

Case Number:	CM15-0186745		
Date Assigned:	10/07/2015	Date of Injury:	09/28/2010
Decision Date:	11/19/2015	UR Denial Date:	09/16/2015
Priority:	Standard	Application Received:	09/22/2015

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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) 61 year old female, who sustained an industrial injury on 9-28-10. The injured worker was diagnosed as having status post left carpal tunnel release in 1-2013, status post left thumb A-1 pulley release in 5-2013, left lateral epicondylitis, left ulnar neuropathy and left De Quervain's disease. As of the PR2 dated 8-21-15, the injured worker reports pain in her left elbow, left thumb, left wrist and hand. She indicated that the Kenalog injection of the left elbow helped 80%. Objective findings include increased edema and deformity of the left basal joint, increased pain with rotation and subluxation of the basal joint and "decreased range of motion with radial and palmar abduction. Current medications include Fexmid, Maxalt, Lunesta, Prilosec, Amitriptyline 10%, Gabapentin 10%, Bupivacaine 5%, Hyaluronic Acid 0.2% and Flurbiprofen 20%, Baclofen 10%, Dexamethasone Micro 0.2%, Hyaluronic Acid 0.2%. Treatment to date has included several cortisone injections to the left elbow and thumb. The treating physician requested Amitriptyline 10%, Gabapentin 10%, Bupivacaine 5%, Hyaluronic Acid 0.2% cream base 240gms, Flurbiprofen 20%, Baclofen 10%, Dexamethasone Micro 0.2%, Hyaluronic Acid 0.2% 240gms and durable medical equipment. The Utilization Review dated 9- 16-15, non-certified the request for Amitriptyline 10%, Gabapentin 10%, Bupivacaine 5%, Hyaluronic Acid 0.2% cream base 240gms, Flurbiprofen 20%, Baclofen 10%, Dexamethasone Micro 0.2%, Hyaluronic Acid 0.2% 240gms and durable medical equipment.

IMR ISSUES, DECISIONS AND RATIONALES

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

Amitriptyline 10 percent, Gabapentin 10 percent, Bupivacaine 5 percent, Hyaluronic Acid 0.2 percent cream base 240gms apply 2-3 times daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: Based on the 08/21/15 progress report provided by treating physician, the patient presents with pain in to the left elbow, left thumb, left wrist and hand. The patient is status post left carpal tunnel release in January 2013, and left thumb A-1 pulley release in May 2013. The request is for AMITRIPTYLINE 10 PERCENT, GABAPENTIN 10 PERCENT, BUPIVACAINE 5 PERCENT, HYALURONIC ACID 0.2 PERCENT CREAM BASE 240GMS APPLY 2-3 TIMES DAILY. RFA with the request not provided. Patient's diagnosis per Request for Authorization form dated 08/21/15 includes other tenosynovitis of hand and wrist. Physical examination on 08/21/15 revealed edema and deformity of the left basal joint, increased pain with rotation and subluxation of the basal joint and decreased range of motion with radial and palmar abduction. Treatment to date has included surgery, injections and medications. Patient's medications include Fexmid, Maxalt, Lunesta, Prilosec and topical creams. Patient's work status not provided. MTUS, Topical Analgesics section, page 111 has the following: Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine whether creams, lotions or gels- are indicated for neuropathic pain. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Analgesics: Non-steroidal antiinflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Per 08/21/15 report, treater states " Directions: Apply a thin layer 2-3 times/day as needed for pain...It is our professional medical opinion that the compounded transdermal cream prescribed is medically necessary for our patient's diagnosis..." MTUS page 111 states that if one of the compounded topical products is not recommended, then the entire product is not. In this case, the requested topical compound contains Gabapentin and Bupivacaine, which are not supported for topical use in lotion form, per MTUS. Furthermore, there is no support for anti-depressant such as

Amitriptyline or hyaluronic acid for topical use in neither MTUS nor ODG. This request is not in accordance with guideline indications. Therefore, this request IS NOT medically necessary.

Flurbiprofen 20 percent, Baclofen 10 percent, Dexamethasone Micro 0.2 percent, Hyaluronic Acid 0.2 percent apply 2-3 times daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: Based on the 08/21/15 progress report provided by treating physician, the patient presents with pain in to the left elbow, left thumb, left wrist and hand. The patient is status post left carpal tunnel release in January 2013, and left thumb A-1 pulley release in May 2013. The request is for FLURBIPROFEN 20 PERCENT, BACLOFEN 10 PERCENT, DEXAMETHASONE MICRO 0.2 PERCENT, HYALURONIC ACID 0.2 PERCENT APPLY 2-3 TIMES DAILY. RFA with the request not provided. Patient's diagnosis per Request for Authorization form dated 08/21/15 includes other tenosynovitis of hand and wrist. Physical examination on 08/21/15 revealed edema and deformity of the left basal joint, increased pain with rotation and subluxation of the basal joint and decreased range of motion with radial and palmar abduction. Treatment to date has included surgery, injections and medications. Patient's medications include Fexmid, Maxalt, Lunesta, Prilosec and topical creams. Patient's work status not provided. MTUS, Topical Analgesics section, page 111 has the following: Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine whether creams, lotions or gels- are indicated for neuropathic pain. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Analgesics: Non-steroidal antiinflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Per 08/21/15 report, treater states " Directions: Apply a thin layer 2-3 times/day as needed for pain...It is our professional medical opinion that the compounded transdermal cream prescribed is medically necessary for our patient's diagnosis..." In this case, given patient's pain symptoms to the wrist and elbow, flurbiprofen portion of this topical would be indicated. However, MTUS page 111 states that if one of the compounded topical products is

not recommended, then the entire product is not. In this case, the requested topical compound contains Baclofen, which is not supported for topical use in lotion form, per MTUS. Furthermore, there is no support for Dexamethasone or hyaluronic acid for topical use in neither MTUS nor ODG. This request is not in accordance with guideline indications. Therefore, this request IS NOT medically necessary.

Durable medical equipment: 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 Official Disability Guidelines (ODG) Knee Chapter, under DME.

Decision rationale: Based on the 08/21/15 progress report provided by treating physician, the patient presents with pain in to the left elbow, left thumb, left wrist and hand. The patient is status post left carpal tunnel release in January 2013, and left thumb A-1 pulley release in May 2013. The request is for DURABLE MEDICAL EQUIPMENT. RFA with the request not provided. Patient's diagnosis per Request for Authorization form dated 08/21/15 includes Other tenosynovitis of hand and wrist. Physical examination on 08/21/15 revealed edema and deformity of the left basal joint, increased pain with rotation and subluxation of the basal joint and decreased range of motion with radial and palmar abduction. Treatment to date has included surgery, injections and medications. Patient's medications include Fexmid, Maxalt, Lunesta, Prilosec and topical creams. Patient's work status not provided. ODG-TWC guidelines, Knee Chapter online for DME states: Recommended generally, if there is a medical need and if the device or system meets Medicare's definition of durable medical equipment (DME) below. The term DME is defined as equipment which: (1) Can withstand repeated use, i.e., could normally be rented, and used by successive patients; (2) Is primarily and customarily used to serve a medical purpose; (3) Generally is not useful to a person in the absence of illness or injury; & (4) Is appropriate for use in a patient's home. (CMS, 2005) Section 4610.5 is added to the Labor Code, to read: (2) "Medically necessary" and "medical necessity" mean medical treatment that is reasonably required to cure or relieve the injured employee of the effects of his or her injury and based on the following standards, which shall be applied in the order listed, allowing reliance on a lower ranked standard only if every higher ranked standard is inapplicable to the employee's medical condition: (A) The guidelines adopted by the administrative director pursuant to Section 5307.27. (B) Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service. (C) Nationally recognized professional standards. (D) Expert opinion. (E) Generally accepted standards of medical practice. (F) Treatments that are likely to provide a benefit to a patient for conditions for which other treatments are not clinically efficacious. Per 08/21/15 report, treater states "DME: Durable Medical Equipment is required at this time." Treater has not provided reason for the request, nor provided description of DME being requested, what it will be used for, and what body part will be treated. There are not discussions of a specific treatment to warrant the necessity of DME being requested. Given lack of documentation, medical necessity for the request cannot be established. Therefore, the request IS NOT medically necessary.