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| Case Number: | CM15-0047812 | | |
| Date Assigned: | 03/19/2015 | Date of Injury: | 04/01/2011 |
| Decision Date: | 05/01/2015 | UR Denial Date: | 02/18/2015 |
| Priority: | Standard | Application Received: | 03/13/2015 |

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: Pennsylvania

Certification(s)/Specialty: Internal 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 38 year old female who sustained an industrial injury on 4/1/11. The injured worker reported symptoms in the back and upper extremities. Diagnoses include status post C5-6 anterior cervical discectomy and fusion with residual bilateral upper extremity radiculopathy, C6-7 right central posterior lateral disc protrusion, cubital tunnel syndrome, and thoracic outlet syndrome with rib resections. She was also noted to have medication induced gastritis and chronic myeloid leukemia. Treatments to date have included epidural injections, trigger point injections, physical therapy, status post cervical disc fusion, status post left ulnar nerve resection, medication and duragesic patches. Currently, the injured worker complains of cervical spine pain with radiation to the upper extremities as well as headaches. Progress notes indicate that valium, anaprox, Zofran, and lyrica were prescribed since at least November 2014. At an office visit on 2/6/15, the physician noted that the injured worker was being weaned off opiate pain medication and was having nausea with relief only with Zofran, with no benefit from Compazine, reglan, and Phenergan. Lyrica was noted to be for neuropathic pain, and valium for anxiety. Examination showed muscle rigidity and tenderness of the posterior cervical musculature with decreased range of motion and weakness with extension of the right hand, with decreased strength of the elbow extensors and wrist extensors on the right and decreased sensation in the right lateral arm and forearm. The physician documented that the injured worker had signs of radiculopathy in C6 or C7 distribution, and element of peripheral neuropathy at the ulnar nerve and possible carpal tunnel syndrome. Medications included anaprox, Prilosec, Zofran, duragesic, valium, clonidine, and lyrica. On 2/18/15, Utilization Review (UR) non-

certified requests for Zofran 8 mg #10, clonidine 0.1 mg #30, lyrica 50 mg #90, anaprox 550 mg #60, and Prilosec 20 mg #60, and modified a request for valium 10 mg #30. UR cited the MTUS and ODG.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zofran ODT 8mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chronic.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter: antiemetics.

Decision rationale: The MTUS does not provide direction for the use of antiemetics. The Official Disability Guidelines recommends against their use for nausea presumed to be caused by chronic opioid intake. Ondansetron (Zofran) is FDA approved for nausea caused by chemotherapy and radiation treatment, postoperative use, and acute gastroenteritis. This injured worker does not have an FDA-approved indication, and the treating physician has documented that Zofran was prescribed for nausea during weaning from opioid medication. The treating physician has not provided an adequate evaluation of any condition causing nausea. The necessary indications are not present per the available guidelines and evidence and the request for Ondansetron is not medically necessary.

Clonidine 0.1mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Clonidine, Intrathecal Page(s): 34. Decision based on Non-MTUS Citation Medically supervised opioid withdrawal during treatment for addiction. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: Clonidine was noted to be prescribed in February 2015. There is no discussion of the indications for this medication or the results of use. The MTUS notes that clonidine is a direct acting adrenergic agonist prescribed historically as an antihypertensive agent, but has been used for treatment of some types of neuropathic pain. The MTUS addresses use of clonidine intrathecal rather than orally, for patients refractory to opioid monotherapy or opioids with local anesthetic. There is no documentation of diagnosis of hypertension. The progress notes discuss weaning from opioids. It is possible that the intent for clonidine was for management of potential withdrawal symptoms related to weaning/discontinuation of opioids. Clonidine may decrease withdrawal symptoms in patients taking low doses of opioids. It is not

approved by the FDA for treatment of opioid withdrawal, although it is commonly used for this purpose. Side effects may include hypotension and subsequent hypertensive rebound. Due to lack of documentation of specific indication, the request for clonidine is not medically necessary.

Valium 10mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Pain, Chronic.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines, Muscle Relaxants Page(s): 24, 66.

Decision rationale: Per the MTUS, benzodiazepines are 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. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long term use may actually increase anxiety. The MTUS states that a more appropriate treatment for anxiety disorder is an antidepressant. The MTUS does not recommend benzodiazepines for long term use for any condition. This injured worker has been prescribed valium for at least three months for the treatment of anxiety. Due to duration of use in excess of the guidelines, the request for Valium is not medically necessary.

Lyrica 50mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anticonvulsants Page(s): 16-22.

Decision rationale: Per the MTUS, anti-epilepsy drugs (AEDs) are recommended for neuropathic pain due to nerve damage. The MTUS notes the lack of evidence for treatment of radiculopathy. This injured worker was noted to have both radiculopathy and peripheral neuropathy. Lyrica (pregabalin) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, and is FDA approved for these indications as well as for fibromyalgia. Side effects include edema, central nervous system depression, weight gain, blurred vision, somnolence, and dizziness. It has been suggested that this medication be avoided in patients who have problems with weight gain. A good response to the use of 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. This injured worker has been prescribed Lyrica for at least three months, without discussion of response to treatment. Antiepileptic drugs (AEDs) are associated with teratogenicity and should be used with caution in women of childbearing age. There is no evidence that the treating physician has discussed this

with this reproductive age female; there was no evidence for informed consent to use a reproductive hazard. Due to lack of documentation of treatment response or functional improvement, and potential for teratogenicity, the request for Lyrica is not medically necessary.

Anaprox DS 550mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67-73.

Decision rationale: Per the MTUS, nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. The MTUS does not specifically reference the use of NSAIDs for long term treatment of chronic pain in other specific body parts. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. NSAIDs can increase blood pressure and may cause fluid retention, edema, and congestive heart failure; all NSAIDS are relatively contraindicated in patients with renal insufficiency, congestive heart failure, or volume excess. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. NSAIDs should be used for the short term only. This injured worker has been prescribed Anaprox for at least three months. There was no documentation of functional improvement as a result of its use. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. Although some blood pressure readings were recorded, no monitoring of laboratory tests was discussed. The documentation notes a history of medication-induced gastritis; this was not further discussed and evaluation was not documented. Due to length of use in excess of the guidelines, lack of functional improvement and potential for toxicity, the request for Anaprox is not medically necessary.

Prilosec 20mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Proton Pump Inhibitors (PPIs); NSAIDs, GI Symptoms & cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-69.

Decision rationale: This injured worker has been prescribed Anaprox, and NSAID, and Prilosec, a PPI. Per the MTUS, co-therapy with a nonsteroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDS such as NSAID plus low dose aspirin).

None of these risk factors were documented. The documentation notes a history of medication-induced gastritis, however there was no documentation of any gastrointestinal signs or symptoms. There is no recent examination of the abdomen on record. There was no discussion of discontinuation of any medication secondary to gastritis or evaluation of this condition. Empiric treatment without evaluation is not indicated. Due to lack of indication, the request for Prilosec is not medically necessary.