

Case Number:	CM15-0050691		
Date Assigned:	03/24/2015	Date of Injury:	10/05/2004
Decision Date:	05/01/2015	UR Denial Date:	02/26/2015
Priority:	Standard	Application Received:	03/17/2015

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: Internal 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:

The injured worker is a 49-year-old female, who sustained an industrial injury on 10/05/2004. She reported that while reaching to prevent merchandise from falling off of a conveyor belt she sustained an injury to her left shoulder and low back secondary to the continuation of merchandise hitting her left shoulder. The injured worker subsequently sustained a fracture of the low back. The injured worker was diagnosed as having spasm of the muscle, thoracic/lumbosacral neuritis/radiculitis unspecified, lumbago, degenerative lumbar/lumbosacral intervertebral disc, post laminectomy syndrome of the lumbar region, and sacroiliitis not elsewhere classified. Treatment to date has included physical therapy, home exercise program, medication regimen, multiple surgeries to the low back, and lumbar spine magnetic resonance imaging. In a progress note dated 02/12/2015 the treating provider reports complaints of an increase in severe back pain with poor sleep quality and a decrease in the injured worker's activity level. The treating physician requested the medications of Flector patch to the back from a quantity of 30 to a quantity of 60 and a sample of Trigeminal Neuralgia TN2 cream with the treating physician noting that the injured worker's back pain has increased since the injured worker has been off of her medication regimen along with a decrease in the injured worker's activity level.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flector patch, sixty count: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs), page 67-73. Decision based on Non-MTUS Citation FDA Prescribing Information Flector Patch <http://www.drugs.com/pro/flector.html>.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. All non-steroidal anti-inflammatory drugs (NSAIDs) have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. The pain management report dated 2/12/15 documented the diagnoses of lumbalgia, lumbar radiculopathy, and cervicgia. The 2/12/15 progress report documented that Flector was tried and failed in the past. Per FDA guidelines, Flector Patch is indicated for the topical treatment of acute pain. Medical records document that the occupational injuries are chronic. The use of the topical NSAID Flector Patch is not supported by MTUS guidelines. The 2/12/15 progress report documented that Flector was tried and failed in the past. Therefore, the request for Flector patch is not medically necessary.

Trigeminal Neuralgia TN2 cream: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no

research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The pain management report dated 2/12/15 documented the diagnoses of lumbalgia, lumbar radiculopathy, and cervicalgia. No diagnosis of trigeminal neuralgia was documented. The treatment plan included a sampling of TN2 cream. The components of the TN2 cream were not documented. The request for a topical product, with unknown ingredients, cannot be endorsed. Topical analgesics in general are not supported by MTUS guidelines. Therefore, the request for Trigeminal Neuralgia TN2 cream is not medically necessary.