

<b>Case Number:</b>	CM14-0046139		
<b>Date Assigned:</b>	07/02/2014	<b>Date of Injury:</b>	04/05/2001
<b>Decision Date:</b>	08/20/2014	<b>UR Denial Date:</b>	04/08/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/15/2014

### 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 & Rehab 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 50-year-old male with an injury date of 04/05/2001. Based on the 03/26/2014 progress report, the patient complains of back pain which radiates from his lower back down to the right leg. The patient's lower back pain radiates specifically to the posterior-lateral thigh and calf including the lateral, bottom, and dorsal aspect of the foot. The 01/29/2014 report states that the patient also had right groin pain which was due to overuse of his right leg. The patient's diagnoses include the following: 1. Spinal/lumbar DDD. 2. Lumbar radiculopathy 3. Spinal stenosis of the lumbar spine. The request is for Lidoderm patches 5% QTY:30 and Ultram 50 mg QTY:45. The utilization review determination being challenged is dated 04/08/2014. The treatment reports provided range from 11/06/2013 - 03/26/2014.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Lidoderm Patches 5% qty 30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidocerm (lidocaine patch) Page(s): 56.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines MTUS has the following regarding lidoderm patches Lidoderm (lidocaine patch) Lidoderm is the brand name for a lidocaine patch produced by Endo Pharmaceuticals. Topical lidocaine may be 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). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. 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. For more information and references, see Topical analgesics.MTUS page 112: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) Page(s): 56-57.

**Decision rationale:** According to the 03/26/2014 report, the patient presents with back pain radiating from his lower back to his right leg. The request is for Lidoderm patches 5% quantity 30. MTUS Guidelines recommend Lidoderm patches for neuropathic pain only stating, "Recommended for localized peripheral pain after there has been evidence of trial of first-line therapy, tricyclic SNRI, antidepressants or an AED such as gabapentin or Lyrica." The 12/31/13 report indicates that the patient has used Lyrica which provided dizziness. The patient has already had a trial with Lyrica which did not provide any benefit which is the reason for trial of lidoderm patch. However, lidoderm patches are not indicated for any neuropathic pain but for "peripheral localized" neuropathic pain. It is not indicated for axial low back pain nor for radicular/neuropathic pain that is diffuse down the extremity. Recommendation is for denial.

**Ultram 50 mg qty 45:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 93-94,113.

**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 (IDDs); 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 function.

Page(s): 60-61.

**Decision rationale:** According to the 03/26/2014 report, the patient presents with back pain radiating down to the right leg. The request is for Ultram 50 mg quantity 45. There is no discussion regarding Ultram in any of the reports provided. The patient has been taking Ultram as early as 11/06/2013; however, discontinued using it once the patient began taking Cymbalta. The patient again restarted Ultram on 01/29/2014. For long-term use of opiates, MTUS Guidelines require documentation of pain and function. Numeric scale or a validated instrument is required once every 6 months to document the patient's function. The guidelines also require mentioning the 4 A's (analgesia, ADLs, adverse effects, and adverse events). In this case, documentation is inadequate. There are no pain scales provided, nor are there any specific functional changes mentioned. Recommendation is for denial.