

Case Number:	CM15-0020427		
Date Assigned:	02/10/2015	Date of Injury:	09/01/2010
Decision Date:	03/30/2015	UR Denial Date:	01/06/2015
Priority:	Standard	Application Received:	02/03/2015

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 51 year old female, who sustained an industrial injury on 9/1/2010. She has reported shoulder pain subsequently involving the right wrist and elbow. The diagnoses have included right shoulder pain, right wrist pain, and elbow pain, and depression. Treatment to date has included Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), muscle relaxer, physical therapy, acupuncture and home exercise. Currently, the IW complains of neck and shoulder pain associated with numbness. On physical examination 10/6/14, the provider documented tenderness to C2-T9 on right side, limited Range of Motion (ROM) to neck and right arm. The plan of care included continuation of medication therapy, acupuncture, and physical therapy. On 1/6/2015 Utilization Review non-certified Flexeril, Terocin, and Relafen, noting the recommendations that medications are not for long term extended use. The MTUS Guidelines were cited. On 2/3/2015, the injured worker submitted an application for IMR for review of Flexeril, Terocin, and Relafen.

IMR ISSUES, DECISIONS AND RATIONALES

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

Relafen: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal Anti-Inflammatory Drugs (NSAIDs), Osteoarthritis (in.

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

Decision rationale: Medical Treatment Utilization Schedule (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. All NSAIDs have the potential to raise blood pressure in susceptible patients. The greatest risk appears to occur in patients taking the following anti-hypertensive therapy: angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers, beta-blockers, or diuretics. Medical records indicate the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. The psychiatric evaluation report dated 10/22/14 documented a diagnosis of hypertension managed with Diovan. Per MTUS, NSAIDs are associated with the risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. MTUS guidelines warn against the use of NSAIDs with patients with hypertension. Long-term NSAID use is not recommended by MTUS. The use of the NSAID Relafen is not supported by MTUS guidelines. Therefore, the request for Relafen is not medically necessary.

Terocin: 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 Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73.. 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. All NSAIDs have the potential to raise blood pressure in susceptible patients. The greatest risk appears to occur in patients taking the following anti-hypertensive therapy: angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers, beta-blockers, or diuretics. 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 indicate the long-term use of NSAIDs. 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. The psychiatric evaluation report dated 10/22/14 documented a diagnosis of hypertension managed with Diovan. Per MTUS, NSAIDs are associated with the risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. MTUS guidelines warn against the use of NSAIDs with patients with hypertension. Long-term NSAID use is not recommended by MTUS. The use of a NSAID is not supported by MTUS guidelines. 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.

Flexeril: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxant (for pain), Cyclobenzaprine (Flexeril) Page(s): 63.

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 Flexeril 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 Flexeril (Cyclobenzaprine) for chronic conditions. Medical records indicate the long-term use of muscle relaxants including Flexeril, which is not supported by MTUS and FDA guidelines. The patient has been prescribed NSAIDs. Per MTUS, using muscle relaxants in combination with NSAIDs has no demonstrated benefit. The use of Flexeril is not supported by MTUS or ACOEM guidelines. Therefore, the request for Flexeril is not medically necessary.