

Case Number:	CM13-0005489		
Date Assigned:	12/27/2013	Date of Injury:	05/01/2009
Decision Date:	03/28/2014	UR Denial Date:	07/17/2013
Priority:	Standard	Application Received:	08/01/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician 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 physician 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 sustained an industrial injury when he bent down to remove a sticker from a box of vegetables and felt pain in his back. The injured worker's original date of injury was May 1, 2009. The diagnoses include chronic low back pain, myofascial pain syndrome, fear-based avoidance of activity, chronic buttocks pain, right shoulder pain, and severe depression. The disputed issues include a request for Tramadol, Flector patch, Ibuprofen, Omeprazole, coverall white tape, and coated for shoulder alignment retraining. A utilization review determination had noncertified these requests on July 17, 2013. The stated rationale for the noncertification of tramadol was that no subjective and or objective functional benefits were noted with tramadol. There was no documentation of urine drug screening according to the reviewer. With regard to ibuprofen, there was "no delineation of measurable pain information such as pain scores and functional improvement as a result of prior medication usage." With regard to Omeprazole, because the NSAID was not recommended, there was no indication for a proton pump inhibitor. With regard to Flector, this was noncertified because there was "no documentation that the claimant has been intolerant or unresponsive to all other treatments including oral pain medications." The reviewer also sites that topical analgesics are "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The reviewer noted that there was no documentation of "possible neuropathy." With regard to taping, the reviewer cited Official Disability Guidelines which state that kinesiotaping is not recommended.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol HCL 50mg 1 BID #60, 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol/Opioid Monitoring Page(s): 94, 77-78.

Decision rationale: The Chronic Pain Medical Treatment Medical Guidelines on page 94 states the following regarding tramadol: "Tramadol is a synthetic opioid affecting the central nervous system. Tramadol is not classified as a controlled substance by the DEA." Because it is an opioid it is subject to the monitoring requirements delineated in the Chronic Pain Medical Treatment Medical Guidelines on pages 77-78. This includes the following: "(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: 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). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000)" The submitted documentation consists of progress notes from an interdisciplinary functional restoration program. The progress notes from May 17, 2013 indicate that the injured worker had improved vocational, social, and recreational productivity as well as improved overall satisfaction. The injured worker was deemed to reach a permanent and stationary status, and demonstrated functional progress in terms of core strength, posture, decrease fear of functional activities. However, what is absent in these notes are the specific functional benefit attributed to tramadol, as well as monitoring of aberrant behaviors. There was no documentation of opioid risk screening, cross-referencing patient prescriptions in the cures database, or random periodic drug screening. Given that these are requirements of ongoing monitoring, this request is recommended for non-certification.

Flector 1.3% patch, 1 patch PRN #30, 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical NSAIDs Page(s): 112.

Decision rationale: The Chronic Pain Medical Treatment Guidelines on page 112 state the following: "Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use." The requesting healthcare provider has requested Flector #30 with 3 refills, which is a 4 month supply of medication. This exceeds the timeline set forth the Chronic Pain Medical Treatment Medical Guidelines which call for 4-12 weeks for topical NSAIDs. Furthermore, the FDA indication is for acute pain only, and the on-label use of this topical medication is for short-term use only. Given these guidelines, this request is recommended for non-certification.

Ibuprofen 400mg 1 QID #15, 3 refills: Upheld

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

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

Decision rationale: The relevant passages of the Chronic Pain Medical Treatment Medical Guidelines are found on pages 67-68 and apply to the treatment of CLBP with NSAIDs: "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 not one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications." In the case of this injured worker, the most relevant progress note on July 2, 2013 does not document the efficacy or possible side effects of ibuprofen, which the patient has been on chronically. This documentation is crucial in order to continue utilizing this medication. Given this lack of documentation from recent progress notes of analgesic efficacy, this request is recommended for noncertification.

Omeprazole 20mg capsule DR 1 BID #60, 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines PPI and NSAID Page(s): 68-69.

Decision rationale: The Chronic Pain Medical Treatment Medical Guidelines on page 68-69 states the following regarding the usage of proton pump inhibitors (PPI): "Clinicians should weight 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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. 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 Åµg 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 absolutely 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. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)" In the case of this injured worker, no gastrointestinal risk factors are identified such as a history of peptic ulcer. The patient's age also does not meet criteria for gastrointestinal risk. Given the guidelines, this request is recommended for noncertification.

Coverall white tape to protect skin, 1 roll: 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), Shoulder Chapter, Kinesiotape.

Decision rationale: The California Medical Treatment and Utilization Schedule and ACOEM do not specifically address kinesiotaping. Therefore, the Official Disability Guidelines are cited which state in the Shoulder Chapter that kinesiotape is: "Not recommended. Utilization of KT for decreasing pain intensity or disability for patients with suspected shoulder tendonitis/impingement is not supported. (Thelen, 2008) Tape is commonly used as an adjunct for treatment and prevention of musculoskeletal injuries. A majority of tape applications that are reported in the literature involve nonstretch tape. The KT method has gained significant popularity in recent years, but there is a paucity of evidence on its use. The suppliers make

claims of neuromuscular re-education." Therefore in this patient with shoulder pain, this request is not recommended given the lack of evidence.

Leuco tape for shoulder alignment retaining, 1 roll: 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), Shoulder Chapter, Kinesiotape.

Decision rationale: The California Medical Treatment and Utilization Schedule and ACOEM do not specifically address kinesiotaping. Therefore, the Official Disability Guidelines are cited which state in the Shoulder Chapter that kinesiotape is: "Not recommended. Utilization of KT for decreasing pain intensity or disability for patients with suspected shoulder tendonitis/impingement is not supported. (Thelen, 2008) Tape is commonly used as an adjunct for treatment and prevention of musculoskeletal injuries. A majority of tape applications that are reported in the literature involve nonstretch tape. The KT method has gained significant popularity in recent years, but there is a paucity of evidence on its use. The suppliers make claims of neuromuscular re-education." Therefore in this patient with shoulder pain, this request is not recommended given the lack of evidence.