

Case Number:	CM14-0019560		
Date Assigned:	04/23/2014	Date of Injury:	02/22/2012
Decision Date:	07/03/2014	UR Denial Date:	01/31/2014
Priority:	Standard	Application Received:	02/17/2014

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 Internal Medicine, and is licensed to practice in Virginia and DC. 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 52-year-old patient who sustained injury on Feb 22 2012 and then developed shoulder and right upper extremity and neck pain. ██████ saw the patient on Jan 20 2014 and diagnosed the patient with reflex sympathetic dystrophy of the right lower extremity, right shoulder pain, joint ankle and foot pain, and right shoulder adhesive capsulitis. Patient was on multiple medications: celebrex, lidocaine ointment 5%, lunesta, lyrica, nortryptaline, omeprazole, stool softener, tramadol. The patient had right sided lumbar sympathetic block on Jan 13 2014. ██████ saw the patient on Nov 25 2013 and Dec 23 2013 and prescribed these medications: lunesta, lyrica, tramadol.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETROSPECTIVE TRAMADOL 37.5/325MG DOS: 1/20/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TRAMADOL (ULTRAM).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 75, 80, 82.

Decision rationale: Per MTUS: Central acting analgesics: an emerging fourth class of opiate analgesic that may be used to treat chronic pain. This small class of synthetic opioids (e.g.,

Tramadol) exhibits opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Central analgesics drugs such as Tramadol (Ultram) are reported to be effective in managing neuropathic pain. (Kumar, 2003) Side effects are similar to traditional opioids. Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (Deshpande, 2007) Opioid analgesics and Tramadol have been suggested as a second-line treatment (alone or in combination with first-line drugs). A recent consensus guideline stated that opioids could be considered first-line therapy for the following circumstances: (1) prompt pain relief while titrating a first-line drug; (2) treatment of episodic exacerbations of severe pain; [&] (3) treatment of neuropathic cancer pain. (Dworkin, 2007) Response of neuropathic pain to drugs may differ according to the etiology of therapeutic pain. There is limited assessment of effectiveness of opioids for neuropathic pain, with short-term studies showing contradictory results and intermediate studies (8-70 days) demonstrating efficacy. (Eisenberg-Cochrane, 2006) (Eisenberg- JAMA, 2005) The results of short-term trials were mixed with respect to analgesia (less than 24 hours of treatment). Intermediate trials (average treatment duration of 28 days) showed statistical significance for reducing neuropathic pain by 20% to 30% (and 30% may be the threshold for describing a meaningful reduction of pain). This medication is not considered first line and therefore is not medically indicated.

RETROSPECTIVE OMEPRAZOLE 40 DOS: 1/20/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI SYMPTOMS AND CARDIOVASCULAR RISK.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines <9792.2> Page(s): 68.

Decision rationale: Per MTUS, 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 μg 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). This patient did not meet criteria for requiring prophylaxis against gastrointestinal events and therefore this medication was not medically necessary.

STOOL SOFTENER 100MG CAPSULE DOS: 1/20/14: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: http://www.medscape.com/viewarticle/427442_5Mannix KA. Gastrointestinal symptoms. In: Doyle D, Hanks GWC, MacDonald N, eds. Oxford textbook of palliative medicine. New York: Oxford University Press, 1998:489-99.

Decision rationale: There were no MTUS or ACOEM guidelines, which addressed this medication, so alternate sources were sought. Stool softeners are used as prophylaxis against constipation when patients take opiate medication. This patient was on tramadol, which is an opiate, and therefore, a stool softener is warranted.

RETROSPECTIVE LIDOCAINE 5% TOPICAL OINTMENT DOS: 1/20/14: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines LIDOCAINE, TOPICAL.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines <9792.2> Page(s): 112.

Decision rationale: Per MTUS, 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 patient was given Lyrica prior to starting Lidocaine and the patient subsequently failed a trial of this medication. Therefore, Lidocaine administration is medically indicated.

RETROSPECTIVE CELEBREX 200MG CAPSULE DOS: 1/20/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines COX-2 INHIBITORS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines <9792.2-.6> Page(s): 70, 21.

Decision rationale: Celecoxib (Celebrex) is the only available COX-2 in the United States. No generic is available. Mechanism of Action: Inhibits prostaglandin synthesis by decreasing cyclooxygenase-2 (COX-2). At therapeutic concentrations, cyclooxygenase-1 (COX-1) is not inhibited. In animal models it works as an anti-inflammatory, analgesic, and antipyretic. It does not have an anti-platelet effect and is not a substitute for aspirin for cardiac prophylaxis. Use: Relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, [and] ankylosing spondylitis. Side Effects: See NSAIDs, hypertension and renal function; & NSAIDs, GI Symptoms and Cardiovascular Risks. Cardiovascular: Hypertension (≤13%) CNS: headache(15.8%), dizziness (1% - 2%), insomnia (2.3%); GI: diarrhea (4% to 11%), dyspepsia (8.8% vs.12.8% for ibuprofen and 6.2% for placebo), diarrhea (5.6%), abdominal pain (4.1% vs. 9% for ibuprofen and 2.8% for placebo), N/V (3.5%), gastroesophageal reflux (≤ 5%), flatulence(2.2%); Neuromuscular/ skeletal: arthralgia (7%), back pain (3%); Respiratory: upper respiratory tract infection (8%), cough (7%), sinusitis (5%), rhinitis (2%), pharyngitis (2%); Skin Rash (2%)- discontinue if rash develops; Peripheral Edema (2.1%). Recommended Dose: 200 mg a day(single dose or 100 mg twice a day). (Celebrex package insert)COX-2 inhibitors (e.g.,Celebrex) may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months, but a 10-to-1 difference in cost. (Rate of overall GI bleeding is 3% with COX-2's versus 4.5% with ibuprofen.) (Homik, 2003) For precautions in specific patient populations, see NSAIDs, GI symptoms & cardiovascular risk. From the documentation provided, it does not appear that the patient did not have risk of GI complications and therefore this was not medically indicated.