

Case Number:	CM15-0161927		
Date Assigned:	08/27/2015	Date of Injury:	07/14/2004
Decision Date:	10/13/2015	UR Denial Date:	08/04/2015
Priority:	Standard	Application Received:	08/17/2015

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:

Current diagnoses include degenerative disc disease-cervical, facet arthropathy-cervical, and shoulder pain. Report dated 07-28-2015 noted that the injured worker presented with complaints that included neck pain with radiation to the left rhomboid region and down the left shoulder, and difficulty sleeping due to pain. Pain level was 9 out of 10 on a visual analog scale (VAS). The physician noted that the medications decrease pain and allow her to perform her daily functions and ability to care for herself and her household. Current medications include Tramadol IR, Ultram ER, Neurontin, Zanaflex, Voltaren gel, and Celebrex. Physical examination performed on 07-28-2015 revealed tenderness to palpation in the midline of the cervical spine, tenderness over the left cervical facet joints, decreased cervical range of motion, and swelling and tenderness at the left thumb metacarpophalangeal joint. Previous treatments included medications, surgical interventions to the cervical spine and right shoulder, cervical epidural steroid injections, and home exercise program. The treatment plan included requests for cervical epidural steroid injection, medications which included Ultram ER, Tramadol IR, Neurontin, Zanaflex, Voltaren gel, and Celebrex, and continue performing home physical therapy. The utilization review dated 08-04-2015, non-certified the request for Neurontin, Celebrex, and Voltaren gel.

IMR ISSUES, DECISIONS AND RATIONALES

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

Neurontin 600mg #120: Overtuned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: The California chronic pain medical treatment guidelines section on Neurontin states: Gabapentin (Neurontin, Gabarone, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen2-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study. The patient has the diagnosis of neuropathic pain in the form of radiculopathy. Therefore, the request is necessary and approved.

Celebrex 200mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: The California chronic pain medical treatment guidelines section on NSAID use and proton pump inhibitors (PPI) states: 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 gastroduodenal 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 (200 mg 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 necessary. Cardiovascular disease: A non-pharmacological choice should be the first option in patients with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short-term needs. An opioid also remains a short-term alternative for analgesia. Major risk factors (recent MI, or coronary artery surgery, including recent stent placement): If NSAID therapy is necessary, the suggested treatment is naproxen plus low-dose aspirin plus a PPI. Mild to moderate risk factors: If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. If naproxen is ineffective, the suggested treatment is: (1) the addition of aspirin to naproxen plus a PPI, or (2) a low-dose Cox-2 plus ASA. Cardiovascular risk does appear to extend to all non-aspirin NSAIDs, with the highest risk found for the Cox-2 agents. (Johnsen, 2005) (Lanas, 2006) (Antman, 2007) (Laine, 2007) Use with Aspirin for cardioprotective effect: In terms of GI protective effect: The GI protective effect of Cox-2 agents is diminished in patients taking low-dose aspirin and a PPI may be required for those patients with GI risk factors. (Laine, 2007) In terms of the actual cardioprotective effect of aspirin: Traditional NSAIDs (both ibuprofen and naproxen) appear to attenuate the antiplatelet effect of enteric-coated aspirin and should be taken 30 minutes after ASA or 8 hours before. (Antman, 2007) Cox-2 NSAIDs and diclofenac (a traditional NSAID) do not decrease anti-platelet effect. (Laine, 2007) The patient does not have risk factors that would require a COX-2 inhibitor over a traditional NSAID. Therefore, the request is not medically necessary.

Voltaren gel 1% #3: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Non-steroidal antiinflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated

specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) 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). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended, as there is no evidence to support use. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves 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) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000) 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. Therefore, criteria for the use of topical NSAID therapy per the California MTUS have not been met and the request is not medically necessary.