

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM14-0032696 | | |
| Date Assigned: | 06/20/2014 | Date of Injury: | 04/14/2009 |
| Decision Date: | 03/16/2015 | UR Denial Date: | 02/12/2014 |
| Priority: | Standard | Application Received: | 03/14/2014 |

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, New York, Florida
 Certification(s)/Specialty: Internal Medicine, Pulmonary Disease, Critical Care 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 46-year-old male who reported an injury on 04/14/2009. The mechanism of injury was not provided. The prior studies were not provided. The documentation submitted for review was dated 11/08/2013 and it was a urinalysis. There was no physician notation or official documentation noted, with the exception of the urinalysis. There were no documented findings. The mechanism of injury, surgical history, and medications were not provided. There was no Request for Authorization.

IMR ISSUES, DECISIONS AND RATIONALES

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

Capsaicin 0.025%, Flurbiprofen 15%, Tramadol 15%, Menthol 2%, Camphor 2% 240 grams: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesic, Topical Capsaicin, Flurbiprofen, Tramadol Page(s): 105.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Capsaicin:

Recommended only as an option in patients who have not responded or are intolerant to other treatments. The guidelines recommend treatment with topical salicylates. 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. 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 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 injured worker had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation indicating the injured worker had not responded or was intolerant to other treatments. There was a lack of documentation indicating a necessity for 2 topical medications with tramadol. The request as submitted failed to indicate the body part to be treated and the frequency. There was a lack of documentation of exceptional factors. Given the above, the request for capsaicin 0.025%, flurbiprofen 15%, tramadol 15%, menthol 2%, camphor 2% 240 grams is not medically necessary.

Gabapentin 10%, Lidocaine 5%, Tramadol 15%, 240 grams: Overturned

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 Tramadol, page 82, Gabapentin, page 113, Topical Analgesics, page 111, Topical Salicylates.

Decision rationale: The California Medical Treatment Utilization Schedule indicates that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety... are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Salicylates are recommended. 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. Gabapentin: Not recommended. There is no peer-reviewed literature to support use. The guidelines indicate that topical lidocaine (Lidoderm) 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). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation indicating the injured worker had not responded or was intolerant to other treatments. There was a lack of documentation indicating a

necessity for 2 topical medications with tramadol. The request as submitted failed to indicate the body part to be treated and the frequency. There was a lack of documentation of exceptional factors. Given the above, the request for gabapentin 10%, lidocaine 5%, tramadol 15%, 240 grams is not medically necessary