

Case Number:	CM15-0186594		
Date Assigned:	09/28/2015	Date of Injury:	04/07/2008
Decision Date:	11/25/2015	UR Denial Date:	09/18/2015
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 52 year old female, who sustained an industrial injury on 4-07-2008. The injured worker was diagnosed as having cervicgia, other pain disorder related to psychological factors, lumbago, and chronic pain syndrome. Treatment to date has included diagnostics, radiofrequency ablation right L2-3, L4-5 on 3-13-2015 (>50% relief but ongoing pain on left), and medications. Currently (9-11-2015), the injured worker complains of diffuse neck and bilateral low back pain, rated 4-8 out of 10 depending on activity level. It was documented that axial pain remained with radiation to the left upper buttock only. Failed treatments were documented as transcutaneous electrical nerve stimulation and home exercise program. Physical therapy was documented as authorized and "she will schedule". She reported that sitting for greater than 30 minutes increased pain. The ongoing pain in her neck and shoulder, with "paresthesias in hands and forearms are worse in the past month and present daily", despite night braces. It was documented that without Topamax her upper extremity paresthesias would become intolerable and all activities of daily living are increasingly impossible. It was documented that her quality of life was better on Norco (3-4 daily) and occasional Percocet was utilized for severe pain. Medication regimen was Naproxen DR 500mg twice daily, Topamax 50mg (100mg twice daily), Tizanidine 4mg twice daily as needed, Norco 10-325mg (one as needed for moderate to severe pain), Valium 5mg twice daily as needed, Neurontin 600mg three times daily. Her current medication regimen was consistent since at least 4-21-2015, at which time pain was rated 4 out of 10, and she received an injection of Toradol. She denied side effects and it was documented that she displayed no aberrant behavior. A

review of symptoms noted a frustrated mood due to persistent pain. Physical exam of the lumbar spine noted spasm and tenderness on palpation of the bilateral paravertebral muscles, positive lumbar facet loading bilaterally, and negative straight leg raise and piriformis stretch. She had a "normal" gait and did not use an assistive device. She was to follow-up in 4 weeks. Urine toxicology (3-24-2015) was positive for opiates and benzodiazepines, otherwise negative. The treatment plan included Naproxen DR 500mg (twice daily) #240, Topamax 50mg (twice daily) #240, Tizanidine 4mg (twice daily) #240, Norco 10-325mg (every 6 hours) #480, Valium 5mg (twice daily) #240, Neurontin 600mg (three times daily) #360, Percocet 10-325mg (once daily) #120, and monthly follow-up visits x3 to assess medications. On 9-18-2015 Utilization non-certified the requested Naproxen DR, Topamax, Tizanidine, Neurontin, and monthly follow up visits to assess medications. The UR modified the Norco to 10-325mg #120, Valium 5mg to #45, and Percocet 10-325mg to #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen DR 500 mg, 240 count: 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 naproxen 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) As stated above, acetaminophen would be considered first-line treatment for chronic pain. In this case, the continued use of an NSAID is supported. The patient appears to have already been approved for this medication which would last through December 2015 if taken as prescribed. As such, the request is not medically necessary.

Topamax 50 mg, 240 count: 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)/Anti-epilepsy drugs (AEDs) for pain.

Decision rationale: The request is for the medication Topamax. This drug is categorized as an anti-epileptic which is usually used for neuropathic pain. The guideline specifically states the following regarding Topamax: Topiramate (Topamax, generic available) has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of "central" etiology. It is still considered for use for neuropathic pain when other anticonvulsants fail. Topiramate has recently been investigated as an adjunct treatment for obesity, but the side effect profile limits its use in this regard. (Rosenstock, 2007) In this case, the use of this medication is indicated. This is secondary to demonstration of pain defined as neuropathic. The patient has already been approved for this medication, and if taken as prescribed should last through December of 2015. As such, the request is not medically necessary.

Tizanidine HCL 4 mg, 240 count: 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.

Norco 10/325 mg, 480 count: 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. In this case, the number of refills is at issue. For continued use of a medication in the opioid class, continued follow-up and screening measures are required. This would be necessary prior to any refills. As such, the request is not medically necessary.

Valium 5 mg, 240 count: 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): Benzodiazepines.

Decision rationale: The request is for the use of a medication in the category of benzodiazepines. It is usually indicated to treat anxiety disorders but has been used short-term as a muscle relaxant. The MTUS guidelines state the following: Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes benzodiazepines are the treatment of choice

in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) In this case, a medication in this class would not be advised for continued use due to the duration of therapy. As such, the request is not medically necessary. All benzodiazepine medications should be titrated down slowly to prevent an acute withdrawal syndrome.

Neurontin 600 mg, 360 count: 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 should also 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 documentation of adequate pain reduction for continued use. The patient already should have a supply of this medication through December of 2015 per previous authorizations. As such, the request is not medically necessary.

Percocet 10/325 mg, 120 count: 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. In this case, the number of refills is at issue. No refills are indicated prior to re-evaluation for side-effects and assessment of pain control,

aberrant behaviors, screen measures, and functional improvement seen. As such, the request is not medically necessary.

Monthly follow-up visits to assess medications, quantity of three: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Independent Medical Examinations and Consultations Chapter (ACOEM Practice Guidelines, 2nd Edition (2004), Chapter 7), page 127.

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)/Office Visits.

Decision rationale: The request is for a pain management consultation. The MTUS guidelines do not address this issue specifically. The ODG state the following regarding this topic. Recommended as determined to be medically necessary. Evaluation and management (E&M) outpatient visits to the offices of medical doctor(s) play a critical role in the proper diagnosis and return to function of an injured worker, and they should be encouraged. The need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The determination is also based on what medications the patient is taking, since some medicines such as opiates, or medicines such as certain antibiotics, require close monitoring. As patient conditions are extremely varied, a set number of office visits per condition cannot be reasonably established. The determination of necessity for an office visit requires individualized case review and assessment, being ever mindful that the best patient outcomes are achieved with eventual patient independence from the health care system through self care as soon as clinically feasible. The ODG Codes for Automated Approval (CAA), designed to automate claims management decision-making, indicates the number of E&M office visits (codes 99201-99285) reflecting the typical number of E&M encounters for a diagnosis, but this is not intended to limit or cap the number of E&M encounters that are medically necessary for a particular patient. Office visits that exceed the number of office visits listed in the CAA may serve as a flag to payers for possible evaluation, however, payers should not automatically deny payment for these if preauthorization has not been obtained. Note: The high quality medical studies required for treatment guidelines such as ODG provides guidance about specific treatments and diagnostic procedures, but not about the recommended number of E&M office visits. Studies have and are being conducted as to the value of virtual visits compared with inpatient visits, however the value of patient/doctor interventions has not been questioned. (Dixon, 2008) (Wallace, 2004) Further, ODG does provide guidance for therapeutic office visits not included among the E&M codes, for example Chiropractic manipulation and Physical/Occupational therapy. See also Telehealth. In this case, the request is reasonable and supported by the documentation. The patient has chronic pain which justifies evaluation by a pain management specialist. Based on prior authorizations, the patient has approval for follow-up through December of 2015. As such, the request is medically necessary.