

Case Number:	CM15-0171320		
Date Assigned:	09/11/2015	Date of Injury:	02/26/2012
Decision Date:	10/15/2015	UR Denial Date:	08/25/2015
Priority:	Standard	Application Received:	08/31/2015

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:

The injured worker is a 60 year old female, who sustained an industrial injury on 2-26-12. The injured worker was diagnosed as having lumbar facet arthropathy; hallux rigidus; osteoarthritis ankle; ganglion; abnormality of gait; sprain elbow-forearm; discopathy of hip; exostosis site unspecified; lumbosacral neuritis; arthroscopy to open surgery-chondromalacia patella; lumbar disc displacement (11-2013). Treatment to date has included physical therapy; status post left shoulder arthroscopy (4-18-13); status post left knee surgery (11-2013); acupuncture; TENS unit; left hip injection (1-26-15); medications. Diagnostics studies included MRI left hip (12-5-12). Currently, the PR-2 notes dated 7-8-15 are an "Initial Pain Medicine Evaluation". The notes indicated the injured worker presented for a main medicine consultation and initial examination. The injured worker reports complaints of low back pain that is frequent and radiates down the bilateral lower extremities and the left lower extremity. She reports the pain is accompanied by tingling frequently in the bilateral lower extremities to the level of the hip to the level of the thigh. She reports the pain is dull and moderate to severe in severity and aggravated by activity, bending, prolonged sitting, standing, turning, twisting and sudden movement of lifting greater than 5 pounds. She reports a moderate amount of difficulty in sleep. She has tingling in the left knee and her left leg with weakness and gives way 3 times a day. The provider documents "pain is rated at 4-5 out of 10 in intensity with medications and rated 9 out of 10 without medications. She reports her pain has worsened and is improved with bed rest and sitting. She reports medications give temporary benefit, acupuncture is helpful and chiropractic therapy is of limited benefit. She reports ongoing activity of daily living in the following areas due to pain: "self-care and hygiene, activity and sleep". The provider documents a physical examination with "tenderness noted on palpation in the spinal vertebral area L4-S1 levels. The range of motion of

the lumbar spine was moderately limited secondary to pain. Pain was significantly increased with flexion and extension. Facet signs were present in the lumbar spine. Sensory exam is within normal limits bilaterally, Straight leg raise at 90 degrees sitting position is negative bilaterally." The lower extremity examination is documented as: "inspection of the right foot reveals a well-healed scar. Tenderness was on palpation noted at the right foot." She is a status post right foot surgery on 3-6-15. A Request for Authorization is dated 8-31-15. A Utilization Review letter is dated 8-25-15 and non-certification was for Lidocaine 5% topical patch, thirty count with one refill; Norco 5/325 mg, sixty count and Prilosec thirty count with one refill. The requested medications were denied for not meeting the CA MTUS guidelines. The provider is requesting authorization of Lidocaine 5% topical patch, thirty count with one refill; Norco 5/325 mg, sixty count and Prilosec thirty count with one refill.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidocaine 5% topical patch, thirty count with one refill: 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 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 antidepressants 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 lower extremity pain, however the patient has no documented failure of all first line agents indicated for the treatment of neuropathic pain as outlined above. Therefore, criteria as set forth by the California MTUS as outlined above have not been met and the request is not medically necessary.

Norco 5/325 mg, sixty count: 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): Opioids for chronic pain.

Decision rationale: The California chronic pain medical treatment guidelines section on opioids states for ongoing management: On-Going Management. Actions Should Include: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side-effects. Pain assessment 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side-effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to non-opioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. When to Continue Opioids: (a) If the patient has returned to work. (b) If the patient has improved functioning and pain. (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004). The long-term use of this medication class is not recommended per the California MTUS unless there documented evidence of benefit with measurable outcome measures and improvement in function. There is documentation of significant subjective improvement in pain such as VAS scores going from a 10/10 to a 4/10 with medications. There is no objective measure of improvement in function or activities due to medication. Work status is not mentioned. For these reasons all the criteria set forth above of ongoing and continued used of opioids have not been met. Therefore, the request is not medically necessary.

Prilosec thirty count with one refill: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

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

Decision rationale: The California chronic pain medical treatment guidelines section on NSAID therapy and proton pump inhibitors (PPI) states: Recommend with precautions as indicated below. 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 gastro duodenal 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 ug 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 absolutely necessary. There is no documentation provided that places this patient at intermediate or high risk that would justify the use of a PPI. There is no mention of current gastrointestinal or cardiovascular disease. For these reasons the criteria set forth above per the California MTUS for the use of this medication has not been met. Therefore, the request is not medically necessary.