MAXIMUS Federal Services

Case Number:	CM14-0192986		
Date Assigned:	11/26/2014	Date of Injury:	02/01/1994
Decision Date:	01/13/2015	UR Denial Date:	11/06/2014
Priority:	Standard	Application Received:	11/18/2014

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 Family Medicine and is licensed to practice in Ohio. 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:

This is a 68 year old female who sustained a work related injury on 2/01/1994. The mechanism of injury is not provided. Per the primary treating physician's progress report dated 10/21/2014, she was status post carpal tunnel release. The date of the surgery is not provided. The injured worker reported pain of 7 on a scale from 0-10 with 10 being the worst pain. She reported partial relief with the current analgesic regimen of medications. Physical examination revealed chronic pain with nociceptive and affective components. Diagnoses included right carpal tunnel syndrome, myofascial pain syndrome, pain disorder with psychological components, and insomnia due to persistent chronic pain. The plan of care included physical therapy and continuation of medication management. Activity modifications were discussed. Work status was permanent disability. On 11/06/2014, Utilization Review non-certified prescriptions for Lidoderm patches #30, Ibuprofen 800mg #100, and Voltaren gel 1% #300gm based on lack of medical necessity. The CA MTUS Chronic Pain Medical Treatment Guidelines were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidoderm Patches #30: 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): 112.

Decision rationale: Topical Lidocaine is 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. Topical Lidocaine is not indicated for non-neuropathic pain: There is only one trial that tested 4% Lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. In this instance, the records submitted from the treating physician indicate that the injured worker has nociceptive and affective pain, not neuropathic pain. A diagnosis of carpal tunnel surgery is present but progress notes from 7/25/2014, 9/19/2014, and 12/1/14 do not include a physical exam to verify ongoing evidence of neuropathic pain, presumably from carpal tunnel syndrome in this instance. Per the guidelines cited, the medical necessity for Lidoderm Patches #30 is not established in the records submitted. Therefore, Lidoderm patches #30 are not medically necessary and appropriate.

Ibuprofen 800mg #100: Overturned

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

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

Decision rationale: NSAIDs such as Ibuprofen are 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. There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain.In this instance, the injured worker has chronic myofascial pain and may or may not have neuropathic pain. The injured worker certainly has

moderate to severe pain as evidenced by consistent pain scores of 7/10. Therefore, Ibuprofen 800mg #100 was medically necessary.

Voltaren gel 1% #300gm: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Topical Analgesics.

Decision rationale: Voltaren gel 1% (Diclofenac): Indicated for relief of osteoarthritis pain in a joint that lends itself to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren, package insert) Clinical trial data suggest that Diclofenac sodium gel (the first topical NSAID approved in the US) provides clinically meaningful analgesia in OA patients with a low incidence of systemic adverse events. The labeling for topical Diclofenac has been updated to warn about drug-induced hepatotoxicity. (FDA, 2009) Voltaren Gel was effective in adults regardless of age. Treatment-related application site dermatitis was more common with Voltaren Gel, but gastrointestinal AEs were infrequent. It is recommended for osteoarthritis after failure of an oral NSAID, or contraindications to oral NSAIDs, or for patients who cannot swallow solid oral dosage forms. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks).In this instance, it would seem that the right hand and wrist pain almost certainly involve some element of osteoarthritis and/or tendonitis. The Voltaren Gel appears to have been in use continuously for at least 4 months (since 7-25-2014). This period of time exceeds that for which would be considered short-term use. Consequently, Voltaren gel 1% #300gm is not medically necessary.