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| Case Number: | CM15-0193412 | | |
| Date Assigned: | 10/07/2015 | Date of Injury: | 05/12/2003 |
| Decision Date: | 12/17/2015 | UR Denial Date: | 09/22/2015 |
| Priority: | Standard | Application Received: | 10/01/2015 |

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: Tennessee, Florida, Ohio
 Certification(s)/Specialty: Surgery, Surgical Critical Care

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 56 year old female, who sustained an industrial injury on 05-12-2003. A review of the medical records indicates that the injured worker (IW) is undergoing treatment for lumbar radiculopathy, vitamin D deficiency, chronic pain, liver cirrhosis, history of hepatitis B, insomnia, and chronic nausea and vomiting. Medical records (04-08-2015 to 09-01-2015) indicate ongoing neck pain with radiating pain down both upper extremities, low back pain with radiating pain down both lower extremities with tingling down to the feet, bilateral wrist pain, and bilateral knee and ankle pain. Average pain levels were 6 out of 10 on a visual analog scale (VAS) with medications and 10 out of 10 without medications. Additionally the IW reported gastrointestinal upset with continuous moderate nausea due to medications. Records also indicate no changes in activity levels or level of functioning. Per the treating physician's progress report (PR), the IW has not returned to work. The physical exam, dated 09-01-2015, revealed tenderness to palpation and spasms in the lumbar paravertebral area at L4-S1, moderately limited range of motion (ROM) in the lumbar spine, increased pain with flexion and extension, and plantar fascia tenderness. Relevant treatments have included; transforaminal epidural steroid injections at L4-S1 (10-2014) with 50-80% overall improvement for 3 months, physical therapy (PT), work restrictions, and pain medications (Restoril, Vitamin D, and Zofran since at least 01- 2015). The treating physician indicates that MRI of the lumbar spine (04-2007) showed disc desiccation and a 3mm posterior disc bulge at L4-5, and mild disc desiccation and mild hypertrophic facet arthropathy at L5-S1. The PR and request for authorization (09-01-2015) shows that the following procedure and medications were requested: outpatient bilateral L4-L5 and S1 transforaminal epidural steroid injection under fluoroscopy, Restoril, Vitamin D

2000 units #60 with 1 refill, and Zofran 4mg #30 with 1 refill. The original utilization review (09-22- 2015) non-certified the request for outpatient bilateral L4-L5 and S1 transforaminal epidural steroid injection under fluoroscopy, Restoril, Vitamin D 2000 units #60 with 1 refill, and Zofran 4mg #30 with 1 refill.

IMR ISSUES, DECISIONS AND RATIONALES

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

Outpatient: Bilateral L4-L5 And S1 Transforaminal Epidural Steroid Injection Under Fluoroscopy: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this. Results of an EMG supporting the patient's neurologic complaints are not documented. Hence, the procedure is not indicated by MTUS guidelines. Therefore, based on the submitted medical documentation, the request for an epidural steroid injection is not medically necessary. Criteria for Epidural Injections: 1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. 2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). 3) Injections should be performed using fluoroscopy (live x-ray) for guidance. 4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections. 5) No more than two nerve root levels should be injected using transforaminal blocks. 6) No more than one interlaminar level should be injected at one session. 7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (Manchikanti, 2003) (CMS, 2004) (Boswell, 2007) 8) Current research does not support a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections.

Restoril 15mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address the topic of this medication. Per the Official Disability Guidelines (ODG), "temazepam is not recommended for long-term use." Likewise, The California MTUS guidelines state that 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." The guidelines go on to state that, "chronic 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." The clinical records submitted do support the fact that this patient has a history of insomnia. However, the records do not support the long term use of this medication for that indication. Therefore, based on the submitted medical documentation, the request for restoril is not medically necessary.

Vitamin D 2000 Unit #60 With Refill of 1: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Medical Food, Vitamin D supplementation.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. According to the Official Disability Guidelines (ODG), Vitamin D is recommended for consideration in chronic pain patients if supplementation is necessary. Musculoskeletal pain is associated with lower Vitamin D levels but the relationship may be explained by physical inactivity and/or other compounding factors. Inadequate Vitamin D may represent an unrecognized source of decreased neuromuscular functioning among patients with chronic pain. Per ODG, physicians who care for patients with chronic, diffuse pain that seems musculoskeletal and involves many areas of tenderness to palpation should consider checking Vitamin D level. Although the patient's medical records support that she has a history of vitamin D deficiency, the clinical information provided for review lack documentation of recent lab work related to the injured worker's Vitamin D level. Testing is recommended during supplementation to ensure overuse does not occur. Therefore, based on the submitted medical documentation, the request for Vitamin D 2000 IU is not medically necessary.

Zofran 4mg #30 With Refill of 1: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Reference: Zofran FDA Prescribing Guidelines <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm271924.htm>.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address this topic. According to its FDA prescribing recommendations, "Ondansetron is used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery." It is in a class of medications called 5-HT₃ receptor antagonists and works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting. This patient has chronic pain. She had not undergone surgery or been diagnosed with the need for chemotherapy/radiation. Thus, the requested medication is being prescribed against FDA indications. Therefore, based on the submitted medical documentation, the request for Ondansetron is not medically necessary.