

Case Number:	CM14-0115088		
Date Assigned:	09/18/2014	Date of Injury:	06/27/2003
Decision Date:	10/17/2014	UR Denial Date:	07/11/2014
Priority:	Standard	Application Received:	07/23/2014

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 & Rehabilitation, has a subspecialty in Pain 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 injured worker is a 53 year-old male with a date of injury of 6/11/2003. The patient's industrially related diagnoses include low back pain and lower extremity radiculopathy. The disputed issues are a Solar Care FIR heating system, a prescription for Amitramadol Cream 240gm, a prescription for CycloKetoLido Cream 240gm, Naproxen 550mg #60 with 1 refill, Prilosec 20mg #30 with 1 refill, EMG/NCV of bilateral lower extremities, and Ultracet 37.5 mg #60 with 1 refill. A utilization review determination on 7/11/2014 had non-certified these requests. The stated rationale for the denial of the Solar Care FIR heating system was that "there is no documentation to suggest that the patient had a condition in which a specialized unit would be necessary over traditional heat therapies." The request for Amitramadol cream was denied because "there is no scientific evidence to support the use of any of the drugs used in this compounded cream." The stated rationale for the denial of CycloKetoLido was that "there is no evidence to support the use of a muscle relaxant, such as Cyclobenzaprine, as a topical product." Naproxen was denied because "the patient was being treated for chronic lumbar spine pain and had utilized this NSAID on an ongoing basis. It appears that the patient previously had gastrointestinal complaints and gastritis associated with chronic medication use. Due to the development of adverse effects, the continuation of this medication would not be medically necessary." The stated rationale for the denial of Prilosec was that "though there were previous reports of gastritis, there was no recent reporting of any gastrointestinal events. Furthermore, the request for Naproxen was also denied." The EMG/NCV studies of the bilateral lower extremities were denied because of the lack of evidence to support clinical radiculopathy. Lastly, the stated rationale for the certification with modification of Ultracet was "there was no sustainable increase in function or significant decrease in pain contributed to the previous use of this medication."

IMR ISSUES, DECISIONS AND RATIONALES

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

1 Solar Care FIR heating system: 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), Low Back - Lumbar & Thoracic (Acute & Chronic)

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 734-735. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Chapter, Infrared therapy (IR)

Decision rationale: The Solar Care FIR heating system is a cordless heating wrap that uses Far Infrared Ray (FIR) technology to provide deep penetrating heat. The California Medical Treatment and Utilization Schedule do not address heat therapy. However, the updated ACOEM guidelines state that there are many forms of heat therapy for treatment of musculoskeletal pain including hot packs, moist hot packs, sauna, warm baths, infrared, diathermy and ultrasound. For the treatment of chronic LBP, self-application of low-tech heat therapy is recommended. However, this still does not address the use of infrared therapy. Therefore, the Official Disability Guidelines Low Back Chapter is consulted. The ODG states that "Infrared therapy (IR) is not recommended over other heat therapies. Where deep heating is desirable, providers may consider a limited trial of IR therapy for treatment of acute LBP, but only if used as an adjunct to a program of evidence-based conservative care." There is no documentation of acute low back pain, and the injured worker's DOI was 6/11/2003. Therefore, based on the Official Disability Guidelines, the Solar Care FIR heating system is not medically necessary.

Amitramadol cream, 240gm 1 refill: 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(s): 111-113.

Decision rationale: Amitramadol cream is a compounded cream containing Amitriptyline and Tramadol. In regards to topical analgesics, The California MTUS Chronic Pain Medical Treatment Guidelines specify: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The California Medical Treatment and Utilization Schedule do not have provisions for topical Tramadol. There is an absence of peer review controlled studies on topical Tramadol and it is not recommended. Amitriptyline is an anti-epilepsy drug. There is no evidence for use of any other anti-epilepsy drug as a topical product. Since neither drug is recommended in topical form, this compounded formulation containing Amitriptyline and Tramadol is not recommended. Therefore, Amitramadol cream 240gm with 1 refill is not medically necessary.

CycloKetoLido Cream 240gm 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Compound, Other Muscle Relaxants, Topical NSAIDs, Lidocaine, topic.

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

Decision rationale: CycloKetoLido Cream is a compounded formulation that contains Cyclobenzaprine, Ketoprofen, and Lidocaine. In regards to topical analgesics, the California MTUS Chronic Pain Medical Treatment Guidelines specify that "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In regards to Cyclobenzaprine it states that there is no evidence for use of any other muscle relaxant, other than Baclofen, as a topical product. Ketoprofen is an agent that is not currently FDA approved for a topical application. Since CycloKetoLido contains two drugs that are not recommended as topical agents, the CycloKetoLido cream 240gm with 1 refill is not medically necessary.

60 Naproxen 550mg 1 refill: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-68,70-71.

Decision rationale: Naproxen 550mg is a non-steroidal anti-inflammatory drug (NSAID). The Chronic Pain Medical Treatment Guidelines recommend NSAIDs as a second-line treatment after acetaminophen for the management of acute exacerbations of chronic low back pain. NSAIDs are recommended as an option for short-term symptom relief only. The guidelines further recommend "that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual patient treatment goals." In the progress report dated 4/14/2014, it was noted on the medication list that the injured worker was taking Mobic 15mg daily with food. Mobic is also an NSAID. The submitted medical records that were available for review did not include a rationale as to why Naproxen 550mg #60 with 1 refill was requested. Therefore, medical necessity cannot be established for Naproxen 550mg at this time.

30 Prilosec 20ng with 1 refill: Overturned

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 and GI & Cardiovascular Risk Page(s): 68-69.

Decision rationale: Prilosec (generic: Omeprazole) is a proton pump inhibitor (PPI). The Chronic Pain Medical Treatment Guidelines recommend that if a patient is at intermediate risk for gastrointestinal events and no cardiovascular disease, then a non-selective NSAID (non-steroidal anti-inflammatory drug) with a PPI (proton pump inhibitor, for example, 20mg Omeprazole daily) can be used. The following criteria is used to determine if the injured worker 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)." In the progress report dated 3/20/2014, the treating physician diagnosed the injured worker with unspecified functional disorder of the stomach (ICD-9 536.9) and prescribed Prilosec 20mg #30. In previous reports, the treating physician documented that the patient had gastritis with stress and chronic meds. On the available medication list, Mobic was listed as one of the medications that the injured worker took daily. Based on the guidelines referenced above, the injured worker is at intermediate risk for gastrointestinal events and Prilosec is recommended. Therefore Prilosec 20mg #30 is medically necessary.

EMG of bilateral lower extremities: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Chapter, Electromyography

Decision rationale: The ACOEM Practice Guidelines state that electromyography (EMG) may be useful to identify subtle, focal neurologic dysfunction in patients with low back symptoms lasting more than three or four weeks. Furthermore, the Official Disability Guidelines state that electromyography is recommended as an option to obtain unequivocal evidence of radiculopathy after 1-month conservative therapy. Although EMG of the lower extremities could be indicated in patients with low back symptoms, the submitted medical records that were available for review did not include the rationale as to why the EMG of bilateral lower extremities was requested. Therefore, medical necessity for EMG of bilateral lower extremities could not be established at this time.

Nerve Conduction study of bilateral lower extremities: 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), Low Back - Lumbar & Thoracic (Acute & Chronic)

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Chapter, Nerve Conduction Studies

Decision rationale: According to the ACOEM Practice Guidelines referenced above, nerve conduction studies are usually normal in radiculopathy but can rule out other causes for lower limb symptoms (generalized peripheral neuropathy, peroneal compression neuropathy at the proximal fibular, etc.) that can mimic sciatica. The Official Disability Guidelines do not recommend nerve conduction studies (NCS) because "there is minimal justification for performing nerve conduction studies when a patient is presumed to have symptoms on the basis of radiculopathy." In this case the ACOEM Practice Guidelines take precedence. However, the submitted medical records that were available for review did not include the rationale as to why the NCV studies of bilateral lower extremities were requested. Therefore, NCV of bilateral lower extremities is not medically necessary at this time.

60 Ultracet 37.5mg with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Ultracet, Weaning of Medications, Opioids, specific drug list. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Tramadol / Acetaminophen (Ultracet, generic available)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Page(s): 76-80.

Decision rationale: Ultracet is a combination of Tramadol 37.5mg and Acetaminophen 325mg. The Chronic Pain Medical Treatment Guidelines state that "Tramadol is a synthetic opioid affecting the central nervous system. Tramadol is not classified as a controlled substance by the DEA." However, as of July 2014, the DEA changed the classification of Tramadol to a schedule IV controlled substance. Since Tramadol is an opioid, it is subject to the ongoing monitoring requirements as stated in the Chronic Pain Medical Treatment Guidelines, which specify that ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects is necessary for management with opioids. Specifically it states: "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 nonadherent) 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)." In the progress reports available for review, the treating physician documented that the "medications help" but did not provide a pain scale rating pain with and without medication. There was documentation of GI side effects with medication use. Addressing functional level, there was no documentation measuring functional improvement with the use of Ultracet. The treating physician actually stated no functional change. In regards to evaluating for aberrant behavior, there was no documentation of urine drug testing or CURES monitoring. According to the guidelines, if there is no overall improvement in function, discontinuation of opioids should be considered. Therefore, due to lack of adequate documentation regarding the use of this opioid, medical necessity cannot be established for Ultracet. Non-certification does not imply abrupt cessation and the requesting healthcare provider should either supply the requisite information for certification, or taper the patient as he or she sees fit.