

Case Number:	CM15-0123455		
Date Assigned:	07/07/2015	Date of Injury:	01/21/2013
Decision Date:	09/15/2015	UR Denial Date:	06/22/2015
Priority:	Standard	Application Received:	06/26/2015

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: New York
 Certification(s)/Specialty: Emergency 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 is a 65 year old female, who sustained an industrial injury on 01/21/2013. Her job involved repetitive keyboarding. She reported numbness of the right hand and fingers. Treatment to date has included medications, injections, physical therapy, acupuncture, chiropractic care, braces and right carpal tunnel release surgery. According to a progress report dated 06/15/2015, the injured worker still had left carpal tunnel and residual right hand pain and tingling. Right hand swelling with left shoulder soreness was noted. Pain was rated 8 on a scale of 1-10 without medication. With medications, she was able to do hygiene, cook and dress. She was unable to work due to no modified work available. Diagnoses included wrist sprain, carpal tunnel syndrome and neck pain. Gabapentin and Theramine were working well to decrease pain. With the addition of Gabapentin and Theramine, pain level was rated 5 and without was rated 8. She noted decreased burning paresthesias of the right hand with Gabapentin. She complained of increased pain sensation to light touch on the right wrist as well as increased burning sensation of her fingers of both hands. The treatment plan included Fenoprofen for pain and inflammation, Prilosec 1-2 every day to treat gastritis from NSAIDS, Flexeril to decrease spasms, Gabapentin, lidocaine patches, Theramine and a trial with Miseflex C for muscle cramps. The provider noted that Miseflex C is a natural medication with ginkgo. Work restrictions included no repetitive use of bilateral hands and stretch for five minutes every 30 minutes. An authorization request dated 06/18/2015 was submitted for review by the provider. Requested services included Cyclobenzaprine, Terocin patch, Fenoprofen, Theramine, Omeprazole, Gabapentin, Miseflex-C and Glfcmk cream. Currently under review is the request for Theramine quantity 90, Terocin

patch quantity 30, Omeprazole 20mg quantity 60, Miseflex-C quantity 90 and Glfcmk cream quantity 2.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine Qty: 90.00: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation The Official Medical Fee Schedule: General Instruction, page 7, Dietary supplements.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter-Medical Food and Other Medical Treatment Guidelines Medscape.

Decision rationale: CA MTUS does not address Theramine. Medscape states that Theramine is a "medical food" containing an amino acid blend that significantly improves chronic low back pain and reduces inflammation compared with low-dose Ibuprofen, a nonsteroidal anti-inflammatory drug (NSAID), or a combination of these 2 treatments, result of a new study show. Official Disability Guidelines do not recommend medical food for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized specific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment chronic pain. In this case, documentation does not address complaints of low back symptoms. Physical examination did not address the low back. There was no specific objective evidence of functional improvement with the use of Theramine. Guidelines do not recommend medical foods for chronic pain. The medical necessity for this request was not established. The requested treatment is not medically necessary.

Terocin patch Qty: 30.00: 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: Per the MTUS Chronic Pain Medical Treatment Guidelines state topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Terocin patches contain lidocaine and menthol. CA MTUS Guidelines recommends topical lidocaine only in the form of the Lidoderm patch for neuropathic pain. Any topical agent with lidocaine is not recommended if it is not Lidoderm. Any compound

product that contains at least one drug (or drug class) that is not recommended is not recommended. The MTUS is silent with regards to menthol. It may be used for relief of dry, itchy skin. This agent carries warnings that it may cause serious burns. In this case, there was no discussion of trial and failure of antidepressants or anticonvulsants. The injured worker was currently taking Gabapentin (anticonvulsant) and was said to be working well. The prescription Terocin patch contains lidocaine in the unapproved form. In addition, there was no specific objective evidence of functional improvement with the use of Terocin patch. The medical necessity for this request is not established. The requested treatment is not medically necessary.

Omeprazole 20mg Qty: 60.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, gastrointestinal symptoms & cardiovascular risk Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Proton Pump Inhibitors.

Decision rationale: According to the California MTUS (2009), omeprazole (Prilosec) is proton pump inhibitor (PPI) that is recommended for patients taking NSAIDs (nonsteroidal anti-inflammatory drugs), with documented gastrointestinal (GI) distress symptoms, or at risk for gastrointestinal events. GI risk factors include: age >65, history of peptic ulcer, GI bleeding, or perforation; concurrent use of aspirin, corticosteroids, and/or anticoagulants, or high dose/multiple NSAIDs. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Official Disability Guidelines (ODG) states that proton pump inhibitors are recommended for patients at risk for gastrointestinal events. Decision to use proton pump inhibitors long-term must be weighed against the risks. The potential adverse effects of long-term proton pump inhibitor use included B12 deficiency, iron deficiency, hypomagnesemia, increased susceptibility to pneumonia, enteric infection and fractures, hypergastrinemia and cancer and more recently adverse cardiovascular effects. Proton pump inhibitors have a negative effect on vascular function, increasing the risk for myocardial infarction. Patients with gastroesophageal reflux disease on proton pump inhibitors had a 1.16 greater risk of myocardial infarction and a 2.00 risk for cardiovascular mortality. Proton pump usage may be serving as a marker for a sicker population, but this is unlikely, given the lack of increased risk seen in patients taking H2 blockers. (Shah, 2015) In this study proton pump inhibitor use was associated with a 1.58 fold greater risk of myocardial infarction and in the case-crossover study, adjusted odds ratios of proton pump inhibitor for myocardial risk were 4.61 for the 7 day window and 3.47 for the 14 day window. However, the benefits of proton pump inhibitors may greatly outweigh the risks of adverse cardiovascular effects, with number needed to harm of 4357. (Shih, 2014) Outpatient proton pump use is associated with a 1.5 fold increased risk of community-acquired pneumonia, with the highest risk within the first 30 days after initiation of therapy. (Lamber, 2015) The updated Beers Criteria, which help prevent adverse drug events in older adults, added a recommendation to avoid the use of proton pump inhibitors for more than 8 weeks, except for long-term NSAID users and patients with erosive esophagitis, Barrett's esophagitis, pathologic hypersecretory condition, or a demonstrated need for maintenance therapy. There are many studies demonstrating, in elderly patients, an increased

risk for Clostridium difficile infection and bones loss and fractures with the long-term use of proton pump inhibitors. (AGS, 2015) In this case, there is no documentation indicating that the injured worker had any GI symptoms or risk factors. The medical necessity for Omeprazole has not been established. The requested medication is not medically necessary.

Miseflex-C Qty: 90.00: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation The Official Medical Fee Schedule: General Instruction, page 7, Dietary supplements.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Medical Foods and Other Medical Treatment Guidelines Enovachem Manufacturing.

Decision rationale: CA MTUS Guidelines does not address Miseflex-C. Enovachem Manufacturing states that Miseflex-C is a nutritional supplement consisting of a combination of calcium, magnesium, chondroitin, bromelain and a proprietary blend consisting of valerian, passiflora and ginkgo biloba extract. Some studies have shown that the listed ingredients listed in Miseflex-C may help with muscle soreness and cramps. These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any diseases. Official Disability Guidelines do not recommend medical food for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized specific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment chronic pain. In this case, documentation did not discuss any dietary deficiencies. In this case, the injured worker was already prescribed Flexeril for muscle spasms. The provider does not discuss the indications for Miseflex-C. Guidelines do not recommend medical foods for chronic pain. The medical necessity for the requested is not established. The requested treatment is not medically necessary.

Glfcmk cream Qty: 2.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111.

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

Decision rationale: Per the MTUS Chronic Pain Medical Treatment Guidelines state topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Further guidelines state "Many agents are compounded as monotherapy or in combination for pain control... There is little to no research to support the use

of many of these agents. Any compounded product that contains at least one drug that is not recommended is not recommended." In this case, it is unclear what the components are of the topical cream being requested. The treating physician's request did not address the ingredients of the cream, the indication for use or concentration, site of application, or directions for use. As the components of this cream are not known, it cannot properly be evaluated for medical necessity. As such, the prescription is not sufficient. The medical necessity for this request is not established. The requested treatment is not medically necessary.