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| Case Number: | CM14-0142677 | | |
| Date Assigned: | 09/10/2014 | Date of Injury: | 06/15/2012 |
| Decision Date: | 11/03/2014 | UR Denial Date: | 08/07/2014 |
| Priority: | Standard | Application Received: | 09/03/2014 |

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, has a subspecialty in Pain 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:

The injured worker is a 58 year old male who sustained an industrial injury on 6/15/2012. The records indicate musculoskeletal complaints, and continued cervical and lumbar symptomatology, shoulder, and headaches. On 2/7/2014, the injured worker underwent right shoulder arthroscopy. The prior peer review dated 8/7/2014 non-certified the requests for diclofenac ER (voltaren SR) 100mg #120, omeprazole 20mg #120, and ondansetron ODT 8mg #30, as the medical necessity was not established. The requests for cyclobenzaprine 7.5mg #120 was modified to allow #20 for weaning purposes, and Tramadol ER 150mg #90 modified to allow #60 to allow opportunity for submission of medication compliance guidelines, otherwise for downward titration and complete discontinuation of the medication on subsequent review. According to the PTP PR-2 dated 7/10/2014, the injured worker complains of constant pain in the low back aggravated by movement, radiation of pain into the lower extremities. Pain is improving. Pain is rated 6/10. He complains of frequent pain in the bilateral wrists/hand aggravated by activity. Pain is unchanged, rated 7/10. On physical examination gait is intact, there is lumbar spine paravertebral tenderness with spasm, positive seated nerve root test, guarded/restricted flexion and extension, tingling and numbness in L4 and L5 dermatomal pattern, full strength, and asymmetric knee reflexes. At the wrist/hand, there is tenderness at volar wrist, positive palmar compression and Tinel's sign, full but painful ROM, diminished sensation in radial digits. Diagnoses are carpal tunnel syndrome and lumbago. Work status is retired. Medications are refilled.

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac Sodium ER (Voltaren SR) 100mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-Steroid Anti-Inflammatory Drugs (NSAIDs).

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

Decision rationale: According to the guidelines, dosages over 150 mg/day PO are not recommended. In this case, daily dosage is 400 mg/day, which is not recommended. In addition, there is no documented improvement or benefit with medication use. Notable improvement in pain level and function with this medication is not apparent. Furthermore, the medical records do not establish standard NSAIDs such as acetaminophen or ibuprofen is not effective. The medical necessity of Voltaren has not been established. The request for Diclofenac Sodium ER (Voltaren SR) 100mg #120 is not medically necessary.

Omeprazole 20mg # 120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-Steroid Anti-Inflammatory Drugs (NSAIDs), GI Symptoms & Cardio.

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

Decision rationale: The guidelines state "PPIs such as Omeprazole may be indicated for patients at risk for gastrointestinal events, which are: 1) age over 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)." However, none of these criteria apply to this patient. The medical records do not establish any of these potential significant risk factors apply to this injured worker. The ODG states 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. The medical records do not document supportive correlating subjective/objective findings documented in a medical report that would establish omeprazole is medically indicated. The medical necessity of omeprazole 20mg #120 has not been established. The request for Omeprazole 20mg # 120 is not medically necessary.

Ondansetron ODT tablets 8mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC Pain Procedure summary last updated 06/10/2014, Ondansetron (Zofran)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-73.. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Antiemetic (for opioid nausea)

Decision rationale: According to the Official Disability Guidelines, Ondansetron (Zofran) is not recommended for nausea and vomiting secondary to chronic opioid use. This medication is recommended for acute use as noted, per FDA-approved indications. Ondansetron is a serotonin 5-HT₃ receptor antagonist that is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also approved for postoperative use and acute use is FDA-approved for gastroenteritis. Chronic use of this medication is not recommended. The medical record do not demonstrate this medication is prescribed for its FDA-approved use. The medical records do not establish Ondansetron is appropriate and medically indicated for treatment of this injured worker. The request for Ondansetron ODT tablets 8mg #30 is not medically necessary.

Cyclobenzaprine Hydrochloride tablets 7.5mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for Pain). Decision based on Non-MTUS Citation ODG-TWC Pain Procedure summary last updated 06/10/2014, non-sedating muscle relaxants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 64.

Decision rationale: According to CA MTUS, Cyclobenzaprine (Flexeril) is recommended as an option, using a short course of therapy. The addition of cyclobenzaprine to other agents is not recommended. Flexeril is recommended as an option, using a short course. The examination on 7/10/2014 documented the presence of lumbar tenderness with spasms. However, the injured worker has not presented with a flare-up or exacerbation unresponsive to first-line interventions. Furthermore, chronic use of muscle relaxants is not recommended by the guidelines. Consequently, Cyclobenzaprine is not medically necessary. The request for Cyclobenzaprine Hydrochloride Tablets 7.5mg #120 is not medically necessary.

Tramadol ER 150mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-97..

Decision rationale: According to the CA MTUS Guidelines, Ultram is recommended as a second-line treatment (alone or in combination with first-line drugs). Tramadol is indicated for moderate to severe pain. , the CA MTUS Guidelines indicate "four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids; pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or

non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors)." The injured worker has not returned to work. There lacks evidence that notable pain relief and functional improvement have been obtained as result of ongoing use of Tramadol. Chronic or long-term use of opioids is not generally recommended. The injured worker reports 6-7/10 level pain. The medical records do not clarify pain levels with and without pain medication use. The injured worker is several months postdate of shoulder surgery. At this juncture, given the clinical presentation, the injured worker should be encouraged to utilize non-narcotic analgesics and non-pharmacologic means to manage chronic pain. The request for Tramadol ER 150mg #90 is not medically necessary.