

Case Number:	CM15-0006628		
Date Assigned:	01/26/2015	Date of Injury:	11/12/2008
Decision Date:	03/17/2015	UR Denial Date:	12/12/2014
Priority:	Standard	Application Received:	01/12/2015

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: Colorado

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:

The injured worker is a 37 year old female who sustained an industrial injury on 11/12/2008. The injured worker is complaining of severe left foot and ankle pain with reflex sympathetic dystrophy. Diagnoses include left lateral ankle sprain; status post ligament repair, reflex sympathetic dystrophy CRPS Type I, causalgia (CRPS Type II) status post nerve decompressions, and lumbar radiculopathy. A physician note dated 12/1/2014 documents the injured worker is noting an increase in the left foot pain. She continues to have allodynia, swelling and discoloration of the left foot. Ambulation is difficult and she is using a cane. Her average pain since her last visit is rated 10/10, and the foot pain radiates up to her back. She complains of burning stinging pain to her left lower extremity, and she has an antalgic gait and is wearing an open shoe. The treating provider is requesting a Trial PC5001 cream #150gm, and continued refill of Zanaflex 4mg #60. On 12/12/2014 the Utilization Review denied the request for Zanaflex 4mg #60, however, 1 month was allowed for weaning, citing California Medical Treatment Utilization Schedule (MTUS)-Chronic Pain Medical Treatment Guidelines. On 12/12/2014 Utilization review non-certified the request for a trial PC5001 cream #150gm, and cited California Medical Treatment Utilization Schedule (MTUS)-Chronic Pain Medical Treatment Guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zanaflex 4mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 63 and 66.

Decision rationale: Per the Guidelines, Tizanidine, a centrally acting muscle relaxant approved for use to treat spasticity, is recommended for musculoskeletal pain associated with spasm, but only for a short course. It has been shown to help low back pain in several studies and to help myofascial pain in one study. The antispasmodic / anti-spasticity drugs have diminishing effects over time, so are not recommended for long term use. No quality consistent evidence exists to support chronic use of Tizanidine. For the patient of concern, the records indicate patient has been using the Zanaflex long term, at bedtime. The records do not indicate any recent exam that confirms spasm for which Zanaflex would be used. The records clearly note that patient pain is consistently 9-10/10 so pain relief does not appear to be achieved with patient's current regimen which includes Zanaflex. As patient has no clear findings to warrant use of muscle relaxers, and as there is no evidence to support long term use of muscle relaxers, the Zanaflex is not medically indicated.

Trial PC5001 cream #150gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 111-113.

Decision rationale: Per the MTUS Guidelines, topical analgesics may be indicated for specific conditions when other therapies have failed. However, the guidelines make it clear that if a drug or drug class in a given topical compound is “not recommended,” then the entire compounded topical is not recommended. The requested compounded topical analgesic, PC5001, is not referenced through the FDA or other entity except in the UR peer review discussion with the treating physician, so the exact percentages of the components in the compound are not known. Per the treating physician, PC5001 includes Lidocaine/Gabapentin/Ketoprofen/Menthol. Per the MTUS Guidelines, Topical lidocaine in the dermal patch formulation, can be recommended for neuropathic pain after a trial of first line therapy has failed. No other formulation of topical Lidocaine is indicated for neuropathic pain. Other topical formulations of Lidocaine (creams or gels) may be useful as local anesthetic or anti-pruritic. There is insufficient evidence to recommend use of topical Lidocaine, any formulation, in non-neuropathic pain. Topical Non-steroidal anti-inflammatory drugs have been studied, but only short term in small numbers, so no substantive evidence supports long term use. Use of topical non-steroidal anti-inflammatory drugs can be recommended for less than 12 weeks, for treatment of osteoarthritis, specifically related to the knee or elbow. No consistent quality evidence exists to use topical non-steroidal

anti-inflammatory drugs for treatment of osteoarthritis of the spine, hip or shoulder, or for treatment of Neuropathic Pain. The only FDA-approved Topical Non-steroidal anti-inflammatory agent is Voltaren Gel 1% (diclofenac). Per the MTUS Guidelines, Gabapentin topical is not recommended. No studies support its use in topical preparations. The MTUS Guidelines do not address topical Menthol, which in this case is not relevant because the Gabapentin, Ketoprofen, and Lidocaine in cream formulation are not recommended, so the entire topical preparation is not recommended and not medically indicated.