

Case Number:	CM13-0044944		
Date Assigned:	12/27/2013	Date of Injury:	02/03/2010
Decision Date:	04/03/2015	UR Denial Date:	10/23/2013
Priority:	Standard	Application Received:	10/29/2013

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. 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: Arizona, California
 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:

This 63 year old female sustained a work related injury on 02/03/2010. A request for authorization dated 10/14/2013 was submitted for review. This was the only record provided for review. Cyclobenzaprine was being prescribed for palpable muscle spasms noted during the examination. The provider noted that the injured worker would also benefit from the off label capacity as a sleep aids as the chronic pain experienced did cause sleep disruption. The injured worker was provided a brief course of this in the past with noted improvement in spasms. The provider noted that there was an acute exacerbation of pain and spasms. Ondansetron was requested, and the provider noted that the injured worker had described relief of nausea with the use of this medication in the past. The provider also noted that there is a known side effect of nausea associated with Cyclobenzaprine which had also been prescribed. Terocin Patch was prescribed to assist with the treatment of mild to moderate acute or chronic aches or pain. On 10/23/2013, Utilization Review modified Cyclobenzaprine HCL 7.5mg tablets #120 and non-certified Ondansetron ODT 8mg tablets #30 x 2 and Terocin Patch #10. According to the Utilization Review physician in regard to Cyclobenzaprine, long term use of muscle relaxants are not supported in CA MTUS, and Official Disability Guidelines recommend use no longer than 2-3 weeks. In regard to Ondansetron, without documentation of nausea, the medical necessity was not established. In order for this medication to be considered for certification on subsequent review, evidence of measurable objective and/or functional benefit as a result of medication and documentation of medical necessity would be required. Official Disability Guidelines were referenced. In regard to Terocin patches, without documentation of failed trials of

anticonvulsant and antidepressants, unresponsiveness and intolerance to all other treatments as well as little evidence to utilize topical non-steroidal anti-inflammatory drugs for treatment of osteoarthritis of the spine, shoulder and hips, the medical necessity of the topical compound is not supported. CA MTUS Chronic Pain Medical Treatment Guidelines were referenced. The decision was appealed for an Independent Medical Review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobenzaprine HCL, 7.5mg tablets, #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain). Decision based on Non-MTUS Citation ODG-TWC Pain Procedure Summary, Non-Sedating Muscle Relaxants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

Decision rationale: According to the MTUS guidelines, Cyclobenzaprine (Flexeril) is more effective than placebo for back pain. It is recommended for short course therapy and has the greatest benefit in the first 4 days suggesting that shorter courses may be better. Those with fibromyalgia were 3 times more likely to report overall improvement, particularly sleep. Treatment should be brief. The addition of Cyclobenzaprine to other agents is not recommended. The claimant had been on Flexeril for an unknown length of time and was requested to continue for a prolonged period. Documentation of spasm response was not noted. The Flexeril use was not substantiated and is not medically necessary.

Ondansetron ODT, 8mg tablets, #30 with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC Pain Procedure Summary, Antiemetics (for opioid nausea).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Antiemetics, page 14.

Decision rationale: According to the ODG guidelines, antiemetics are not recommended for nausea and vomiting secondary to chronic opioid use. Zofran (Ondansetron) is a serotonin 5-HT₃ receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. In this case, the claimant does not have the above diagnoses and Ondansetron is not medically necessary.

Terocin Patches, #10: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: Terocin patch contains .025% Capsacin, 25% Menthyl Salicylate, 4% Menthol and 4% Lidocaine. According to the MTUS guidelines, topical analgesics are recommended as an option as indicated below. They are largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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. Lidocaine is 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). In this case, there is no documentation of failure of 1st line medications. In addition, other topical formulations of Lidocaine are not approved. Any compounded drug that is not recommended is not recommended and therefore Terocin patches are not medically necessary.