MAXIMUS Federal Services

Case Number:	CM15-0186606		
Date Assigned:	09/28/2015	Date of Injury:	07/03/2004
Decision Date:	11/24/2015	UR Denial Date:	09/21/2015
Priority:	Standard	Application Received:	09/22/2015

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:

The injured worker is a 60 year old female, who sustained an industrial injury on 7-3-04. The injured worker was diagnosed as having encounter for long-term use of other medications; disc displacement without myelopathy; sprains-strains of the neck; late effect of surgical and medical care complication; chronic pain syndrome; neck strain; myofascial pain; carpal tunnel syndrome grater right. Treatment to date has included status post anterior cervical disc fusion (ACDF) C4-C5 (4-24-14); acupuncture therapy; medications. Currently, the PR-2 notes dated 8-11-15 indicated the injured worker is a i status post anterior cervical disc fusion C4-C5 of 4-24-14. The surgery was complicated by dysphagia and lymphedema. The provider documents an Interim History "Returned to pharmacy since last visits lidocaine patch, Ambien not provided. Since Lidoderm wasn't approved patient using TENS unit more, but it is irritating her skin with increased use. Arm pain seems reduced with current dosing of Lyrica 25, 25,100. Sleep is OK with increased Lyrica (but no Ambien). She is happy to try to keep off Ambien, but would like it available as needed. (Patient brought in copies of 5 A's for each medication to be scanned in). Has refills coming up on 8-20-15. Not sure what is approved given most recent denial, but provision of medications after pharmacist spoke with adjustor. She denies fevers, chills, bowel or bladder changes or night sweats-worse pain. (Rather she endorses frequent 'sweats'). Occupational Therapy coming 9-4-15 for her car evaluation. Medications allow her improved function, decreased pain by roughly 30-40% such that she is better able to do ADL [activities of daily living]. Without medications, she isn't able to keep up with house hold chores and has difficulty with mobility. Patient has filled out 5 A's on all medications." On physical

examination, the provider documents "ambulates without a device. Her gait is normal. Inspection of cervical spine reveals wearing a cervical Jovi collar. Range of motion of cervical spine is limited in all directions but guarded and painful. Spurling's maneuver, on the right side, causes pain in the muscles of the neck radiating to upper extremity greater than left. The treatment plan included pain management counseling, chronic pain support group, Functional Restoration Program evaluation with hotel stay for pain management due to recent denials, obstructions to care and support for proposed medication weaning, and discussion of weaning medications. The provider notes a CURED report was pulled and notes "no abnormal or unexpected activity". Will repeat request for medications. Medical documentation submitted indicates these medications have been prescribed back as far as the PR-2 note included dated 2-24-15. A Request for Authorization is dated 9-22-15. A Utilization Review letter is dated 9-17-15 and modified the certification for Tramadol ER 100mg #60 with two refills to authorize one refill only; Meloxicam 15mg #90 with two refills to authorize #30 with one refill only and Flexeril 10mg #90 with two refills with no refills. The Utilization Review letter additionally non-certified Senna Plus Tab #60 with two refills (unspecified strength). A request for authorization has been received for Tramadol ER 100mg #60 with two refills; Meloxicam 15mg #90 with two refills; Senna Plus Tab #60 with two refills (unspecified strength) and Flexeril 10mg #90 with two refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol ER 100mg #60 with two refills: 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, criteria for use.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. As part of the pain treatment agreement, it is advised that "Refills are limited, and will only occur at appointments". In this case, at issue is the number of refills requested which based on the guidelines, should occur only at appointments. As such, the request is not medically necessary.

Meloxicam 15mg #90 with two refills: Upheld

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

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)/NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: The request is for the use of a medication in the NSAID class. The ODG state the following regarding this topic: Specific recommendations: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) 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 no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006) See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications. (AGS, 2009)In this case, at issue is the number of refills requested. Due to the duration of use and side effect profile of NSAIDS, prior to further refills, a re-assessment is indicated. As such, the request is not medically necessary.

Senna Plus Tab #60 with two refills (unspecified strength): Upheld

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

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 is appropriate. In this case, the use of this medication is supported by the guidelines but the number of refills is not indicated due to the need for re- evaluation prior to continued long-term use. As such, the request is not medically necessary.

Flexeril 10mg #90 with two refills: 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.