

<b>Case Number:</b>	CM14-0087658		
<b>Date Assigned:</b>	08/06/2014	<b>Date of Injury:</b>	08/04/2005
<b>Decision Date:</b>	09/25/2014	<b>UR Denial Date:</b>	05/20/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/11/2014

### 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. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 patient is a 51-year-old female who sustained injuries to her shoulders when lifting a heavy table on 08/16/05 while employed as a housekeeper. She had two surgeries of the right shoulder, last one was done on 03/04/09. The patient complains of neck pain and muscle spasms as constant, moderate to severe, 7-8/10 radiating pain, numbness and tingling of the bilateral upper extremities, greater in the left. She is status post right shoulder rotator cuff repair with residual pain; burning bilateral shoulder pain radiating down the arm/fingers with muscle spasms, pain rated as 7-8/10 bilaterally. Bilateral shoulder pain is sharp, stabbing and frequent constant moderate to severe. The medications give her temporary relief. There are well-healed surgical incisions at the right shoulder, crepitus and tenderness at acromioclavicular (AC) joint subacromial space bilaterally. The patient had AC joint arthrosis, decreased range of motion of shoulders secondary to pain, a positive Neer impingement test bilaterally and decreased sensation and motor strength. The patient's diagnoses included cervical spine pain, cervical spine radiculopathy, a left shoulder rotator cuff tear, status post right shoulder rotator cuff repair and bilateral shoulder AC arthrosis. Recent treatment included medication management and subacromial injections. She was prescribed Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, capsaicin, Flurbiprofen, Tramadol, Menthol and was awaiting EMG/NCV studies of bilateral upper extremities. The UR included requests for Deprizine, Tramadol, Capsaicin, Menthol, Cyclobenzaprine, Fanatrex, Tabradol, Synapryn, Terocin Patches, Flurbiprofen and Dicopanol, ; all which were denied due to lack of medical necessity.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Deprizine (quantity and dosage unspecified): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation website, <http://www.webmd.com/drugs/2/drug-153722/deprizine-oral/details/list-conditions>.

**Decision rationale:** The MTUS ACOEM and Non-MTUS ODG do not address the issue. Deprizine (Ranitidine) is used for the treatment of Increased Stomach Acid from Systemic Mastocytosis, Benign Tumors of the Hormone Producing Glands, Zollinger-Ellison Syndrome, and Inflammation of the Esophagus with erosion (i.e. duodenal ulcer). In this case, there is no documentation of any of the required diagnoses. There is no evidence of gastritis or GI upset. Furthermore, the injured worker is not at high risk for development of peptic ulcer (age > 65 years; history of peptic ulcer, GI bleeding or perforation; concurrent use of aspirin (ASA), corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID) in which proton pump inhibitor (PPI) is recommended. Therefore, the medical necessity of the requested medication is not established based on the available clinical information.

**Tramadol (quantity and dosage unspecified): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111.

**Decision rationale:** According to the California MTUS Guidelines, Tramadol (Ultram) is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic, it is indicated for moderate to severe pain. Tramadol is not approved for topical use as there is no research based evidence to demonstrate its efficacy. Therefore, the medical necessity of Tramadol has not been established.

**Capsaicin (quantity and dosage unspecified): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111.

**Decision rationale:** According to the California MTUS guidelines, topical analgesics are an option with specific indications, many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents, as they

are largely experimental. Topical analgesics Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. In the absence of documented failure of other medication and any significant treatment intolerance, the request is not medically necessary according to the guidelines.

**Menthol (quantity and dosage unspecified): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111.

**Decision rationale:** According to the California MTUS guidelines, topical analgesics are an option with specific indications, many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents, as they are largely experimental. There is no evidence based guidelines to demonstrate the efficacy of Menthol in the form of topical compounded cream. The request is not medically necessary according to the guidelines.

**Cyclobenzaprine (quantity and dosage unspecified): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111.

**Decision rationale:** According to the California MTUS guidelines, topical analgesics are recommended as a treatment option as these agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control. 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. According to the California MTUS guidelines, muscle relaxants, such as Cyclobenzaprine, are not recommended in topical formulation. As per the guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Consequently, the request is not medically necessary according to the guidelines.

**Fanatrex (quantity and dosage unspecified): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines  
Gabapentine Page(s): 18.

**Decision rationale:** Fanatrex is a combination of Gabapentin and glucosamine sulphate. As per California MTUS guidelines, Gabapentin may be used for a first-line treatment for neuropathic pain. The records review indicates that this patient has neuropathic pain (radiculopathy), however, it is unclear as to why the patient is unable to take pill or capsule orally, which is the commercially available form of Gabapentin. Also, there is no rationale for glucosamine sulphate. Therefore, the request for Fanatrex is not medically necessary and is not medically necessary.

**Tabradol (quantity and dosage unspecified):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines  
Cyclobenzaprine Page(s): 41.

**Decision rationale:** Tabradol contains Methsulfonylemethane (MSM) and Cyclobenzaprine. As per California MTUS guidelines, Cyclobenzaprine is recommended for a short course of therapy for the treatment of acute exacerbations in patients with chronic low back pain. There is no documentation of substantial spasm refractory to first line treatment. Additionally, it is unclear as to why the employee is unable to take a pill form of Cyclobenzaprine. Also, there is no mention of indication for Methsulfonylemethane (MSM) in this injured worker. As such, the request for Tabradol is not medically necessary and is not medically necessary.

**Synapryn (quantity and dosage unspecified):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 76-94.

**Decision rationale:** Synapryn contains Tramadol hydrochloride and Glucosamine as active ingredients. According to the California MTUS Guidelines, Tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic, it is indicated for moderate to severe pain. Furthermore, there is no mention of any indication for Glucosamine in this injured worker. Therefore, the request is not medically necessary.

**Terocin Patches (quantity and dosage unspecified):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111.

**Decision rationale:** According to the references, Terocin patches contain Lidocaine and Menthol. The California MTUS state only Lidocaine in the formulation of Lidoderm patch may be considered for localized peripheral pain; such as shingles and painful diabetic polyneuropathy, after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica). The guidelines state no other commercially approved topical formulations of Lidocaine are indicated for neuropathic pain. Topically applied Lidocaine is not recommended for non-neuropathic pain. The medical records do not establish this topical patch is appropriate and medically necessary for this patient. The request of Terocin Patches is not medically necessary.

**Fluriprofen (quantity and dosage unspecified):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111.

**Decision rationale:** According to the California MTUS guidelines, topical analgesics are an option with specific indications, many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents, as they are largely experimental. There is no research based evidence to demonstrate the long term efficacy of topical NSAIDs. The California MTUS and ODG states that the only NSAID that is FDA approved for topical application is Diclofenac (Voltaren 1% Gel). It states that Flurbiprofen is not approved for topical use. Therefore, the medical necessity of this compounded topical product is not established.

**Dicoprofanol (quantity and dosage unspecified):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:<http://www.webmd.com/drugs/2/drug-153723/dicoprofanol-oral/details>.

**Decision rationale:** The MTUS, ACOEM and ODG do not address the issue. Dicoprofanol, is Diphenhydramine oral suspension, used for the treatment of Parkinson Symptoms, Parkinson's Disease, extrapyramidal reaction, allergic conjunctivitis, inflammation of the nose due to an allergy, stuffy nose, itching, welt from pressure on skin, hives, sensation of spinning or whirling, chronic trouble sleeping, sneezing, cough, nausea and vomiting, motion sickness, life threatening allergic reaction. In this case, there is no substantial evidence of any of the above conditions.

Furthermore, commercial form of Diphenhydramine is available. Thus, the request is considered not medically necessary.