

Case Number:	CM14-0119784		
Date Assigned:	08/06/2014	Date of Injury:	07/22/2013
Decision Date:	09/10/2014	UR Denial Date:	07/22/2014
Priority:	Standard	Application Received:	07/28/2014

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 and Rehabilitation 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 patient is a 46-year-old male with date of injury 7/22/13. The patient was at work for the [REDACTED] when a food cart with a 90-pound container started to tip and struck his shins. The force caused him to fall backwards, landing on his back. The last available treating physician report dated 6/20/14 indicates that the patient presents with pain affecting low back that is constant and is aggravated by bending, lifting, twisting, pushing, pulling, prolonged sitting, prolonged standing and walking multiple blocks. Current physical examination findings reveal that the pain is sharp and radiates into the lower extremities. The patient has had x-rays of the lumbar spine and left and right tibia and fibula, physical therapy, medications, chiropractic treatment, massage, MRI of the lumbar spine, EMG/NCV bilateral lower extremities, acupuncture, and two lumbar epidural injections for back and leg pain prior to this injury. Pain level is 8/10. Patient is on modified duties. The current diagnosis is: 1.Lumbago. The utilization review report dated 7/22/14 denied the request for Diclofenac sodium ER (Voltaren SR) 100 mg #120 based on the rationale that the documentation provided for review does not identify significant functional/vocational benefit with the use of NSAIDs and guidelines indicate they should be used at the lowest dose possible for the shortest duration possible for treatment of moderate to severe pain. Prior use of NSAIDs lacked efficacy so ongoing use of NSAIDs would not be supported. The UR report dated 7/22/14 denied the request for Omeprazole 20 mg #120 based on the rationale that in this case the treating physician recommends the use of Omeprazole for gastrointestinal upset secondary to chronic NSAID use. As long-term NSAID use is not supported in the current clinical setting the request for Omeprazole 20 mg #120 is not medically necessary. The UR report dated 7/22/14 denied the request for Ondansetron 8 mg ODT #30 based on the rationale that Zofran is indicated to prevent nausea and vomiting that may be caused by surgery or by medicine to treat cancer, which has not been documented in the medical records

provided. The UR report dated 7/22/14 denied the request for Cyclobenzaprine hydrochloride tablets 7.5 mg #120 based on the rationale that Cyclobenzaprine is recommended for a short period to address flare-ups of low back pain, and patient has utilized multiple muscle relaxants but does not describe significant analgesic effect or quantifiable functional benefit with use. The UR report dated 7/22/14 denied the request for Tramadol ER 150 mg #90 based on the rationale that the treating physician does not quantifiably document any functional improvement or pain relief with VAS scores pre- and post-opioid use. Also no documentation is provided of a pain contract on file and no results of urine specimens are provided. The UR report dated 7/22/14 denied the request for Menthoderm gel based on the rationale that topical NSAIDs are only recommended for a short duration. Their use is only supported for osteoarthritis of joints amenable to topical treatment. Topical NSAIDs are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. In this case medical records provided do not document a failure of trials of oral analgesics such as antidepressants or anticonvulsants.

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac Sodium ER (Voltaren SR) 100mg #120: Upheld

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

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

Decision rationale: This is a 46-year-old male who presents with low back pain radiating to both extremities. The current request is for Diclofenac sodium ER (Voltaren Sr) 100 mg #120. MTUS Guidelines recommend NSAID usage at the lowest dose possible for the shortest duration possible for treatment of moderate to severe pain. There is no documentation that patient's symptoms are improving with the use of NSAIDs thus far. MTUS page 8 states, "The physician should periodically review the course of treatment of the patient and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of pain management depends on the physician's evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities." In this case, the treating physician has failed to provide documentation of any improvements with the medications prescribed and does not document any progress toward treatment objectives. Recommendation is that this request is medically not necessary.

Omeprazole 20mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms 7 cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk - Page(s): 68-69.

Decision rationale: This is a 46-year-old male who presents with low back pain radiating to both extremities. The current request is for Omeprazole 20 mg #120. This was prescribed in conjunction with Diclofenac sodium. The MTUS Guidelines state that Omeprazole may be appropriate for patients also prescribed NSAIDs to protect a patient who is at risk for gastrointestinal events. The treating physician has not documented any gastric complaints and there is no diagnosis of gastritis. Recommendation is also that Omeprazole for gastric protection is not medically necessary.

Ondansatron 8mg ODT #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines for Pain regarding Antiemetics (for opioid nausea).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Guidelines Online Pain Chapter Not recommended for nausea and vomiting secondary to chronic opioid use. See Antiemetics (for opioid nausea). Antiemetics (for opioid nausea) Not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. (Moore 2005) Promethazine (Phenergan®): This drug is a phenothiazine. It is recommended as a sedative and antiemetic in pre-operative and post-operative situations. Multiple central nervous system effects are noted with use including somnolence, confusion and sedation. Tardive dyskinesia is also associated with use. This is characterized by involuntary movements of the tongue, mouth, jaw, and/or face. Choreoathetoid movements of the extremities can also occur. Development appears to be associated with prolonged treatment and in some cases can be irreversible. Anticholinergic effects can occur (dry mouth, dry eyes, urinary retention and ileus). Ondansetron (Zofran®): This drug is a serotonin 5-HT₃ receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis. See also Nabilone (Cesamet®), for chemotherapy-induced nausea, but not pain.

Decision rationale: This is a 46-year-old male who presents with low back pain radiating to both extremities. The current request is for Ondansetron 8 mg ODT #30. ODG Guidelines

Online Pain Chapter states that antiemetics are not recommended for nausea and vomiting secondary to chronic opioid use. Ondansetron is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. There is no indication patient has undergone chemotherapy or radiation treatment. Ondansetron is also FDA-approved for postoperative use, which there is no evidence that this patient has undergone surgery. There is no mention in the records provided why Ondansetron is being prescribed. Recommendation is that this request is not medically necessary.

Cyclobenzaprine Hydrochloride 7.5mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-66.

Decision rationale: This is a 46-year-old male who presents with low back pain radiating to both extremities. The current request is for Cyclobenzaprine Hydrochloride 7.5 mg #120. Cyclobenzaprine is recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. The patient was prescribed Flexeril 7.5 mg #120, 1 PO Q8H / PRN pain and spasm on 4/22/14. If the patient took this medication one p.o. every 8 hours as prescribed this prescription was for 40 days' worth of medication. The patient has had no noted improvement with the medication in the records provided. If there were documentation of benefit from the medication an argument could be made for approval. Recommendation is that this request is medically not necessary.

Tramadol ER 150mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TRAMADOL, MTUS, On Tramadol Specific Opioids: Tramadol, Tramadol (Ultram; Ultram ER; Page(s): 80,82,84,93,94.

Decision rationale: This is a 46-year-old male who presents with low back pain radiating to both extremities. The current request is for Tramadol ER 150 mg #90. MTUS Guidelines state that "A recent Cochrane review found that this drug decreased pain intensity, produced symptom relief and improved function for a time period of up to three months but the benefits were small (a 12% decrease in pain intensity from baseline)." The MTUS Guidelines go on to say "There are no long-term studies to allow for recommendations for longer than three months." On 4/22/14 the patient was prescribed Tramadol ER 150 mg #90 to take one tablet once a day as needed for pain. The medical records provided do not provide any information as to how long the patient has been taking Tramadol and there is no documentation of the effects of the

medication. MTUS also requires documentation of the four A's (analgesia, ADL's, Adverse effects and Adverse behavior). In this case, such documentation is not provided. MTUS further discusses under "outcome measures," documentation of average pain level, time it takes for medication to work, duration of relief with medication, etc. are required. In this patient, none of these are provided. Without proper documentation of the effects of this medication it is impossible to know if continued usage follows the MTUS guidelines. Recommendation is that this request is medically not necessary.

Menthoderm gel #120: 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: This is a 46-year-old male who presents with low back pain radiating to both extremities. The current request is for Mentoderm gel #120, which is topical cream containing methyl salicylate and menthol. The MTUS Guidelines state that topical NSAIDs are not supported for the treatment of the spine as MTUS states, "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." This topical cream is not supported by MTUS for the treatment of radicular pain as the treater has stated is present. Recommendation is that this request is medically not necessary.