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| Case Number: | CM15-0068508 | | |
| Date Assigned: | 04/16/2015 | Date of Injury: | 07/10/2000 |
| Decision Date: | 05/15/2015 | UR Denial Date: | 03/25/2015 |
| Priority: | Standard | Application Received: | 04/10/2015 |

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: North Carolina

Certification(s)/Specialty: Family Practice

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/work injury on 7/10/00. She reported initial complaints of right shoulder pain. The injured worker was diagnosed as having impingement syndrome of the right shoulder with labral tear. Treatment to date has included medication, transcutaneous electrical nerve stimulation (TENS) unit, hot/cold wraps, and surgery (decompression and labral repair of right shoulder). Currently, the injured worker complains of right shoulder discomfort along with issues with sleep and headaches, but not depression. Per the primary physician's progress report (PR-2) on 3/11/15, examination revealed tenderness of the rotator cuff, weakness to restricted function. Further testing (MRA) noted persistent labral tear but appropriate decompression. The requested treatments include Fenoprofen Calcium, Pantoprazole Sodium, and Lidopro cream.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fenoprofen Calcium 400mg #60: Overturned

Claims Administrator guideline: Decision based on MTUS ACOEM Page(s): 47. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Anti-inflammatory Medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAID
Page(s): 68-72.

Decision rationale: The California chronic pain medical treatment guidelines section on NSAID therapy states: Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) This medication is recommended for the shortest period of time and at the lowest dose possible. The shortest period of time is not defined in the California MTUS. The requested medication is within the maximum dosing guidelines per the California MTUS. Therefore, the request is medically necessary.

Pantoprazole Sodium 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Proton Pump Inhibitors.

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

Decision rationale: The California chronic pain medical treatment guidelines section on NSAID therapy and proton pump inhibitors (PPI) states: Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastro duodenal lesions. Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.). Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. There is no documentation provided that places this patient at intermediate or high risk that would justify the use of a PPI. There is no mention of current gastrointestinal or

cardiovascular disease. For these reasons the criteria set forth above per the California MTUS for the use of this medication has not been met. Therefore, the request is not medically necessary.

Lidopro cream 1 bottle 121g: 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 California chronic pain medical treatment guidelines section on topical lidocaine states: Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007, the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995) This medication is recommended for localized peripheral pain. There is no documentation of failure of first line neuropathic pain medications. Therefore, criteria as set forth by the California MTUS as outlined above have not been met and the request is not medically necessary.