

<b>Case Number:</b>	CM15-0067106		
<b>Date Assigned:</b>	04/14/2015	<b>Date of Injury:</b>	08/20/2000
<b>Decision Date:</b>	05/13/2015	<b>UR Denial Date:</b>	03/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/08/2015

### 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 64-year-old female, who sustained an industrial injury on 8/20/2000. Diagnoses include chronic sprain/strain lumbar spine, discogenic low back pain and right shoulder pain. Treatment to date has included surgical intervention (thoracic laminectomy and decompression 7/10/2014) and medications. Per the Primary Treating Physician's Progress Report dated 3/11/2015, the injured worker reported constant sharp waxing and waning pain in the right shoulder. The pain is tolerable with medication. Her low back pain is described as constant achy pain that is mild and managed with medication. Physical examination revealed moderate scoliosis with the apex to the left. Her right pelvis is higher than her gluteal region. There was restricted back and slight limited hip range of motion, otherwise fair lower extremity range of motion. The plan of care included medications and authorization was requested for Colace, Relafen, Lyrica, Lidoderm patch and Butrans patch.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Lyrica 300 mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 19 - 20.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lyrica Page(s): 19.

**Decision rationale:** The California MTUS section on Lyrica states: Pregabalin (Lyrica, no generic available) has been documented to be effective in treatment of diabetic neuropathy and post-herpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. This medication is designated as a Schedule V controlled substance because of its causal relationship with euphoria. (Blommel, 2007) This medication also has an anti-anxiety effect. Pregabalin is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder. In June 2007, the FDA announced the approval of pregabalin as the first approved treatment for fibromyalgia. (ICSI, 2007) (Tassone, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Crofford, 2005) (Stacey, 2008) The patient does not have either of these indicated diagnoses and therefore is not medically necessary.

**Lidoderm 5% patches, sixty count:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 56 - 57.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

**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 is currently on 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 been met and the request is medically necessary.

**Butrans 20 mcg/hr, four count:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 26.

**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 4A'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 no documented significant improvement in VAS scores. There are also no objective measurements of improvement in function. Therefore, criteria for the ongoing use of opioids have not been met and the request is not medically necessary.