

Case Number:	CM13-0042258		
Date Assigned:	12/27/2013	Date of Injury:	05/07/2013
Decision Date:	04/30/2014	UR Denial Date:	10/14/2013
Priority:	Standard	Application Received:	10/30/2013

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 Internal Medicine, has a subspecialty in Pulmonary Diseases 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 47-year-old male who reported injury on 05/07/2013. The mechanism of injury was the patient was moving a pallet using a manual pallet lift and felt pain in his back. There was no documentation dated 06/18/2013 or 07/17/2013 submitted for review. Documentation of 06/26/2013 revealed the patient had a complaint of pain in the back, neck, legs, and arms, and a fear of sleeping, fear of darkness, pain upon waking, and was very emotional. Objectively, the patient was noted to have positive Waddell's signs for symptom magnification and the patient had leg pain bilaterally; however, he ambulated normally and comfortably. The patient had positive tenderness from the suboccipital to the sacrum and an exaggerated response to very light touch. The patient had restricted range of motion with no muscle atrophy. The diagnoses were noted to include cervical contusion and back contusion. Subsequent documentation of 07/03/2013 was handwritten and difficult to read. However, it was discernible that the patient had low back pain with radiation to bilateral extremities, and it was indicated in the bilateral extremities the patient was standing and walking and was unable to sit or lay down. The strength was a grade IV weakness. The requested medications were for topical compounds and Medrox patches.

IMR ISSUES, DECISIONS AND RATIONALES

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

MEDROX PATCHES DISPENSED ON 06/18/13 AND 07/17/13: 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 Topical Salicylate, Topical Analgesic Page(s): 105,111.

Decision rationale: California MTUS indicates that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Additionally it indicates that topical salicylates are approved for chronic pain. According to the Medrox package insert, Medrox is a topical analgesic containing menthol 5.00% and 0.0375% capsaicin and it is indicated for the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness, and stiffness. Capsaicin is not approved and Medrox is being used for chronic pain. The clinical documentation submitted for review failed to indicate a necessity for 2 forms of capsaicin. There was a lack of documentation indicating that the patient had tried and failed antidepressants and anticonvulsants. Given the above, the request for Medrox Patches is not medically necessary.

TOPICAL COMPOUND FLURBIPROFEN/TRAMADOL PROVIDED ON 06/18/13 AND 07/17/13: 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 Flurbiprofen, Topical Analgesics, Tramadol Page(s): 72,111,82.

Decision rationale: The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. A thorough search of FDA.gov did not indicate there was a formulation of topical tramadol that had been FDA approved. The approved form of tramadol is for oral consumption, which is not recommended as a first line therapy. The clinical documentation submitted for review failed to indicate the patient had neuropathic pain. There

was a lack of documentation indicating the patient had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation indicating a necessity for 2 compounds with flurbiprofen. Given the above, the request for the topical cream is not medically necessary.

**COMPOUNDED TOPICAL CAPSAICIN/FLURBIPROFEN/METHYL SALICYLATE
DISPENSED ON 06/18/13 AND 07/17/13: 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 Flurbiprofen, Topical Analgesics, Topical Capsaicin, Topical Salicylates, pages Page(s): 72,111,.

Decision rationale: California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety, and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. California MTUS guidelines recommend topical salicylates. The clinical documentation submitted for review failed to indicate the necessity for 2 forms of capsaicin and 2 topicals with flurbiprofen. There was lack of documentation of trial and failure of antidepressants and anticonvulsants. There was lack of documentation indicating the patient was intolerant or had not responded to other treatments. Given the above, the request for Caps/Flur/Meth is not medically necessary.