

<b>Case Number:</b>	CM15-0199470		
<b>Date Assigned:</b>	10/14/2015	<b>Date of Injury:</b>	11/05/2007
<b>Decision Date:</b>	12/01/2015	<b>UR Denial Date:</b>	09/10/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/09/2015

### 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: Texas, California

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:

This is a 51-year-old female patient who sustained an industrial injury on 11-6-2007. Diagnoses have included degeneration of cervical intervertebral disc, and shoulder joint pain. Per the progress note provided dated 4-6-2015 she had complaints of left shoulder pain, neck pain with radiation to the left upper extremity, with numbness, tingling, and weakness. The physical examination revealed tenderness and pain with cervical range of motion, painful left shoulder abduction with 4/5 strength; decreased sensation in the radial forearm, thumb, and fingers. The medications list includes lidocaine patch and ointment, voltaren gel, terbinafine, lutera and ibuprofen. Voltaren and Lidocaine patches are stated to provide "significant" pain relief as well as relief of neuropathy down the left arm, and enable the patient to work without having to take time off. They are also noted to improve her activities of daily living. Other therapy done for this injury was not specified in the records provided. The treating physician's plan of care includes Flector transdermal patches #60 with 6 refills, and Lidocaine 5 percent topical ointment, quantity 2 with 6 refills which were both non-certified on 9-10-2015.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flector 1.3% transdermal patch, Qty 60 with 6 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 10/09/15) Flector patch (diclofenac epolamine).

**Decision rationale:** Flector patch contains diclofenac. The MTUS Chronic Pain Guidelines regarding topical analgesics state, "Largely experimental in use with few randomized controlled trials to determine efficacy or safety, primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Any intolerance or contraindication to oral medications is not specified in the records provided. Failure of an antidepressant or anticonvulsant is not specified in the records provided. In addition, according to the ODG guidelines, flector patch is "Not recommended as a first-line treatment," topical diclofenac is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs, after considering the increased risk profile with diclofenac, including topical formulations. Flector patch is FDA indicated for acute strains, sprains, and contusions. (FDA, 2007) 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. The request for Flector 1.3% transdermal patch, Qty 60 with 6 refills is not medically necessary or fully established for this patient at this juncture.

**Lidocaine 5% topical ointment, Qty 2 with 6 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the MTUS Chronic Pain Guidelines regarding topical analgesics state that the use of topical analgesics is "Largely experimental in use with few randomized controlled trials to determine efficacy or safety, primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed". There is little to no research to support the use of many of these agents. According to the MTUS Chronic Pain Guidelines "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." MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. Failure of antidepressant and anticonvulsant is not specified in the records provided. Intolerance to oral medications is not specified in the records provided. Any evidence of post-herpetic neuralgia is not specified in the records provided. The request for Lidocaine 5% topical ointment, Qty 2 with 6 refills is not medically necessary or fully established for this patient.