MAXIMUS Federal Services

Case Number:	CM15-0148794		
Date Assigned:	08/12/2015	Date of Injury:	08/25/2001
Decision Date:	09/15/2015	UR Denial Date:	07/02/2015
Priority:	Standard	Application Received:	07/31/2015

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: Arizona, Michigan
Certification(s)/Specialty: Preventive Medicine, Occupational 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 64-year-old female, with a reported date of injury of 08-25-2001. The mechanism of injury was not indicated in the medical records provided for review. The injured worker's symptoms at the time of the injury were not indicated. The diagnoses include right elbow pain, status post right elbow arthroscopic surgery, chronic right wrist and hand pain, right carpal tunnel syndrome, status post right carpal tunnel release, demyelinating sensory polyneuropathy of the right hand, myofascial pain syndrome, and depression. Treatments and evaluation to date have included a TENS (transcutaneous electrical nerve stimulation) unit with benefit, oral medications, and topical pain medications. According to the medical report dated 06-24-2015, the diagnostic studies to date have included electrodiagnostic studies of the right upper extremity on 07-21-2009 which showed carpal tunnel syndrome. The medical report dated 06-24-2015 indicates that the injured worker continued to experience constant aching, right upper extremity pain, which radiated into the neck and posterior shoulder region. She had pain in the right wrist, thumb, and palm. The injured worker described the radiating pain as burning and sharp. It was noted that the injured worker had not been taking Lyrica for the past 5-6 months, since she had not been able to pick it up from her pharmacy. The injured worker complained of increased pain and decreased function. She rated her pain 7 out of 10. The objective findings includes an anxious mood; moderate discomfort; guarding of the right upper extremity; a normal gait; severe tenderness over the bilateral upper trapezius muscles, right greater than left; limited range of motion in the right elbow; a well-healed scar on the lateral epicondyle of the right elbow; a well-healed linear volar scar on the right wrist; pain on palpation

of the right wrist; no atrophy or swelling of the extremities; and intact skin integrity. The injured worker was noted as permanent and stationary. The treatment plan included the refill of prescriptions for Cymbalta with two refills, Lyrica with two refills, Lidoderm patches with two refills, Zantac with two refills, and the purchase of the TENS unit. The treating physician requested Cymbalta, Lyrica, Lidoderm patches, Zantac, compound cream, and purchase of a TENS unit.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cymbalta 30mg quantity 60 with two refills: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants (for chronic pain).

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

Decision rationale: The CA MTUS Chronic Pain Guidelines indicate that duloxetine (Cymbalta) is recommended as an option in first-line treatment for neuropathic pain. Cymbalta is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRI). The injured worker has been taking Cymbalta since at least 02-27-2014. The guidelines indicate that it has FDA approval for the treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy. The treating physician documented that Cymbalta was beneficial in reducing neuropathic pain and improving the injured worker's mood. The injured worker had been diagnosed with depression. The most frequent side effects include nausea, dizziness, and fatigue. There was documentation that the injured worker had been previously given the generic version of Cymbalta and developed nausea and stomach upset when taking the medication. The guidelines also indicate that the long-term effectiveness of anti-depressants has not been established. The treating physician documented that Cymbalta was beneficial in reducing neuropathic pain and improving the injured worker's mood. Therefore, the request for Cymbalta is medically necessary.

Lyrica 50mg quantity 60 with two refills: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti Epilepsy Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) and Pregabalin (Lyrica) Page(s): 16-20 and 99.

Decision rationale: The CA MTUS Chronic Pain Guidelines indicate that Pregabalin (Lyrica) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia. There is no evidence that the injured worker had been diagnosed with diabetic neuropathy or fibromyalgia. There was evidence that she had

neuropathic pain in the right upper extremity. A "good" response to the use of antiepileptic drugs (AEDs) is defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. Lack of at least a 30% response per the MTUS would warrant a switch to a different first line agent or combination therapy. After initiation of treatment, there should be documentation of pain relief with improvement in function, and documentation of any side effects, with continued use of AEDs dependent on improved outcomes versus tolerability of adverse effects. In this case, there was no documentation of a good response to Lyrica. The treating physician documented that the Lyrica reduced her neuropathic pain by 50%. She tried to increase the Lyrica dose to 75mg in the past but was unable to tolerate it as it caused gastrointestinal (GI) upset. The injured worker has been taking Lyrica since at least 02-27-2014. There was documentation that the Cymbalta, Lyrica, and Lidoderm patches were effective in reducing the injured worker's pain to a tolerable level where she could participate in her normal daily activities including cooking by herself, cleaning, gardening, and driving. For these reason, the request for Lyrica with two refills is medically necessary.

Lidoderm patches quantity 60 with two refills: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch) and Topical Analgesics Page(s): 56-57 and 111-113.

Decision rationale: The CA MTUS Chronic Pain Guidelines indicate that topical analgesics are "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The injured worker had been taking Cymbalta (an antidepressant), but there was no indication that the medication had failed. The guidelines also indicate that topical analgesics are "largely experimental in use with few randomized controlled trials to determine effectiveness or safety." The MTUS recommends Lidoderm only for localized peripheral neuropathic pain after trials of tricyclic or SNRI (serotonin- norepinephrine reuptake inhibitor) anti-depressants or an anti-epileptic drug such as Gabapentin or Lyrica. The injured worker has been prescribed and continued to take Lyrica, with benefit. The guidelines state that topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain. There was evidence that she had neuropathic pain in the right upper extremity. The treating physician prescribed 1-2 patches to the skin 12 hours on and 12 hours off as needed for pain. The injured worker is documented to have improved pain and functioning with the use of Lidoderm patches, therefore based on her clinical response, the request for Lidoderm patches quantity 60 with two refills is medically necessary.

Zantac 150mg quantity 60 with two refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MS Consult Drug Monograph.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Proton Pump Inhibitors (PPIs.

Decision rationale: Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria 1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Per the ODG, PPI's are "Recommended for patients at risk for gastrointestinal events. Prilosec (omeprazole), Prevacid (lansoprazole) and Nexium (esomeprazole magnesium) are PPIs. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. (Donnellan, 2010) In this RCT omeprazole provided a statistically significantly greater acid control than lansoprazole. (Miner, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. The guidelines recommend a PPI over H2 blockers for NSAID induced gastritis and a review of the injured workers medical records did not yield documentation that would suggest that the injured worker is at increased risk for a gastrointestinal event, therefore the request for Zantac is not medically necessary.

Compound Cream 240gm with two refills: 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 Analgesics Page(s): 111-113.

Decision rationale: The CA MTUS Chronic Pain Guidelines indicate that topical analgesics are "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The injured worker had been taking Cymbalta (an antidepressant), but there was no indication that the medication had failed. The guidelines also indicate that topical analgesics are "largely experimental in use with few randomized controlled trials to determine effectiveness or safety." The treating physician's request did not include the name, concentration, quantity, site

of application, or directions for use. As such, the prescription is not sufficient and not medically necessary.

Purchase of a TENS unit: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy Page(s): 114-116.

Decision rationale: The CA MTUS Chronic Pain Guidelines do not recommend TENS (transcutaneous electrical nerve stimulation) units as a primary treatment. The treating physician prescribed trial of the TENS unit on 08-07-2014 for three months. On 01-12-2014 there was documentation that the injured worker obtained authorization for the TENS unit trial for one month; however, she had not yet received the unit. The MTUS states that a one-month home-based TENS trial may be considered as a non-invasive conservative option, if used in addition to a program of evidence-based functional restoration. The medical report dated 06-24-2015 indicates that the injured worker used the TENS unit at least once weekly, and it helped reduce her pain from a rating of 7 out of 10 to 5 out of 10. There was no evidence of when the injured worker actually first started use of the unit. On 06-24-2015, the treating physician requested the purchase of a TENS unit. The purchase of the unit was requested for additional non-pharmacologic pain relief. The guidelines indicate that there has been a recent meta-analysis that came to a conclusion that there was a significant decrease in pain when electrical nerve stimulation of most types was applied to any anatomic location of chronic musculoskeletal pain (back, knee, hip, neck) for any length of treatment. There is no evidence that the injured worker had a trial of the TENS unit for one month as recommended by the guidelines. Therefore, the request for the purchase of a TENS unit is not medical necessary.