

Case Number:	CM15-0181831		
Date Assigned:	09/23/2015	Date of Injury:	07/05/2006
Decision Date:	11/16/2015	UR Denial Date:	09/01/2015
Priority:	Standard	Application Received:	09/15/2015

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 is a 42 year old female with a date of injury on 7-5-2006. A review of the medical records indicates that the injured worker is undergoing treatment for status post anterior-posterior discectomy-fusion with instrumentation at L4-L5 and L5-S1 performed in 2009 with residual bilateral lower extremities radiculitis; cervical spine musculoligamentous sprain-strain with multilevel disc osteophyte and stenosis and sternoclavicular joint pain secondary to surgical positioning. Medical records (3-16-2015 to 8-4-2015) indicate ongoing neck pain radiating to the right greater than left upper extremity rated four to six out of ten. According to the progress report dated 8-4-2015, the injured worker was awaiting clearance by neurology for cervical spine surgery due to a history of transient ischemic attack (TIA). She complained of sharp pain in her shoulder blades, right side greater than left rated six out of ten. She also complained of ongoing low back pain with flare ups. Per the treating physician (8-14-2015), the injured worker was temporarily totally disabled. The physical exam (8-14-2015) revealed tenderness to palpation over the lumbar spine. Exam of the cervical spine revealed slight spasm over the paravertebral musculature. Treatment has included surgery and medications. On 3-16-2015, the injured worker reported that Neurontin made her nauseated; same kind of nausea with prior use of Ultram. The injured worker was dispensed a trial of Lyrica on 3-16-2015. The request for authorization dated 8-14-2015 was for refills of Ultram, Prilosec, Fexmid and Lyrica and start Colace. The original Utilization Review (UR) (9-1-2015) denied requests for Ultram, Fexmid and Colace. Utilization Review modified a request for Lyrica 75mg #60 to #15.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ultram 50mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: Tramadol is a pain medication in the category of a centrally acting analgesic. They exhibit opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Centrally acting drugs are reported to be effective in managing neuropathic type pain although it is not recommended as first line therapy. The side effect profile is similar to opioids. For chronic back pain, it appears to be efficacious for short-term pain relief, but long term (>16 weeks) results are limited. It also did not appear to improve function. The use of tramadol for osteoarthritis is indicated for short-term use only (<3 months) with poor long-term benefit. In this case, the patient does not meet the qualifying criteria. This is secondary to the duration of use, with this medication being indicated on a short-term basis only. As such, the request is not medically necessary.

Fexmid 7.5mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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.

Colace 100mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic: Opioid-induced constipation treatment).

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)/Opioid-induced constipation treatment.

Decision rationale: The request is for a medication to aid in constipation. The Official Disability Guidelines state the following regarding this topic: Recommended as indicated below. In the section, Opioids, criteria for use, if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications don't work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. An oral formulation of methylnaltrexone (Relistor) met the primary and key secondary end points in a study that examined its effectiveness in relieving constipation related to opioid use for non-cancer-related pain. The effectiveness of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic non-cancer-related pain. There was an 80% improvement in response with the 450 mg dose and a 55% improvement with 300 mg. Constipation drug lubiprostone (Amitiza) shows efficacy and tolerability in treating opioid-induced constipation without affecting patients' analgesic response to the pain medications. Lubiprostone is a locally acting chloride channel activator that has a distinctive mechanism that counteracts the constipation associated with opioids without interfering with the opiates binding to their target receptors. (Bader, 2013) (Gras-Miralles, 2013) See also Tapentadol (Nucynta), which has improved gastrointestinal tolerability for patients complaining of constipation, nausea, and/or vomiting. The FDA has approved methylnaltrexone bromide (Relistor) subcutaneous injection 12 mg/0.6 mL for the treatment of opioid-induced constipation in patients taking opioids for non-cancer pain. (FDA, 2014) As stated above, measures to combat constipation for patients on opioids are needed. In this case, the use of this medication is not indicated. The opioid medication has been non-certified for use negating the need for over the counter stool softeners. As such, there is lack of need for this medication. The request is not medically necessary.

Lyrica 75mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

Decision rationale: The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. There also should be documentation of functional improvement and side effects incurred with use. Disease states which prompt use of these medications include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, there is lack of documentation of adequate pain reduction for continued use. The records also do not reveal functional improvement. Both of these are required for continued use of a medication in this class. As such, the request is not medically necessary.