

Case Number:	CM14-0211031		
Date Assigned:	12/24/2014	Date of Injury:	07/05/2014
Decision Date:	02/20/2015	UR Denial Date:	12/09/2014
Priority:	Standard	Application Received:	12/16/2014

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:

This is a 45 year old female patient who sustained a work related injury on 7/5/14. Patient sustained the injury due to slip and fall incident. The current diagnoses include lumbar sprain and hip contusion. Per the doctor's note dated 11/13/14, patient has complaints of burning radicular pain and muscle spasms of low back at 7/10 and burning left hip pain at 7/10. Physical examination revealed restriction with lumbar flexion, extension, and rotation, tenderness at the anterior aspect of the hip with diminished range of motion, Faber's test was positive. The physical exam also states L2; L3, L4, L5, and S1 myotomes decreased motor strength secondary to pain and sensory and reflex examinations were normal. The current medication lists include Flexeril and Ibuprofen. The patient has had X-ray of the lumbar spine and left hip; MRI of the low back on 7/22/14 that revealed bulging of discs without stenosis; MRI of the hip on 8/4/14 that revealed labral tear and bursitis. Any surgical or procedure note related to this injury were not specified in the records provided. The patient has received an unspecified number of PT visits for this injury.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% cream 165gm: 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 Chronic Pain - Topical Analgesics. Page(s): 111-112.

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.... 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." MTUS guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. Any trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Any intolerance or contraindication to oral medications was not specified in the records provided. Ketoprofen is a NSAID. Per the cited guidelines, " Non-steroidal ant inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration". The medical necessity of the request for Ketoprofen 20% cream 165gm is not fully established in this patient.

Cyclobenzaprine 5% cream 100gm: 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 Chronic Pain - Topical Analgesics. Page(s): 111-112.

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. Any trial of antidepressants and anticonvulsants for these symptoms were not specified in the records provided. Any intolerance or contraindication to oral medications was not specified in the records provided. Any 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."In addition, as cited above, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Cyclobenzaprine is not recommended by MTUS.The medical necessity of the medication Cyclobenzaprine 5% cream 100gm is not fully established in this patient.

Synapryn 10mg/1ml suspension 500ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugsdb.eu/drug.php?d=synapryn&m=fusion%20pharmaceuticals%20llc&=7bdbe51a-e381-4d83-ba8e-a7562cd650f.xml>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Central acting analgesics, Opioids for neuropathic pain, Glucosamine (and Chondroitin Sulfate) P.

Decision rationale: 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; [&] (3) treatment of neuropathic cancer pain. "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. Any evidence of osteoarthritis was not specified in the records provided. Any X-ray report was also not specified in the records provided. In addition, response to prior use of Glucosamine was not specified in the records provided. The medical necessity of Synapryn 10mg/1ml oral suspension 500ml is not established for this patient.

Deprizine 15mg/ ml oral suspension 250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/deprizine.html>

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Thomson Micromedex Ranitidine(zantac) Hydrochloride-FDA-Labeled Indications

Decision rationale: Deprizine contains ranitidine hydrochloride in oral suspension form. According to the Thomson Micromedex , FDA labeled indications for ranitidine are "Duodenal ulcer disease, Duodenal ulcer disease, Maintenance, Erosive esophagitis, Gastric hypersecretion, Gastric ulcer, Gastric ulcer, Maintenance, Gastroesophageal reflux disease, Helicobacter pylori gastrointestinal tract infection, Indigestion, Non-ulcer, Zollinger-Ellison syndrome." Any of the above listed indications in this patient is not specified in the records provided. Rationale for prescribing this drug in a 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. The medical necessity of Deprizine 15mg/ml oral suspension 250ml is not established for this patient.

Dicopanol 5mg/ml oral suspension 150ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation
<http://www.drugs.com/cdi/dlphenhydramine.html>

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Thompson Micromedex FDA labeled indication-diphenhydramine

Decision rationale: The active ingredient of diclopanol is diphenhydramine hydrochloride in suspension form. Per the cited guidelines (ODG), "Over-the-counter medications: Sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness." A detailed evaluation of insomnia in this patient was not specified in the records provided. The presence or absence of side effects of the use of diclopanol (diphenhydramine) in this patient was not specified in the records provided. According to the Thomson Micromedex FDA labeled indication for the diphenhydramine includes "Chemotherapy-induced nausea and vomiting, extra pyramidal disease - Medication-induced movement disorder, Hyperemesis gravidarum." Any indication listed above that would require the use of diphenhydramine is not specified in the records provided. In addition, rationale for prescribing the medication 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. The medical necessity of Dicopanol (diphenhydramine) 5mg/ml oral suspension 150ml is not fully established for this patient at this time.

Fanatrex 25mg/ ml oral suspension 420ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 18-19.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin (Neurontin, Gabarone, generic available). Page(s): 18-19.

Decision rationale: Fanatrex contains gabapentin in oral suspension form. Gabapentin is an anti-epileptic drug. According to the CA MTUS Chronic pain guidelines "Gabapentin (Neurontin) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain." Per the cited guidelines, "CRPS: Recommended as a trial. (Serpell, 2002)Fibromyalgia: Recommended as a trial. (Arnold, 2007)Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement found in walking distance, pain with movement, and sensory deficit found in a pilot study" The rationale for prescribing the medication 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. The medical necessity of Fanatrex 25mg/ ml oral suspension 420ml is not fully established for this patient at this time.

Tabradol 1mg/ml oral suspension 250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation
<http://dailymed.nlm.nih.gov/dailymed/archives/fdadruginfo.cfm?archivelid=22434>
<http://www.ncbi.nlm.nih.gov/pubmed/16309928>
<http://en.wikipedia.org/wiki/Methylsulfonylmethane>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available). Page(s): 64. Decision based on Non-MTUS Citation MSM (methylsulfonylmethane) See CRPS, medications, DMSO. DMSO (dimethylsulfoxide). See CRPS, medications

Decision rationale: Tabradol contains cyclobenzaprine hydrochloride in oral suspension form along with methyl sulfonyl methane (MSM). MSM is also known by another name - DMSO (dimethylsulfoxide). 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, 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 methyl sulfonyl methane (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 1mg/ml oral suspension 250ml is not established for this patient.