

<b>Case Number:</b>	CM13-0034657		
<b>Date Assigned:</b>	12/11/2013	<b>Date of Injury:</b>	12/07/1999
<b>Decision Date:</b>	02/12/2014	<b>UR Denial Date:</b>	09/30/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/15/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Emergency Medicine, and is licensed to practice in New York and Tennessee. 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 physician 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 56-year-old female with continuing neck and back pain. Date of injury was December 7, 1999. MRI of the cervical spine done n June 23, 2011 showed multilevel spondylosis, central disc protrusion with severe central canal stenosis at C3-4 and C4-5 , mild right foraminal encroachment at C4-5, moderate to severe central canal stenosis at C5-6, and mild to moderate narrowing of the central canal with mild bilateral neural foraminal narrowing at C6-7. Physical examination showed normal motor strength in the upper extremities and mild decreased sensation over C5-65 bilaterally. Diagnosis was cervical pain and cervical disc disorder. The patient was treated with topical and oral medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flector 1.3% patch #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Flector patch.

**Decision rationale:** Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Topical NSAIDs have been shown to be superior to placebo in the treatment of osteoarthritis, but only in the short term and not for extended treatment. The effect appears to diminish over time. Absorption of the medication can occur and may have systemic side effects comparable to oral form. Adverse effects for GI toxicity and renal function have been reported. Flector, the topical NSAID diclofenac, is not recommended as a first-line treatment. Flector patch is FDA indicated for acute strains, sprains, and contusions. On 12/07/09 the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac. Post marketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. The efficacy in clinical trials for topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. In addition, there is no data that substantiate Flector efficacy beyond two weeks.

**Ultram 50mg #120:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): s 74-96.

**Decision rationale:** Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain or function. It is recommended for short term use if first-line options, such as acetaminophen or NSAIDs have failed. In this case the medication was not prescribed for short term use and the criteria for opioid use were not met. Opioids are considered a second-line treatment for several reasons: (1) head-to-head comparisons have found that opioids produce more side effects than TCAs and gabapentin; (2) long-term safety has not been systematically studied; (3) long-term use may result in immunological and endocrine problems (including hypogonadism); (4) treatment may be associated with hyperalgesia; & (5) opioid use is associated with misuse/abuse. Opioids may be a safer choice for patients with cardiac and renal disease than antidepressants or anticonvulsants. Tramadol is a synthetic opioid affecting the central nervous system. It has several side effects which include increasing the risk of seizure in patients taking SSRI's, TCA's and other opioids. The request for Ultram 50mg #120 is not medically necessary and appropriate.

