

Case Number:	CM14-0080069		
Date Assigned:	07/18/2014	Date of Injury:	05/14/2010
Decision Date:	08/25/2014	UR Denial Date:	04/30/2014
Priority:	Standard	Application Received:	05/30/2014

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 Physical Medicine and Rehabilitation, has a subspecialty in Interventional Spine and is licensed to practice in California. 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:

The patient is a 39-year-old female with a date of injury of 05/14/2000. The listed diagnosis per [REDACTED] is reflex sympathetic dystrophy of lower extremity. According to progress report 02/22/2014 by [REDACTED], the patient presents with reflex sympathetic dystrophy of the lower legs, fibromyositis, depressive disorder, and anxiety. The patient complains of pain in the right upper extremity elbow to hand, left upper extremity elbow to hand, and bilateral lower extremity hips to feet. The patient rates pain as 8/10 and constant. The patient reports she is keeping up with the use of her non-pharmacological tools to manage her pain as well as medications. She states she has "significant amount of pain when she does not take Lyrica, ibuprofen, and Cymbalta." The treater is requesting ibuprofen 800 mg #60 with 3 refills, promethazine 25 mg #20 with 3 refills, and Norco 5/325 mg #30. Utilization review denied the request on 04/30/2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ibuprofen 800mg, #60 with 3 refills: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications, Ibuprofen Page(s): 22, 72.

MAXIMUS guideline: Decision based on the MTUS Chronic Pain Medical Treatment Guidelines, Chronic Pain Medical Treatment Guidelines ,Anti-inflammatory medications (p22, Chronic pain MTUS) For specific recommendations, see NSAIDs (non-steroidal anti-inflammatory drugs). Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. (Van Tulder-Cochrane, 2000) A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) in chronic LBP and of antidepressants in chronic LBP. (Schnitzer, 2004) See also Nonprescription Medications. 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. NSAIDs (non-steroidal anti-inflammatory drugs) (MTUS pgs 67,68)

Specific recommendations:

Osteoarthritis (including knee and hip): 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 - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007)

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. Neuropa.

Decision rationale: This patient presents with continued pain secondary to her centralized right lower extremity complex regional pain syndrome type 1. The patient also has regional myofascial pain. The treater is requesting ibuprofen 800 mg #60 with 3 refills. Utilization

review denied the request stating doses greater than 400 mg have not provided greater relief of pain. For anti-inflammatory medications, the MTUS Guidelines page 22 states "anti-inflammatories are the traditional first line of treatment to reduce pain, so activity and functional restoration can resume, but long term use may not be warranted." This patient has sympathetic dystrophy of lower extremity and reports significant amount of pain without medications including ibuprofen. Given patient's chronic pain and medication efficacy, recommendation is for approval.

Promethazine 25mg #20 with 3 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic): Antiemetics (for opioid nausea).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)ODG guidelines on antiemetics for opiates:Not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. (Moore 2005)Promethazine (Phenergan®): This drug is a phenothiazine. It is recommended as a sedative and antiemetic in pre-operative and post-operative situations. Multiple central nervous system effects are noted with use including somnolence, confusion and sedation. Tardive dyskinesia is also associated with use. This is characterized by involuntary movements of the tongue, mouth, jaw, and/or face. Choreoathetoid movements of the extremities can also occur. Development appears to be associated with prolonged treatment and in some cases can be irreversible. Anticholinergic effects can occur (dry mouth, dry eyes, urinary retention and ileus).Ondansetron (Zofran®): This drug is a serotonin 5-HT3 receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis. See also Nabilone (Cesamet®), for chemotherapy-induced nausea, but not pain.

Decision rationale: This patient presents with continued pain secondary to her centralized right lower extremity complex regional pain syndrome type 1. The patient also has regional myofascial pain. The treater is requesting a refill of Phenergan (promethazine) daily for patient's nausea related to severe pain. MTUS and ACOEM guidelines do not discuss Phenergan. However, ODG guidelines states "Promethazine (Phenergan) is a phenothiazine. It is recommended as a sedative and antiemetic in pre-operative and post-operative situations." It is not recommended as an antiemetic for chronic opiates use. Recommendation is for denial.

Norco 5/325mg #30: Overturned

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

Opioids for chronic pain, Hydrocodone/Acetaminophen Page(s): 80-81, 91, 93-94.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain (MTUS 60,61) Recommended as indicated below. Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. (Chou, 2006) There are multiple medication choices listed separately (not all recommended). See Anticonvulsants for chronic pain; Antidepressants for chronic pain; Anti-epilepsy drugs (AEDs); Anti-Inflammatories; Benzodiazepines; Boswellia Serrata Resin (Frankincense); Buprenorphine; Cannabinoids; Capsaicin; Cod liver oil; Curcumin (Turmeric); Cyclobenzaprine (Flexeril); Duloxetine (Cymbalta); Gabapentin (Neurontin); Glucosamine (and Chondroitin Sulfate); Green tea; Herbal medicines; Implantable drug-delivery systems (IDDSs); Injection with anaesthetics and/or steroids; Intrathecal drug delivery systems, medications; Intravenous regional sympathetic blocks (for RSD, nerve blocks); Ketamine; Methadone; Milnacipran (Ixel); Muscle relaxants; Nonprescription medications; NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs, GI symptoms & cardiovascular risk; Opioids (with links to multiple topics on opioids); Pycnogenol (maritime pine bark); Salicylate topicals; Topical analgesics; Topical analgesics, Compounded; Uncaria Tomentosa (Cat's Claw); Venlafaxine (Effexor); White willow bark; & Ziconotide (Prialt).**CRITERIA FOR USE OF OPIOIDS** (MTUS pgs 88, 89) Long-term Users of Opioids (6-months or more) 1) Re-assess (a) Has the diagnosis changed? (b) What other medications is the patient taking? Are they effective, producing side effects? (c) What treatments have been attempted since the use of opioids? Have they been effective? For how long? (d) Document pain and functional improvement and compare to baseline. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of Page(s): 60-61.

Decision rationale: This patient presents with continued pain secondary to her centralized right lower extremity complex regional pain syndrome type 1. The treater is requesting a refill for Norco "to be used for flare-ups." Treater states the patient is not taking this medication on a daily basis. Treater states the medication allows the patient to effectively manage her pain and maintain current levels of function. Page 78 of MTUS requires "Pain Assessment" that should include, "current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts." Furthermore, "The 4 A's for ongoing monitoring" are required that include analgesia, ADL's, adverse side effects and aberrant drug-seeking behavior. Medical records show the patient was given a refill of Norco in December 2013. On 02/11/2014, the treater requested another refill of this medication and it would appear that the patient may be going through #30 in several months. Given the patient's diagnosis, and the fact that such small amount of Norco is being used with some functional improvement, recommendation is for authorization.