

Case Number:	CM15-0190501		
Date Assigned:	10/02/2015	Date of Injury:	08/05/2011
Decision Date:	11/18/2015	UR Denial Date:	08/31/2015
Priority:	Standard	Application Received:	09/28/2015

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: Texas, 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:

The injured worker is a(n) 39 year old male, who sustained an industrial injury on 8-5-11. The injured worker was diagnosed as having headaches, lumbar radiculopathy, right knee medial meniscus tear and right ankle joint derangement. The physical exam (3-23-15 through 7-20-15) revealed 4-8 out of 10 pain, decreased lumbar and right knee range of motion, a positive straight leg raise test bilaterally and decreased sensation to pin-prick and light touch at the L4, L5 and S1 dermatomes bilaterally. Treatment to date has included a lumbar, right ankle and right knee MRI on 6-23-15, Tabradol, Cyclobenzaprine, Ketoprofen (since at least 3-23-15). As of the PR2 dated 8-21-15, the injured worker reports pain in his lower back, right knee, right ankle and headaches. He rates his pain 5-8 out of 10. There is no documentation that the injured worker has tried and failed oral pain medications. Objective findings include decreased lumbar and right knee range of motion, a positive straight leg raise test bilaterally and decreased sensation to pin-prick and light touch at the L4, L5 and S1 dermatomes bilaterally. The treating physician requested Tabradol, Cyclobenzaprine, Ketoprofen. On 8-21-15 the treating physician requested a Utilization Review for Tabradol, Cyclobenzaprine, Ketoprofen. The Utilization Review dated 8-31-15, non-certified the request for Tabradol, Cyclobenzaprine, Ketoprofen. The patient's surgical history includes right knee surgery in 2011. The medication list include Tabradol 1mg/ml oral suspension, that contains Cyclobenzaprine, Cyclobenzaprine cream, Synapryn, Fanatrex, Dicopanor, Deprizine and Ketoprofen cream. Patient had received ESI for this injury. A recent detailed clinical examination of the gastrointestinal tract was not specified in the records provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tabradol 1mg/ml Oral Suspension 500ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Cyclobenzaprine (Flexeril).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, MSM (methylsulfonylmethane) See CRPS, medications, DMSO, DMSO (dimethylsulfoxide) See CRPS, medications.

Decision rationale: Tabradol contains cyclobenzaprine hydrochloride in oral suspension form along with methylsulfonylmethane (MSM). MSM is also known by another name - DMSO Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant. According to California MTUS, Chronic pain medical treatment guidelines, Cyclobenzaprine is "Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. This medication is not recommended to be used for longer than 2-3 weeks." According to the cited guidelines cyclobenzaprine is recommended for short term therapy and not recommended for longer than 2-3 weeks. In addition, the rationale for prescribing these medications, in suspension form is not specified in the records provided. Inability to take the tablet form of the medication is not specified in the records provided. A detailed valid rationale for combining the cyclobenzaprine with methylsulfonylmethane (MSM) was not specified in the records provided. Per the cited guidelines, regarding MSM or DMSO, "CRPS medications because long-term controlled studies have not been conducted, DMSO should be considered investigational and used only after other therapies have failed. (FDA, 2010)" The presence of CRPS is not specified in the records provided. The failure of other therapies was not specified in the records provided. The medical necessity of MSM or DMSO is not fully established in this patient. The request for Tabradol 1mg/ml oral suspension is not medically necessary.

Cyclobenzaprine 5% Cream, 110 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Cyclobenzaprine (Flexeril).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: According to the MTUS Chronic Pain Guidelines regarding topical analgesics state that the use of topical analgesics is "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." Cyclobenzaprine is a muscle relaxant. Per the cited guidelines, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. A trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Intolerance or contraindication to oral medications was not specified in the records provided. Evidence of diminished effectiveness of oral medications was not specified in the records provided. Topical Cyclobenzaprine is not recommended in this patient. The request for the topical medication Cyclobenzaprine 5% Cream, 110 grams is not medically necessary.

Ketoprofen 20% Cream, 167 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, specific drug list & adverse effects. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), NSAIDs (Non-Steroidal Anti-Inflammatory Drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: According to the MTUS Chronic Pain Guidelines regarding topical analgesics state that the use of topical analgesics is "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." MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. A trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Intolerance or contraindication to oral medications was not specified in the records provided. Evidence of diminished effectiveness of oral medications was not specified in the records provided. Ketoprofen is a NSAID. Per the cited guidelines, "Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis." Topical Ketoprofen is not recommended in this patient. The request for the topical medication Ketoprofen 20% Cream, 167 grams is not medically necessary.