

Case Number:	CM15-0194804		
Date Assigned:	10/12/2015	Date of Injury:	10/09/2010
Decision Date:	12/15/2015	UR Denial Date:	09/11/2015
Priority:	Standard	Application Received:	10/05/2015

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: 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:

This 55 year old male sustained an industrial injury on 10-9-10. Documentation indicated that the injured worker was receiving treatment for a right ankle fracture with persistent right ankle pain. Bone scan and triple phase scan of the feet and ankles (5-18-15) contained findings suggestive of the presence of infection or inflammation. The radiologist noted that the findings were nonspecific without x-ray or magnetic resonance imaging and recommended comparison to magnetic resonance imaging or x-ray and, if infection was being considered, an indium labeled white blood cell scan. On 9-11-5, Utilization Review non-certified a request for magnetic resonance imaging right foot and ankle, right distal tibia over wound, Indium labeled white blood cell scan of both feet and ankles, orthopedic consultation evaluate and treat and medication refills: Naproxen Sodium 500mg #50, Omeprazole 20mg #60, Cyclobenzaprine 7.5mg #60, Ketoprofen ointment 120gm and FCMC ointment 120gm.

IMR ISSUES, DECISIONS AND RATIONALES

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

MRI Right Foot & Ankle Right Distal Tibia Over Wound: Upheld

Claims Administrator guideline: Decision based on MTUS Ankle and Foot Complaints 2004, Section(s): Special Studies.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ankle & Foot (Acute & Chronic)/MRI.

Decision rationale: The request is for an MRI. The official disability guidelines state the following regarding this topic: Recommended as indicated below: MRI provides a more definitive visualization of soft tissue structures, including ligaments, tendons, joint capsule, menisci and joint cartilage structures, than x-ray or Computerized Axial Tomography in the evaluation of traumatic or degenerative injuries. (Colorado, 2001) (ACR-ankle, 2002) (ACR-foot, 2002) The majority of patients with heel pain can be successfully treated conservatively, but in cases requiring surgery (eg, plantar fascia rupture in competitive athletes, deeply infiltrating plantar fibromatosis, masses causing tarsal tunnel syndrome), MR imaging is especially useful in planning surgical treatment by showing the exact location and extent of the lesion. (Narvaez, 2000) MRI is being used with increasing frequency and seems to have become more popular as a screening tool rather than as an adjunct to narrow specific diagnoses or plan operative interventions. This study suggests that many of the pre-referral foot or ankle MRI scans obtained before evaluation by a foot and ankle specialist is not necessary. (Tocci, 2007) Second-look arthroscopy is not necessary to evaluate repaired talar cartilage compared to MRI. (Lee2, 2010) MRI has very high specificity and positive predictive value in diagnosing tears of the anterior talofibular ligament, calcaneofibular ligament and osteochondral lesions. However sensitivity was low with MRI. In a symptomatic patient with ligamentous and chondral pathology in the ankle, negative results on MRI must be viewed with caution and an arthroscopy may still be required for a definitive diagnosis and treatment. (Joshy, 2010) Magnetic resonance imaging (MRI) reliably detects acute tears of the anterior talofibular ligament and calcaneofibular ligament. After acute trauma, MRI is highly sensitive, specific and accurate for determining the level of injury to the ankle syndesmotomous ligaments. (Kaminski, 2013) See also ACR Appropriateness Criteria. Indications for imaging -- MRI (magnetic resonance imaging): Chronic ankle pain, suspected osteochondral injury, plain films normal. Chronic ankle pain, suspected tendinopathy, plain films normal. Chronic ankle pain, pain of uncertain etiology, plain films normal. Chronic foot pain, pain and tenderness over navicular tuberosity unresponsive to conservative therapy, plain radiographs showed accessory navicular. Chronic foot pain, athlete with pain and tenderness over tarsal navicular, plain radiographs are unremarkable. Chronic foot pain, burning pain and paresthesias along the plantar surface of the foot and toes, suspected of having tarsal tunnel syndrome. Chronic foot pain, pain in the 3-4 web space with radiation to the toes, Morton's neuroma is clinically suspected. Chronic foot pain, young athlete presenting with localized pain at the plantar aspect of the heel, plantar fasciitis is suspected clinically. Repeat MRI is not routinely recommended, and should be reserved for a significant change in symptoms and/or findings suggestive of significant pathology. (Mays, 2008) In this case, this study is not guideline-supported. This is secondary to inadequate documentation received of a qualifying indication as listed above. Pending receipt of medical records indicating why the study is requested and planned course of management, the request is not medically necessary.

Indium labeled white blood cell scan of both feet and ankles: 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).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Foot & Ankle/Bone scan.

Decision rationale: The request is for a bone scan. The official disability guidelines state the following regarding this topic: Recommended as indicated below: Bone scanning is generally accepted, well established and widely used. Bone scanning is more sensitive but less specific than MRI. (Colorado, 2001) (ACR-foot, 2002) Indications for imaging - Bone Scan (Radioisotope Bone Scanning): Bone scans may be utilized to rule out: Tumor (suspected neoplastic conditions of the lower extremity). Stress fractures in chronic cases (occult fractures, especially stress fractures, may not be visible on initial x-ray; a follow-up radiograph and/or bone scan may be required to make the diagnosis). Infection (99MTechnecium diphosphonate uptake reflects osteoblastic activity and may be useful in metastatic/primary bone tumors, stress fractures, osteomyelitis, and inflammatory lesions, but cannot distinguish between these entities.). Complex regional pain syndrome/CRPS-I/Reflex sympathetic dystrophy (discontinued nomenclature), if plain films are not diagnostic. In this case, this test is not guideline-supported. This is secondary to inadequate documentation submitted revealing one of the qualifying factors as listed above as well as the plan of action based on the result or change in management proposed. As such, the request is not medically necessary.

Orthopedic consultation evaluate and treat: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM, Chapter 7 Independent Medical Examinations and Consultations, page 127.

MAXIMUS guideline: Decision based on MTUS General Approaches 2004, Section(s): General Approach to Initial Assessment and Documentation.

Decision rationale: The request is for orthopedic surgery consultation. The ACOEM guidelines state the following regarding this topic: In assessing acute or sub acute complaints, the occupational health practitioner should first exclude conditions that could threaten life or limb if not diagnosed and treated emergently or urgently. The recommended process is therefore to: Seek red flags 1 for potentially dangerous underlying conditions. In the absence of red flags, work-related complaints can be handled safely and effectively by occupational and primary care providers. The focus is on monitoring for complications, facilitating the healing process, and facilitating return to work in a modified or full-duty capacity. Evaluation and treatment generally can proceed in the acute phase without special studies because the findings from such studies seldom alter treatment. Yet, in some body systems (e.g., eye, bone, and head injuries), special studies may be mandatory. The term red flag, as generally used by payors, is not applicable to this discussion. Payors generally use red flags to earmark a case that may become problematic from a claims management perspective. In these guidelines, red flag is a non-pejorative term that refers only to serious medical conditions. They are defined as a sign or symptom of a potentially serious condition indicating that further consultation, support, or

specialized treatment may be necessary. The term yellow flag is used to indicate psychosocial or other barriers to recovery. In this case, there is inadequate submitted documentation to support an orthopedic surgery consultation. There are no notes indicating why such a referral is needed or what specific issue necessitates further specialty evaluation. Pending receipt of this information, the request is not medically necessary.

Refill Naproxen 500mg #60 (twice a day as needed): Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: The request is for the use of a medication in the NSAID class. The ODG state the following regarding this topic: Specific recommendations: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-

Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006) See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications. (AGS, 2009) As stated above, acetaminophen would be considered first-line treatment for chronic pain. In this case, the continued use of an NSAID is supported for ongoing pain relief. As such, the request is medically necessary.

Refill Omeprazole 20mg #60 (twice a day as needed): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: The request is for the use of a medication in the class of a proton pump inhibitor. It is indicated for patients with peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain. Unfortunately, they do have certain side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically. Criteria for risk are as follows: "(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)." Due to the fact the patient does not meet to above stated criteria, the request for use is not medically necessary.

Refill Cyclobenzaprine 7.5mg #60 (twice a day as needed): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to

diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long-term use, the request is not medically necessary.

Refill KETO ointment 120gm (as needed in afternoon): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/Ketoprofen, topical.

Decision rationale: The request is for the use of Ketoprofen topically. The official disability guidelines state the following regarding this topic: Not recommended in the [REDACTED], as there are currently no FDA-approved versions of this product, but it is a first-line drug in [REDACTED]. See Topical analgesics, Non-steroidal anti-inflammatory agents (NSAIDs), and the ketoprofen topical listing, for more information and references. Topical NSAIDs are generally recommended for short-term use for acute sprain/strains and longer term for osteoarthritis of the knee and hand, particularly in individuals with risk for GI ulceration, but they are not indicated for treatment of the low back or neuropathic pain. At this time, the only available FDA-approved topical NSAID is diclofenac, but recent high quality studies have identified a dangerous increased risk profile with diclofenac, including topical formulations, making it a second-line recommended treatment in ODG. Topical ketoprofen has been approved by the European FDA (the European Medicines Agency), and the European EULAR and NICE guidelines state these approved formulations of topical ketoprofen should be a first-line treatment, and should be considered before oral NSAIDs because they have shown efficacy significantly superior to placebo and similar to oral NSAIDs, without the same risks of adverse effects. While there are no FDA approved formulations of topical ketoprofen available in the [REDACTED], the product is available from compounding pharmacies. Compound medications are not FDA approved, but they are allowed under state pharmacy regulations. See Compound drugs. Because each compounding pharmacy may create their own version, FDA cannot be a source of information on safety and effectiveness of each version, or on generic equivalency. At this time, there are no high quality studies of any of the various pharmacy-compounded formulations of topical ketoprofen available in the [REDACTED]. Also, while topical ketoprofen has been used extensively in [REDACTED], in 2009 [REDACTED] removed this product from the market due to photosensitivity reactions. The drug has been reinstated, but this may be a serious problem. See the ketoprofen topical listing in Topical analgesics, Non-steroidal anti-inflammatory agents. Note: Topical ketoprofen is not listed on the ODG Drug Formulary because the scope of the ODG Drug Formulary only includes FDA approved drugs. (Formulary Scope) In this case, the use of this medication is not guideline-supported. This is secondary to no FDA-approved versions of this product. As such, the request is not medically necessary.

Refill FCMC ointment 120gm (as needed in the morning): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: The request is for a topical analgesic medication. The MTUS guidelines state the following regarding this topic: Recommended as an option as indicated below: Largely experimental in use with few randomized controlled trials to determine efficacy or safety, primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic (fentanyl transdermal system).] In this case, the use of this medication is not guidelines-supported. This is secondary to inadequate clinical evidence of effectiveness. As such, the request is not medically necessary.