by ODG guidelines. Therefore, the current request IS NOT medically necessary.

Gabadone, unspecified QTY and dosage: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS.
Decision based on Non-MTUS Citation ODG Pain Chapter: Medical food

Decision rationale: According to the 12/04/2014 report, this patient presents with left leg pain with history of fracture of the left tibia, fibula. The current request is for Gabadone unspecified qty. and dosage. The MTUS and ACOEM guidelines are silent with regards to this product. However, the ODG guidelines state not recommended. Gabadone is a medical food from [REDACTED], [REDACTED], that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. The ODG guidelines do not support the use of Gabadone for chronic pain or for sleep aid. Therefore, the request IS NOT medically necessary.

Sentra AM, unspecified QTY and dosage: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain Chapter: Medical food

Decision rationale: According to the 12/04/2014 report, this patient presents with left leg pain with history of fracture of the left tibia, fibula. The current request is for Sentra AM unspecified qty. and dosage; a medical food. Sentra AM is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome, and neurotoxicity-induced fatigue syndrome. Sentra AM is a patented blend of neurotransmitter and neurotransmitter precursors (choline bitartrate and glutamate); activators of precursor utilization (acetyl-Lcarnitine, glutamate, and cocoa powder). The MTUS and ACOEM guidelines are silent when it come to this product. ODG on medical food states that for Choline, There is no known medical need for choline supplementation. MTUS also states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, choline, and ingredient in Sentra is not supported by ODG guidelines. Therefore, the current request IS NOT medically necessary.