

Case Number:	CM14-0184575		
Date Assigned:	11/12/2014	Date of Injury:	04/21/2008
Decision Date:	12/18/2014	UR Denial Date:	10/28/2014
Priority:	Standard	Application Received:	11/05/2014

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 Internal Medicine and is licensed to practice in California. 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:

This is a case of a 55 year old female with a date of injury of 4/29/2008 and 2/8/2012. She was lifting a 12 lb box at work on 4/29/2008 and injured her back. In a primary treating physicians progress note dated 10/21/2014 by [REDACTED], the patient was being evaluated for her chronic lumbosacral pain. She had an epidural steroid injection (ESI) with [REDACTED] a few weeks prior and felt no pain at all for 5 days. She did not have to take any medications. She notes that the pain is recurring and she has resumed her medications but not at the past levels. She is on less than 2 Norco per day and not taking diclofenac or lyrica daily. On physical examination, she is in no acute distress. Her gait is normal. On lumbar spine range of motion, she has restricted flexion to 60 degrees, extension to 15 degrees, right lateral bending 10 degrees, and left lateral bending to 10 degrees. There is mild tenderness to palpation of the paravertebral muscles bilaterally and no spinous process tenderness noted. Heel to toe walk was normal. Lumbar facet loading is positive on the right side. Straight leg raise is positive on the right side. Strength of the extensor hallucis longus is 4/5 on the right and 5/5 on the left. Hyperesthesia is noted over the lateral calf, posterior thigh, medial thigh, lateral thigh, and the right side of the groin. Patellar reflexes are 2/3 bilaterally. Hamstring reflexes are 2/3 bilaterally. Achilles reflex is 0/3 on the right and 2/3 on the left. The patient was diagnosed with lumbar or lumbosacral disc degeneration, unspecified myalgia and myositis, and lumbar radiculitis. The treatment plan indicated that she had marked improvement after 2 ESIs and is using medications less. She has better mood and more function. She is a candidate for additional ESI. The goals are for her to be able to be on minimal medications and be able to work with better tolerances. All her medications including Norco 10/325, Lyrica 75, Diclofenac Sodium 100mg and Cymbalta 60 mg will be continued. She has tapered her medications and is recommended to keep the quantity the

same and consider further taper at her next visit. The patient has been on these 4 medications since at least April of 2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-82.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 72-80.

Decision rationale: Based on MTUS guidelines, short-acting opioids are seen as an effective method in controlling pain. They are often used for intermittent or breakthrough pain. These agents are often combined with other analgesics such as acetaminophen and aspirin. These adjunct agents may limit the upper range of dosing of short-acting agents due to their adverse effects. The duration of action is generally 3-4 hours. When considering opioids for on-going management of chronic pain, adequate review and documentation of pain relief, functional status, appropriate medication use, and side effects should be documented. 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 the pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Consideration of a consultation with a multidisciplinary pain clinic is recommended if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Some of the reasons for discontinuation of opioids include if there is no overall improvement in function, unless there are extenuating circumstances, if there is continuing pain with evidence of intolerable adverse effects, if there is decrease of functioning, or resolution of pain. Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. Using opioids for chronic back pain appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. In this case, the patient has been on Norco for at least 8 months which far exceeds the recommended trial period for opioids and therefore based on MTUS guidelines and the evidence in this case, the request for Norco 10/325 mg #120 is not medically necessary.

Lyrica 75mg #540: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy Drug Page(s): 17.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-20.

Decision rationale: Based on MTUS guidelines, ant epilepsy drugs (AEDs) such as Lyrica are recommended for neuropathic pain. There is lack of consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at post herpetic neuralgia and painful polyneuropathy. There are few RCTs directed at central pain and none for painful radiculopathy. A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); (2) combination therapy if treatment with a single drug agent fails. After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. Lyrica specifically has been documented to be effective in treatment of diabetic neuropathy and post herpetic neuralgia and has FDA approval for both indications. This medication also has an anti-anxiety effect and is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder. In June 2007 the FDA announced approval of Lyrica as the first approved treatment for fibromyalgia. In this case, the patient has not been diagnosed with anxiety, diabetic neuropathy, post herpetic neuralgia or fibromyalgia. It appears to be prescribed for a non-FDA approved indication. Therefore, based on the MTUS guidelines and the evidence in this case, the request for Lyrica 75mg #540 is not medically necessary.

Diclofenac Sodium ER 100mg #180: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67-68.

Decision rationale: Nonsteroidal Antiinflammatory medication (NSAIDs) such as Diclofenac are recommended as second-line treatment after acetaminophen for acute low back pain and acute exacerbations of chronic pain. In general there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute low back pain. NSAIDs are recommended as an option for short-term symptomatic relief. They were found to be no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The Cochrane review of the literature also found that NSAIDs had more side effects than placebo, and acetaminophen but fewer effects than muscle relaxant and narcotic analgesics. For chronic low back pain, NSAIDs are recommended as an option for short-term symptomatic relief. As stated earlier, the patient has been on Diclofenac for at least 8 months which appears to be longer than what is recommended in the MTUS guidelines. Therefore, based on the evidence in this case and the MTUS guidelines, the request for Diclofenac Sodium ER 100 mg #180 is not medically necessary.

Cymbalta 60mg #270: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 13-16.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 43-44.

Decision rationale: Based on MTUS guidelines, Cymbalta (Duloxetine) is recommended as an option in first-line treatment option in neuropathic pain. It has FDA approval for treatment of depression, generalized anxiety disorder, and for treatment of pain related to diabetic neuropathy, with effect found to be significant by the end of week 1. It has also been found to be effective for treating fibromyalgia in women with and without depression. The FDA notes that although Cymbalta was effective for reducing pain in patients with and without major depressive disorder, the degree of pain relief may have been greater in those with co-morbid depression. In this case, the patient has not been diagnosed with neuropathic pain related to diabetic neuropathy, depression, generalized anxiety disorder or fibromyalgia. Therefore, its current use in this case is for a non FDA approved diagnosis. Therefore based on the evidence in this case and the review of the MTUS guidelines, the request for Cymbalta 60mg # 270 is not medically necessary.