

Case Number:	CM13-0010205		
Date Assigned:	06/06/2014	Date of Injury:	07/22/2008
Decision Date:	07/31/2014	UR Denial Date:	08/01/2013
Priority:	Standard	Application Received:	08/16/2013

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 Anesthesia, has a subspecialty in Acupuncture and 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 53 year old male injured at worker with a date of injury 7/22/08 with related low back pain. Per 1/9/14 progress report, he reported pain in his left low back with radiating pain along the postero lateral dermatomes to the dorsum of the left foot. He also reported pain in his neck and bilateral shoulders with radicular pain radiating along the lateral aspect of the left upper extremity. He described the pain as constant with intermittent exacerbation, dull, achy, sharp-shooting, and burning with pins and needles sensations. He reported tingling and numbness in his lower left extremity and weakness of LLE that required him to use a cane. An MRI of the lumbar spine dated 4/18/11 revealed: Transitional S1 vertebral body; mild grade 1 anterolisthesis of L4 on L5 and L5 on S1; Mild central stenosis at L5-S1. (AP 8 mm); L5-S1 5mm central/left paracentral disc protrusion with abutment of left exiting nerve root of 1mm displacement; Moderate right sided and mild to moderate left neural foraminal stenosis at L5-S1. EMG/NCV of the upper extremities dated 10/26/11 revealed Left C6-C7 radiculopathy; left carpal tunnel syndrome of mild severity. He has been treated with injections, physical therapy and medication management.

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac Sodium 100MG #60 QTY: 60.00: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67-69.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 37, 67-68, 71.

Decision rationale: In regards to the use of NSAIDs for chronic low back pain, the MTUS CPMTG states that it is 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. Per the MTUS guidelines, voltaren is approved for use as chronic maintenance therapy, and is indicated to treat the injured worker's moderate pain. I respectfully disagree with the Utilization Review physician. Review of the latest documentation, which was not available to the Utilization Review physician, does not indicate that the injured worker is receiving NSAIDs from multiple providers. The request is medically necessary.

Omeprazole 20MG #30 QTY: 30.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Nsaids, Gi Symptoms and Cardiovascular Risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68.

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (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). CPMTG guidelines further specify: Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g., ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease : (1) a non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardio protection) and a PPI. If cardiovascular risk is greater than GI risk, the suggestion is naproxyn plus low-dose aspirin plus a PPI. Since this injured worker is negative for history of peptic ulcer, GI bleeding or perforation, and does not have cardiovascular disease, his risk for gastrointestinal events is low. Furthermore, the documentation submitted for review make no mention of gastrointestinal side effects secondary to his use of Diclofenac, as such, this request is not medically necessary.

Terocin 120 ML QTY: 1.00: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 25, 60, 105, 111-113.

Decision rationale: Terocin is capsaicin, lidocaine, menthol, methyl salicylate, and boswellia serrata. The California MTUS p112 with regard to capsaicin: Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. Capsaicin has no indication for use on the head. Methyl salicylate may have an indication for chronic pain in this context. The California MTUS p105, Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. However, the other ingredients in Terocin are not indicated. The preponderance of evidence indicates that overall this medication is not medically necessary. Regarding topical lidocaine, MTUS states (p112) Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. The California MTUS p25 Boswellia Serrata Resin is not recommended for chronic pain. Terocin topical lotion contains menthol. The California MTUS, Official Disability Guidelines, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to not recommended. Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. Therefore, it would be optimal to trial each medication individually. Therefore, the request is not medically necessary.

Cyclobenzaprine HCL 7.5MG #30 QTY: 30.00: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41-42.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-64.

Decision rationale: With regard to muscle relaxants, the MTUS CPMTG states: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Regarding Cyclobenzaprine: Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. A review of the submitted documentation indicates that the injured worker had a left L4, L5; S1 TFESI on 8/22/13, and per 1/9/14 progress report, pain was beginning to return. As he was not using this medication on a continuous basis prior to this progress report, this is an acute exacerbation of LBP and the request is indicated. I respectfully disagree with the Utilization Review physician's assertion that the injured worker's use of this medication has been chronic and daily. The latest documentation that was not available to the Utilization Review physician does not suggest this. The request is medically necessary.

Theramine #90 QTY: 90.00: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Food Drug Administration.

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), Theramine.

Decision rationale: The MTUS is silent on the topic of medical food. With regard to the treatment of chronic pain, the Official Disability Guidelines says this about Theramine: Not recommended. Theramine is a medical food from Physician Therapeutics, Los Angeles, CA, that is a proprietary blend of gamma-amino butyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-amino butyric acid (GABA), where it says, There is no high quality peer-reviewed literature that suggests that GABA is indicated; Choline, where it says, There is no known medical need for choline supplementation; L-Arginine, where it says, This medication is not indicated in current references for pain or inflammation; & L-Serine, where it says, There is no indication for the use of this product. Theramine is not recommended by the Official Disability Guidelines. Therefore, the request is not medically necessary.