MAXIMUS Federal Services

Case Number:	CM15-0056553		
Date Assigned:	04/01/2015	Date of Injury:	05/26/2007
Decision Date:	05/07/2015	UR Denial Date:	02/27/2015
Priority:	Standard	Application Received:	03/25/2015

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 36 year old female, who sustained an industrial injury on 5/26/07. The injured worker has complaints of back pain. The documentation on 2/17/15 noted that her pain has slightly decreased with the cymbalta. The diagnoses have included lumbago; thoracic or lumbosacral neuritis or radiculitis; other symptoms referable to back and other postsurgical status. Treatment to date has included lidoderm patch and norco. The request was for Terocin external patch 12 hours on 12 hours off #30 and Retro Cyclobenzaprine 10mg #30 30 days UR DOS 2/18/15.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin external patch 12 hours on 12 hours off #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73.

Capsaicin, topical Page 28-29. Decision based on Non-MTUS Citation Terocin http://www.drugs.com/pro/terocin.html.

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. Besides Lidoderm, no other commercially approved topical formulation of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Further research is needed to recommend topical Lidocaine for chronic neuropathic pain disorders other than post-herpetic neuralgia. Topical Lidocaine is not recommended for non-neuropathic pain. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. 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. MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All 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. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC complete blood count and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Capsaicin is only an option in patients who have not responded or are intolerant to other treatments. Terocin is a topical analgesic, containing methyl salicylate, capsaicin, menthol and lidocaine hydrochloride. Medical records document that the patient's occupational injuries are chronic. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. Methyl salicylate is a NSAID. Medical records do not document a diagnosis of post-herpetic neuralgia, which is the only FDA approved indication for topical Lidocaine. The use of topical Lidocaine is not supported. There is no documentation that the patient has not responded or is intolerant to other treatments. Per MTUS, this is a requirement for the use of topical Capsaicin. Per MTUS guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for Terocin is not supported by MTUS guidelines. Therefore, the request for Terocin is not medically necessary.

Retro Cyclobenzaprine 10mg #30 30 days UR DOS 2/18/15: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-49,Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Pages 41-42. Muscle relaxants Pages 63-66. Decision based on Non-MTUS Citation FDA Prescribing Information Cyclobenzaprine http://www.drugs.com/pro/flexeril.html.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) addresses muscle relaxants. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) states that muscle relaxants seem no more effective than NSAIDs for treating patients with musculoskeletal problems, and using them in combination with NSAIDs has no demonstrated benefit. Muscle relaxants may hinder return to function by reducing the patient's motivation or ability to increase activity. Table 3-1 states that muscle relaxants are not recommended. Chronic Pain Medical Treatment Guidelines addresses muscle relaxants. Muscle relaxants should be used with caution as a second-line option for short-term treatment. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. According to a review in American Family Physician, muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Chronic Pain Medical Treatment Guidelines state that Cyclobenzaprine (Flexeril) is an option for a short course of therapy. Treatment should be brief. The addition of Cyclobenzaprine to other agents is not recommended. FDA guidelines state that Cyclobenzaprine is indicated for acute musculoskeletal conditions. Cyclobenzaprine should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available. Medical records document that the patient's occupational injuries are chronic. MTUS, ACOEM, and FDA guidelines do not support the use of Cyclobenzaprine (Flexeril) for chronic conditions. The use of Cyclobenzaprine (Flexeril) is not supported by MTUS or ACOEM guidelines. Therefore, the request for Cyclobenzaprine (Flexeril) is not medically necessary.