

Case Number:	CM15-0149333		
Date Assigned:	08/12/2015	Date of Injury:	05/25/1995
Decision Date:	09/15/2015	UR Denial Date:	07/17/2015
Priority:	Standard	Application Received:	07/31/2015

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 52 year old female, who sustained an industrial injury on May 25, 1995. Treatment to date has included opioid pain medications, NSAIDS, topical pain patches, anti-depressants. Currently, the injured worker complains of bilateral abdominal-pelvic pain. She describes her pain as aching, burning, gnawing, pins-needles sensation, shock-like, stabbing, and throbbing pain. She rates her pain a 7 on a 10 point scale. She reports the effectiveness of her medication is unchanged since her previous evaluation and she reports her functional impairment as severe. Her medication regimen includes OxyContin, ibuprofen, Lidoderm patch, sumatriptan, and Prozac. The diagnosis associated with the request is neuropathic and nociceptive lower extremity pain. The treatment plan includes continuation of current medication regimen, and follow-up evaluation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidoderm 5%, apply 1-3 patches every 12 hours for 30 days, #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch); Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical lidocaine Page(s): 111-112.

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 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 medication is recommended for localized peripheral pain. There is no documentation of failure of first line neuropathic pain medications. Therefore criteria as set forth by the California MTUS as outlined above have not been met and the request is not medically necessary.

Ibuprofen 600mg, 1 tablet twice daily for 30 days, #60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Nonselective NSAIDs: Ibuprofen (Motrin, Advil [otc], generic available).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAID Page(s): 68-72.

Decision rationale: The California chronic pain medical treatment guidelines section on NSAID therapy states: 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 naproxen being the safest drug). There is no evidence of long-term effectiveness for pain or function.

(Chen, 2008) (Laine, 2008) 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. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. This medication is recommended for the shortest period of time and at the lowest dose possible. The dosing of this medication is within the California MTUS guideline recommendations. The definition of shortest period possible is not clearly defined in the California MTUS. Therefore, the request is medically necessary.

Oxycontin 15mg, 1 tablet twice daily for pain with a maximum of 2 per day, #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list - Oxycodone immediate release; Opioids, criteria for use; Weaning of Medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 76-84.

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 nonopioid 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 no documented significant decrease in objective pain measures such as VAS scores for significant periods of time. There are no objective measures of improvement of function. Therefore all criteria for the ongoing use of opioids have not been met and the request is not medically necessary.