

<b>Case Number:</b>	CM15-0093112		
<b>Date Assigned:</b>	05/19/2015	<b>Date of Injury:</b>	11/04/1998
<b>Decision Date:</b>	06/22/2015	<b>UR Denial Date:</b>	05/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/14/2015

### 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: California

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

### 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 60 year old male sustained an industrial injury to the low back on 11/4/98. Recent treatment included home exercise, transcutaneous electrical nerve stimulator unit and medications. In a PR-2 dated 4/2/15, the complained of low back pain with radiation down the left legs described as pins and needles. The injured worker's pain medications had been denied by his insurance. The injured worker was only taking diabetic medications. The injured worker reported being unable to manage his pain with poor sleep quality. The injured worker was trying to perform home exercise for pain relief. The injured worker reported that his quality of life, social activity and activities of daily living had remained the same since his last office visit. The injured worker was not working. The injured worker reported that samples of Flector patches had been helpful. Current diagnoses included lumbar radiculopathy, low back pain, chronic pain syndrome and depression. The treatment plan included Terocin patches, Flector pain patch, compounded topical cream, Ibuprofen, continuation of [REDACTED] gym membership and a transcutaneous electrical nerve stimulator unit.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Terocin pain patch, #30 with 2 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26 Page(s): 111-112.

**Decision rationale:** According to the MTUS, compounds containing lidocaine are not recommended for non-neuropathic pain. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. In addition, there is little to no research to support the use of many of these Compounded Topical Analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Terocin pain patch, #30 with 2 refills is not medically necessary.

**Flector pain patch, #60 with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26 Page(s): 111-112.

**Decision rationale:** Not recommended as a first-line treatment. 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 failure. Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. (FDA, 2009) 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. Flector pain patch, #60 with 2 refills is not medically necessary.

**Compounded topical cream (unspecified) with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26 Page(s): 111.

**Decision rationale:** According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least

one drug (or drug class) that is not recommended is not recommended. An unspecified prescription cannot be recommended. Compounded topical cream (unspecified) with 2 refills is not medically necessary.