MAXIMUS Federal Services

Case Number:	CM15-0224385		
Date Assigned:	11/20/2015	Date of Injury:	07/01/1997
Decision Date:	12/30/2015	UR Denial Date:	10/30/2015
Priority:	Standard	Application Received:	11/16/2015

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:

This is a 71-year-old male with a date of industrial injury 7-1-1997. The medical records indicated the injured worker (IW) was treated for rotator cuff syndrome of the right shoulder. In the progress notes (7-10-15), the IW reported intermittent right shoulder pain. He was stable on pain medication and advised there was "no pain with medications", but noticed some stomach pain with Ibuprofen. He had previous success with Lidoderm patches, and had failed over the counter stomach medications. On examination (7-10-15 notes), there was pain with resisted motion of the right shoulder and pain with external rotation, decreased pain with internal rotation and decreased shoulder flexion. Atrophy of the right shoulder was noted. Treatments included Ibuprofen, Voltaren 1% gel and Lidoderm 5% patch. The IW was temporarily totally disabled. The physical exam did not indicate the IW had neuropathic pain. A Request for Authorization was received for Ibuprofen 800mg, #90 with 5 refills; Lidoderm 5% 700mg per patch, #30 with 5 refills; and Voltaren 1% topical gel, #5 with 5 refills. The Utilization Review on 10-30-15 non-certified the request for Ibuprofen 800mg, #90 with 5 refills and Lidoderm 5% 700mg per patch, #30 with 5 refills; and modified the request for Voltaren 1% topical gel, #5 with 5 refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

One (1) prescription of Ibuprofen 800mg #90 with 5 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steriodal anti-inflammatory drugs).

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) Back Pain-Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. This medication is recommended for the shortest period of time and at the lowest dose possible. The dosing of this medication is within the California MTUS guideline recommendations. The definition of shortest period possible is not clearly defined in the California MTUS. However, the request is for 5 refills. Without evidence of ongoing benefit, this cannot be deemed necessary. Therefore, the request is not medically necessary.

One (1) prescription of Lidoderm 5% 700mg/patch #30 with 5 refills: Upheld

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

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

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. The patient does have peripheral pain complaints. 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.

One (1) prescription of Voltaren 1% topical gel #5 with 5 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steriodal anti-inflammatory drugs).

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

Decision rationale: The California Chronic Pain Medical Treatment Guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Topical analgesic NSAID formulations are not indicated for long-term use and have little evidence for treatment of the spine, hip or shoulder. This patient does not have a diagnosis of osteoarthritis or neuropathic pain that has failed first line treatment options. The patient has shoulder pain complaints. Therefore, criteria for the use of topical NSAID therapy per the California MTUS have not been met and the request is not medically necessary.