

Case Number:	CM14-0033353		
Date Assigned:	07/21/2014	Date of Injury:	08/07/2012
Decision Date:	09/08/2014	UR Denial Date:	03/05/2014
Priority:	Standard	Application Received:	03/17/2014

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 C 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 injured worker is a 66 year old male who reported an injury on 08/07/2012 due to unknown circumstances. The injured worker's diagnoses were status post L2-5 fusion and degenerative joint disease of the left knee. The injured worker's past surgeries included L2-5 posterior lumbar interbody fusion dated 09/06/2013. The injured worker complained of having some residual pain in the lumbar spine as it related to the lumbar fusion. The injured worker also complained of left knee pain. On the physical examination dated 02/13/2014 of the lumbar spine, it revealed pain over the top of what appeared to be palpable implants. There was no radiculopathy and there were no significant neurological deficits in the lower extremity. Upon examination of the left knee, there was tenderness and pain to palpation in the anterior joint linespace, most pronounced in the medial joint compartment, with a positive patellar grind test and positive McMurray's. The injured worker's medications were Tramadol Hydrochloride ER 150 mg, Naproxen sodium tablets 550 mg, Omeprazole Delayed release 20 mg, Ondansetron ODT tablets 8 mg, Terocin patch and Cyclobenzaprine Hydrochloride tablet 7.5 mg. The provider's treatment plan was for the injured worker to continue a comprehensive home exercise program as part of the transition from physical therapy. The rationale for the request was for inflammation, pain and gastrointestinal symptoms. The Request for Authorization form dated 02/27/14 was provided with the documentation submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol Hydrochloride ER 150 mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines On-Going Management Page(s): 78.

Decision rationale: The request for Tramadol Hydrochloride ER 150 mg #90 is not medically necessary. According to the California Medical Treatment Utilization Schedule (MTUS) Guidelines, it states that criteria for the use of ongoing management of opioids include ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. The guidelines state that the 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. The guidelines also state that 4 domains have proposed as the most relevant for the ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. The documentation submitted for review indicated on the most current clinical that the injured worker reported significant improvement in his overall symptomatology with no further radicular pain in the lower extremities. There was no documentation of adverse side effects with use of the opioid. He was also not noted to have had issues with aberrant drug taking behavior; however, there was no documentation submitted from a recent urine drug screen showing consistent results to verify appropriate medication use. There was a lack of documentation of a VAS pain score, average pain, intensity of pain, or longevity of pain. In addition, the proposed request lacked mention of a frequency for the proposed medication. In the absence of consistent results on a urine drug screen to verify compliance, the criteria for ongoing use of opioid medications have not been met. The request is not medically necessary.

Naproxen Sodium tablets 550 mg #100: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67.

Decision rationale: The request for Naproxen tablets 550 mg #100 is not medically necessary. The California MTUS Guidelines state that NSAIDs are recommended as an option for short-term symptomatic relief in low back pain. There is no literature on drug relief for low back pain suggesting that NSAIDs are more effective than any other drugs, such as acetaminophen, narcotic analgesics, and muscle relaxants. A review found that NSAIDs had more adverse effects than placebo and acetaminophen, but fewer effects than muscle relaxants and narcotic analgesics. The injured worker has undergone a multilevel lumbar reconstruction and reported that he had significant improvement in his overall symptomatology with no further radicular pain to the lower extremities, but minor residual pain related to the lumbar implants. There was no documentation on a clinical assessment regarding current pain on a VAS. There was no

quantified information regarding pain relief. In addition, the proposed request lacked the frequency for the proposed medication. In the absence of documentation of a comprehensive pain assessment, and a quantified VAS score, the request is not medically necessary.

Omeprazole Delayed-release 20 mg #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, GI symptoms & cardiovascular risk Page(s): 67.

Decision rationale: The request for Omeprazole delayed release 20 mg #120 is not medically necessary. According to the California MTUS Chronic Pain Guidelines, it is stated that proton pump inhibitors may be recommended to treat dyspepsia secondary to NSAID therapy. The addition of a proton pump inhibitor is also supported for patients taking NSAID medications who have cardiovascular disease or significant risk factors of a gastrointestinal event. The injured worker was noted to be taking naproxen sodium 550 mg; however, there was no documentation indicating that the injured worker had a complaint of dyspepsia with the use of medication, cardiovascular disease, or a significant risk for gastrointestinal events. In the absence of this documentation, the request is not supported by the evidence-based guidelines. Additionally, the request failed to include the frequency of the medication. As such, the request for omeprazole 20 mg #120 is not medically necessary.

Ondansetron ODT tablets 8 mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Antiemetic's (For opioid nausea).

Decision rationale: The request for Ondansetron ODT tablets 8 mg #60 is not medically necessary. According to the Official Disability Guidelines, antiemetics are not recommended for nausea and vomiting secondary to chronic opioid use. It is recommended for acute use as per FDA-approved indications. Nausea and vomiting is common with the use of opioids. These side effects tend to diminish over days to weeks for continued exposure. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated. Current research for the treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer or those utilizing opioids for acute postoperative therapy. The injured worker was noted to be taking Ultram hydrochloride ER 150 mg and naproxen sodium tablets 550 mg. However, there was no documentation indicating that the injured worker had complaints of nausea or vomiting. In the absence of documentation, the request is not supported by the evidence-based guidelines. Additionally, the request failed to include the frequency of the

medication. As such, the request for ondansetron ODT tablets 8 mg #60 is not medically necessary.

Terocin Patch #30: 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 Analgesic Page(s): 111-112.

Decision rationale: The request for Terocin patch #30 is not medically necessary. According to the California MTUS Chronic Pain Guidelines, topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The injured worker underwent a multilevel lumbar reconstruction and reported significant improvement overall in symptomatology and had no further radicular pain into the lower extremities. The Terocin patch contains Lidocaine and menthol. Lidocaine is an indication for neuropathic pain and is recommended for localized peripheral pain after there has been evidence of a trial of first line therapy of a tricyclic or antidepressant or an antiepilepsy drug such as gabapentin or Lyrica. Topical Lidocaine in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulation, whether creams, lotions, or gels, are indicated for neuropathic pain. Nondermal patch formulations are generally indicated as local anesthetic and antipruritics. There was a lack of documentation and evidence of a first line trial therapy with an antidepressant or an antiepilepsy drug. In the absence of this documentation and given the above, the request is not supported by the evidence-based guidelines. Additionally, the request failed to include the frequency and body location for the proposed medication. As such, Terocin patch #30 is not medically necessary.

Levofloxacin 750 mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult last updated 11/25/11.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low back, antibiotics.

Decision rationale: The request for Levofloxacin 750 mg #30 is not medically necessary. According to the Official Disability Guidelines (ODG), researchers have found bacteria in herniated disc of about 40% of chronic low back pain could be caused by this bacteria and significant percentage of people with low back pain following a herniated disc and swelling in the microorganism. The injured worker reported that he had significant improvement in his overall symptomatology and had no radicular pain component in the lower extremities, with some residual pain lumbar that is associated with the fusion implants. There was a lack of

documentation within the medical records indicating that the injured worker was having any symptoms of infection due to the lumbar fusion. In the absence of this documentation, the request is not supported by the guidelines. In addition, the request failed to include the frequency of the medication. As such, the request for levofloxacin 750 mg #30 is not medically necessary.

Cyclobenzaprine Hydrochloride tablets 7.5 mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines low back muscle relaxants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-64.

Decision rationale: The request for Cyclobenzaprine Hydrochloride tablets 7.5 mg #120 is not medically necessary. According to the California MTUS Guidelines, muscle relaxants are recommended non-sedating with caution as a second line option for the short-term of exacerbation in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility. However, in most low back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Cyclobenzaprine is recommended for a short course of therapy with mixed evidence does not allow for a recommendation for chronic use. The injured worker reported significant improvement in his overall symptomatology. However, the length of time the injured worker has been utilizing this medication was not provided. In addition, the request failed to include the frequency of the medication. As such, the request Cyclobenzaprine Hydrochloride tablets 7.5 mg #120 is not medically necessary.