

Case Number:	CM15-0209533		
Date Assigned:	10/28/2015	Date of Injury:	05/22/2014
Decision Date:	12/15/2015	UR Denial Date:	09/23/2015
Priority:	Standard	Application Received:	10/23/2015

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 was a 44 year old male, who sustained an industrial injury, May 22, 2014. The injured worker was undergoing treatment for lumbar disc displacement, HNP (herniated nucleus pulposus), radiculitis of the lower extremity, lumbar spine degenerative disc disease, Schmorl's node at L5, lumbar radiculopathy, and lumbar spine strain and strain. According to progress note of July 30, 2015, the injured worker's chief complaint was burning, radicular low back pain and muscle spasms. The pain was rated at 7 out of 10. The pain was constant, moderate to severe. The pain was associated with numbness and tingling of the bilateral lower extremities, greater on the right side. The pain was aggravated by prolonged positioning including sitting, standing, walking, bending, raising from a seated position, ascending and descending stairs and stooping. The pain was aggravated by activities of daily living. The objective findings were normal lordosis of the lumbar spine. There was tenderness with palpation at the lumbar spine muscles. There was trigger points noted. There was decreased range of motion in all range of motion of the lumbar spine. The slightly decreased sensation to pin- prick and light touch at the L4, L5 and S1 dermatomes bilaterally. The motor strength was 4 out of 5 in all the represented muscle groups in the bilateral lower extremities. The injured worker previously received the following treatments Tabradol 1mg-ml 250ml since March 23, 2015; Synapryn 10mg-1 ml 500ml since March 23, 2015; Cyclobenzaprine 5% cream 110 grams since February 23, 2015, physical exam, lumbar spine MRI on May 21, 2015 and x-rays of the lumbar spine on October 22, 2014. Per the note dated 8/31/15 the patient had complaints of low back pain with radiation, numbness, tingling and muscle spasm. The patient has had MRI of the

lumbar spine on 5/31/15 that revealed disc protrusions, foraminal narrowing, and degenerative changes. The medication list includes Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Gabapentin and Cyclobenzaprine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobenzaprine 5% cream 110 grams: Upheld

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

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

Decision rationale: Cyclobenzaprine 5% cream 110 grams. 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. The medication list contains Gabapentin. The detailed response of the Gabapentin for this injury was not specified in the records provided. Intolerance or contraindication to oral medications was not specified in the records provided. Evidence of diminished effectiveness of medications was not specified in the records provided. 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. Topical Cyclobenzaprine is not recommended by MTUS. The medical necessity of the medication Cyclobenzaprine 5% cream 110 grams is not fully established in this patient therefore is not medically necessary.

Synapryn 10 mg/1 ml 500 ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for neuropathic pain.

Decision rationale: Synapryn 10 mg/1 ml 500 ml. California MTUS Chronic Pain Medical Treatment Guidelines, Page 50, Glucosamine (and Chondroitin Sulfate). Synapryn contains tramadol and glucosamine in oral suspension form. Tramadol is a centrally acting synthetic opioid analgesic. According to MTUS guidelines Central acting analgesics: an emerging fourth class of opiate analgesic that may be used to treat chronic pain. This small class of synthetic opioids (e.g., Tramadol) exhibits opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Central analgesics drugs such as Tramadol (Ultram) are reported to be effective in managing neuropathic pain. (Kumar, 2003)

Cited guidelines also state that, a recent consensus guideline stated that opioids could be considered first-line therapy for the following circumstances: (1) prompt pain relief while titrating a first-line drug; (2) treatment of episodic exacerbations of severe pain. The rationale for prescribing drugs in suspension form is not specified in the records provided. Inability to take the tablet form is not specified in the records provided. The rationale for the use of the tramadol on a daily basis without documented consistent improvement in function is not specified in the records provided. The rationale for combining the tramadol with glucosamine is not specified in the records provided. According to the Chronic Pain Medical Treatment Guidelines MTUS, Glucosamine (and Chondroitin Sulfate) is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. The Glucosamine Chondroitin Arthritis Intervention Trial (GAIT) funded by the National Institutes of Health concluded that glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing knee pain in the study group overall; however, these may be effective in combination for patients with moderate-to-severe knee pain. Despite multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee), controversy on efficacy related to symptomatic improvement continues. Therefore there is no high grade scientific evidence to support the use of Glucosamine for this patient. The response to prior use of Glucosamine was not specified in the records provided. The medical necessity of Synapryn 10 mg/1 ml 500 ml is not established for this patient therefore is not medically necessary.

Tabradol 1 mg/ml 250 ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

MAXIMUS 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 chapter MSM (methylsulfonylmethane) See CRPS, medications, DMSO. DMSO (dimethylsulfoxide). See CRPS, medications.

Decision rationale: Tabradol 1 mg/ml 250 ml 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 medical necessity of Tabradol 1 mg/ml 250 ml is not established for this patient therefore is not medically necessary.