

Case Number:	CM15-0123918		
Date Assigned:	07/08/2015	Date of Injury:	08/27/2003
Decision Date:	08/25/2015	UR Denial Date:	06/16/2015
Priority:	Standard	Application Received:	06/29/2015

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:

This is a 52-year female patient who sustained an industrial injury on August 27, 2003. The diagnoses include lumbar spine sprain/strain rule out herniated nucleus pulposus, lumbar radiculopathy, bilateral knee sprain/strain rule out internal derangement, and status post bilateral knee surgery with residual pain. She sustained the injury due to cumulative trauma. Per the doctor's note dated 2/23/2015, she had complaints of low back pain with radiation to the left hip and bilateral knee pain. The physical examination revealed tenderness to palpation at the lumbar paraspinal muscles, decreased range of motion was decreased, tenderness to palpation over the medial and lateral joint line, decreased range of motion to both the right and left knee with flexion and slight decreased sensation to pin prick and light touch at the L4, L5, and S1, dermatomes bilaterally. Patient was prescribed deprizine, dicoprofol, synapryn, tabradol, fanatrex and topical analgesic creams. She has undergone 3 knee surgeries. She has had physical therapy visits for this injury. The treatment request included medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% Cream 165grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, pages 111-113, Ketoprofen is an NSAID.

Decision rationale: Ketoprofen 20% Cream 165grams; the MTUS Chronic Pain Guidelines regarding topical analgesics state, "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. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, and antidepressants). (Argoff, 2006) 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. Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis." The cited guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. Failure of antidepressants and anticonvulsants for this injury is not specified in the records provided. Intolerance to oral medication is not specified in the records provided. In addition, ketoprofen is not recommended by the cited guidelines for topical use as cited because of the absence of high-grade scientific evidence to support their effectiveness. The medical necessity of Ketoprofen 20% Cream 165grams is not fully established for this patient.

Cyclobenzaprine 5% Cream 100grams; Tabradol 1mg/ MI 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, pages 111-113, Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available), page 64. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 07/15/15) MSM (methylsulfonylmethane) See CRPS, medications, DMSO. DMSO (dimethylsulfoxide). See CRPS, medications.

Decision rationale: Cyclobenzaprine 5% Cream 100grams; Tabradol 1mg/MI 250ml and Regarding Tabradol 1mg/MI 250ml Cyclobenzaprine is a muscle relaxant. The MTUS Chronic Pain Guidelines regarding topical analgesics state, "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. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, and antidepressants). (Argoff, 2006) 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. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." The cited guidelines recommend topical analgesics for neuropathic pain only when trials of antidepressants and anticonvulsants have failed to relieve symptoms. Failure of antidepressants and anticonvulsants

for this injury is not specified in the records provided. Intolerance to oral medication is not specified in the records provided. In addition, cyclobenzaprine is not recommended by the cited guidelines for topical use as cited because of the absence of high-grade scientific evidence to support their effectiveness. The medical necessity of Cyclobenzaprine 5% Cream 100grams is not fully established for this patient. Regarding Tabradol 1mg/MI 250ml: 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, rationale for prescribing drugs, 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 1mg/MI 250ml is not established for this patient.

Synapryn 10mg/1ml Oral Suspension 500ml, Dicopanol 5mg/MI Oral Suspension 150 MI 150ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Central acting analgesics, page 75, Opioids for neuropathic pain, page 82. Decision based on Non- MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 07/15/15) Insomnia treatment, Other Medical Treatment Guideline or Medical Evidence Thompson Micromedex FDA labeled indication-diphenhydramine.

Decision rationale: Synapryn 10mg/1ml Oral Suspension 500ml, Dicopanol 5mg/MI Oral Suspension 150 MI 150ml. Regarding synapryn, 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. The medical necessity of Synapryn 10mg/1ml Oral Suspension 500ml is not established for this patient. Regarding diclopanol: 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 Thompson 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 Diclopanol 5mg/ml Oral Suspension 150ml is not fully established for this patient at this time.

Deprizine 15mg/ML Oral Suspension 50/250ml, Fanatrex 25mg/ML Oral Suspension 420ml:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin (Neurontin, Gabarone, generic available) page(s) 18-19. Decision based on Non-MTUS Citation Thompson Micromedex Ranitidine (zantac) Hydrochloride-FDA-Labeled Indications Regarding deprizine.

Decision rationale: Deprizine 15mg/ML Oral Suspension 50/250ml, Fanatrex 25mg/ML Oral Suspension 420ml. Deprizine contains ranitidine hydrochloride in oral suspension form. According to the Thompson 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 drugs 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 Deprizine 15mg/ML Oral Suspension 50/250ml is not established for this patient. Regarding Fanatrex; 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.