

Case Number:	CM15-0133613		
Date Assigned:	07/28/2015	Date of Injury:	11/03/2014
Decision Date:	09/29/2015	UR Denial Date:	07/01/2015
Priority:	Standard	Application Received:	07/10/2015

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: New York, 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:

The injured worker is a 46 year old male who sustained an industrial injury on 11/03/2014 resulting in injury to the low back and left shoulder after falling down some stairs. Treatment provided to date has included: chiropractic therapy; medications: acetaminophen in addition to current medications; and conservative therapies/care. Diagnostic testing was not provided or results discussed. Comorbidities included diabetes, hypertension and high cholesterol. There were no other dates of injury noted. On 06/24/2015, a physician progress report (PR) noted complaints of low back pain and left shoulder pain. This report provided no pain rating or description of pain. A PR dated 06/17/2015, stated complaints of low back and shoulder pain with difficulty in completing self-care and activities of daily living (ADLs) and a pain severity rating of 8/10 at the time of exam and 10/10 without medications. Current medications on both reports include: Lidopro ointment twice daily for local pain for which the injured worker reports decreased allodynia, decreased cutaneous pain, and improvement in function of the limbs; Norflex 100mg every 12 hours as needed for which the injured worker reports using sparingly, increased ROM in the low back and decreased muscle spasms and pain with use; Relafen 750mg every 12 hours as needed for which the injured worker reports using this medication for breakthrough pain thus reducing pain by 30% and allows for performance in activities of daily living; and tramadol (Ultram) ER 150mg. The physical exam revealed decreased range of motion (ROM) in the lumbar spine with spasms, tenderness and guarding; numbness in the left lower extremity over the L4 dermatome with radiation of pain to the left lower extremity over the L4- S1 dermatomes; decreased ROM in the left shoulder with positive impingement sign; and tenderness over the L5-S1 dermatome. The provider noted diagnoses of lumbosacral

radiculopathy and shoulder impingement. Plan of care, per the PR dated 06/24/2015, includes continued current medications. The PR dated 06/17/2015 stated a treatment plan that included refills of current medications with the addition of Relafen. The injured worker's work status remained temporarily totally disabled. The request for authorization and IMR (independent medical review) includes: Lidopro topical pain relief ointment (capsaicin, Lidocaine, Menthol, and methyl salicylate #1 121gm with 5 refills, Norflex 100mg #60 with 5 refills, Relafen 750mg #60 with 5 refills, and Ultram ER 150mg #160 with 5 refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidopro Topical Pain relief ointment (Capsaicin, Lidocaine, Menthol, and Methyl Salicylate) #1 121 grams with 5 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (Lidocaine patch) and Topical Analgesics Page(s): 56-57, 111-113.

Decision rationale: According to the MTUS guidelines: "Topical Analgesic are 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. 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 MTUS goes on to specify that "topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia." Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. In this case, the injured worker has already been prescribed and using the Lidoderm patch. Additionally, topical Lidocaine is not recommended in creams, lotions or gels. Moreover, it was noted that the specific formulation was not indicated. Therefore, topical Lidopro topical pain relief ointment (capsaicin, Lidocaine, Menthol, and methyl salicylate #1 121gm with 5 refills is not medically necessary.

Norflex 100mg #60 with 5 refills: 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: The MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP (low back pain) as they can reduce pain from muscle tension and possibly increase mobility. However, in most cases involving LBP, they provide no more benefit beyond NSAIDs in pain and overall improvement. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Orphenadrine (Norflex) is a muscle relaxant which is used to treat muscle spasms, muscle rigidity, and cramping or inflammation of the muscles. Orphenadrine is similar to diphenhydramine, but has increased anticholinergic effects (drowsiness, urinary retention, dry mouth). The method of action is not clear, but it has been reported to be abused for euphoria and to have mood elevating effects. Upon review of medical records, it was noted that the injured worker has been prescribed and using this medication since 2014 with insufficient evidence of benefit or functional improvement as there were multiple reports of increased pain and spasm since the initiation of therapy. Also, muscle relaxants are not recommended for long-term use. Additionally, there are multiple prescriptions and request for authorization with multiple refills 1-2 weeks apart. As such, the requested Norflex 100mg #60 with 5 refills is not medically necessary.

Relafen 750mg #60 with 5 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73.

Decision rationale: Relafen (Nabumetone) is a non-specific non-steroidal anti-inflammatory drug (NSAID). Oral NSAIDs are recommended for the treatment of chronic pain and control of inflammation as a second-line therapy after acetaminophen. ODG states that NSAIDs are recommended for acute pain, osteoarthritis, acute low back pain (LBP) and acute exacerbations of chronic pain, short-term pain relief in chronic LBP, and short-term improvement of function in chronic LBP. There is no evidence of long-term effectiveness for pain or function. There is inconsistent evidence for the use of NSAIDs to treat long-term neuropathic pain. Guidelines recommended that the lowest effective dose be used for the shortest duration of time consistent with treatment goals. In this case, the injured worker has not had prior use of NSAIDs. However, the injured worker is being seen every 1-2 weeks for re-evaluation. The plan of care with each evaluation shows prescriptions for Relafen with multiple refills. Since the injured worker is being evaluated so often, it is appropriate to assess benefit of Relafen during these exams and prescribe this medication as necessary. Medical necessity of the requested Relafen, with multiple refills on a frequent basis, has not been established. The request for Nabumetone (Relafen) 750mg #60 with 5 refills is not medically necessary.

Ultram ER 150mg #160 with 5 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: Ultram (tramadol) is an opioid medication used to treat moderate to severe pain. MTUS discourages long term usage unless there is evidence of 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, return to work, or improved quality of life. Opioids are to be weaned and discontinued if there is no overall improvement in function, unless there are extenuating circumstances. After reviewing the clinical documentation submitted for review, it is found that the treating physician does not document: 1) the least reported pain over the period since last assessment; 2) intensity of pain after taking the opioid; 3) how long it takes for pain relief; 4) how long pain relief lasts; 5) improvement in pain; or 6) improvement in function. These are necessary to meet MTUS guidelines. Additionally, the progress reports show that the injured worker has been prescribed this medication for several months with increased pain levels since the initiation of the tramadol. As such, the request for Ultram ER 150mg #160 with 5 refills is not medically necessary.