

Case Number:	CM13-0020080		
Date Assigned:	10/11/2013	Date of Injury:	10/16/2012
Decision Date:	01/17/2014	UR Denial Date:	08/29/2013
Priority:	Standard	Application Received:	09/04/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Oklahoma and Texas. 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 physician 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:

This patient is a 41-year-old male with a reported date of injury of October 16, 2012. The mechanism of injury was described as securing the entry door to the main kitchen, and the key jammed in the key tumbler; when he pulled the key out, he felt a sharp to his left elbow area. He was taken to surgery on April 11, 2013 for anterior subcutaneous translocation of the ulnar nerve and release of the ulnar nerve at the ligament and release of the ulnar nerve at the cubital tunnel aponeurosis and resection of the medial intermuscular septum, left distal humerus. He was prescribed Dicopanol, Deprizine, Fanatrex, Synapryn and Tabradol, on July 17, 2013. On July 19, 2013, he returned to clinic and had full range of motion of the left elbow. He was to be sent to Physical Therapy for complaints of tightness and locking into his left elbow. On August 12, 2013, he was prescribed compounded Ketoprofen, compounded Cyclobenzaprine, Dicopanol, Deprizine, and Fanatrex, Synapryn, and Tabradol. On August 23, 2013, a supplemental report was submitted indicating a urine drug screen was performed to check for the presence of illicit and prescription drugs and was negative for all drug categories tested. On September 17, 2013, he was prescribed compounded Ketoprofen and compounded Cyclobenzaprine. He returned to clinic on October 02, 2013 and had range of motion of 115 degrees to his elbow with extension at 0. He had 3+ tenderness on the medial and lateral aspect of the elbow joint line and medial and lateral forearm. There was bilateral weakness in the myotome testing at C5 to C8 and T1 and L3 to S1. He had hypoesthesia at L3, L4, L5, and S1 demonstrated no sensory deficits. Deep tendon reflexes were present, active, and symmetric bilaterally. Diagnosis was status post anterior subcutaneous translocation of the ulnar nerve, release of the ulnar nerve as the ligament of Struthers, release of the ulnar nerve at the cubital tunnel aponeurosis, resection of the medial intermuscular

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% in Pluronic Lecithin Organogel (PLO-Gel), 120gm: 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): 111-113.

Decision rationale: This request is for compounded Ketoprofen 20% in Pluronic Lecithin Organogel (PLO-Gel), 120 grams, quantity of 1. MTUS Chronic Pain Guidelines address this medication in pages 111 to 113 and indicate this type of medication is largely experimental in use with few randomized-controlled trials to determine efficacy or safety. Furthermore, MTUS Chronic Pain Guidelines indicate there is little to no research to support the use of any of these agents in any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. Specifically for Ketoprofen, as a non-steroidal anti-inflammatory, the MTUS Chronic Pain Guidelines indicate that the efficacy in clinical trials for this treatment modality has been inconsistent and most studies were small and of short duration. Topical NSAIDs have been shown, per the MTUS Chronic Pain Guidelines, 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. Furthermore, it was recommended for short-term use. Records indicate this claimant has been on this medication since at least July 17, 2013, and the overall efficacy of this medication has not been documented by the records provided. There is lack of documentation with significant pain reduction as the most recent clinical note fails to describe this patient's pain objectively and fails to indicate that there is reduction of discomfort and/or inflammation with the use of this medication. The records indicate this medication has been used for longer than short term as recommended by guidelines. Therefore, this medication is not supported at this time and is non-certified.

Cyclobenzaprine 5% in PLO-Gel, 120gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

Decision rationale: This request is for compounded Cyclobenzaprine 5% in PLO-Gel, 120 grams, quantity of 1. The MTUS Chronic Pain Guidelines in discussing this medication in pages 111 to 113 indicate this type of medication is largely experimental in use with few randomized-controlled trials to determine efficacy or safety and is primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Furthermore, the MTUS Chronic Pain Guidelines indicate there is little to no research to support the use of any of these agents in any compounded product that contains at least 1 drug or drug class that is not

recommended, as it is not recommended. The MTUS Chronic Pain Guidelines also indicate that "there is no evidence for use in any other muscle relaxant as a topical product." The records indicate this patient has been on this medication since July 17, 2013 and the overall efficacy of this medication has not been demonstrated by the records provided. There is no indication of significant muscle spasms, but there is no indication that the muscle spasms have been reduced by use of this medication. As such, the overall efficacy of this medication has not been demonstrated by the records provided. Cyclobenzaprine is otherwise recommended as an option using a short course of therapy. As he has been on this medication since July 17, 2013, he has been on it longer than a short period of time. As there is lack of support for compounded medications and compounded muscle relaxants and continued use of this medication past short term use, and there is lack of efficacy of this medication documented by the records, this request is not considered medically necessary and is non-certified.

Synapryn 10mg/mL: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine, Tramadol Page(s): 50, 48, 113.

Decision rationale: This request is for Synapryn. This medication contains Tramadol and Glucosamine as well as other proprietary ingredients. The MTUS Chronic Pain Guidelines indicate Glucosamine is recommended as an option given its low risk in patients with moderate arthritic pain, especially for knee osteoarthritis. The most recent records fail to indicate this patient has significant osteoarthritis for which Glucosamine may be supported by the guidelines. Tramadol is another component of this medication and per the MTUS Chronic Pain Guidelines is a centrally-acting synthetic opiate analgesic and it is not recommended as a first-line oral analgesic. Furthermore for this type of medication, the MTUS Chronic Pain Guidelines advocate the use of the 4 A's. This would include monitoring for analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. The records do not indicate that proper analgesia has occurred with this medication as a pain score has not been objectively documented by the records. The records do not indicate he has had increased activities of daily living (ADLs) with the use of this medication. While there is a supplemental report indicating a urine drug screen had been performed to check the presence of illicit and prescription drugs, this was reported as negative for all drug categories. However, the drug screen itself was not provided for this review. Therefore, the 4 A's have not been adequately monitored for use of this medication. There is a lack of indication that he has been prescribed other lesser medications as recommended. Therefore, the use of this medication, Synapryn, at this time is not supported by guidelines and is non-certified.

Tabradol 1mg/mL: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42, 63, 37-38.

Decision rationale: This request is for Tabradol 1mg/mL Oral Suspension 250 mL QTY: 1.00. Tabradol contains cyclobenzaprine, methylsulfonylmethane, and other proprietary ingredients. The MTUS Chronic Pain Guidelines indicate that cyclobenzaprine, also known as Flexeril, is recommended as an option using a short course of therapy. The addition of cyclobenzaprine to other agents is not recommended by the MTUS Chronic Pain Guidelines. The records indicate that he has been on this medication since approximately July 17, 2013. This does not indicate that he has been a short course of this medication. The overall efficacy of this medication has not been demonstrated by the records provided. Methylsulfonylmethane can also be described as dimethyl sulfoxide (DMSO). The MTUS Chronic Pain Guidelines indicate there is some evidence of the efficacy for topical DMSO cream for Complex regional pain syndrome (CRPS). The records do not indicate this patient has the diagnosis of CRPS. Therefore, the request for this medication is not supported by guidelines, and the request is non-certified.

Deprizine 15mg/mL: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 68.

Decision rationale: The request is for Deprizine 15 mg/mL oral suspension 250 mL. Deprizine contains ranitidine and other proprietary ingredients. A Letter of Medical Necessity from [REDACTED] indicates that many patients who are on oral NSAID treating acute or chronic pain are at risk for gastrointestinal perforation/hemorrhage. This letter notes that the FDA now requires NSAIDs to carry a black box warning explaining the risk for serious cardiovascular and gastrointestinal adverse events. This letter indicates that histamine 2 receptor antagonists such as ranitidine play an important role in the prophylactic treatment for NSAID-induced gastrointestinal (GI) ulcer/bleeds. "There are studies showing proton pump inhibitors (PPIs) such as esomeprazole were no different than H2RA." In addressing the treating doctor's Letter of Medical Necessity, the MTUS Chronic Pain Guidelines indicate that for patients on nonsteroidal anti-inflammatories, the provider should determine if the patient is at risk for GI events. This would include age greater than 65 years, history of peptic ulcers, GI bleeding, or perforation, concurrent use of ASA, corticosteroids and/or an anticoagulant, high-dose/multiple NSAIDs such as NSAID plus low-dose ASA, and recent studies tend to show that Helicobacter pylori does not act synergistically with NSAIDs to develop gastroduodenal lesions. After determining cardiovascular risk, the MTUS Chronic Pain Guidelines indicate that patients at intermediate risk for GI events with no cardiovascular disease may take a nonselective NSAID with either a PPI, such as omeprazole or misoprostol or a COX-2-selective agent. They caution that long-term PPI use greater than 1 year has been shown to increase the risk of hip fractures. The submitted records do not indicate this patient has significant GI events either at current clinical evaluations or in the past. The records do not indicate he has had significant cardiovascular risk either.

Therefore, the use of this medication has not been supported by guidelines and the request is non-certified.

Dicopanol 5mg/mL: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation PDR, Diphenhydramine

Decision rationale: This request is for Dicopanol 5 mg/mL oral suspension, 150 mL. Dicopanol contains diphenhydramine and other proprietary ingredients. Diphenhydramine also known as Benadryl, and per PDR, is used for the relief of nasal and non-nasal symptoms of various allergic conditions. This is an antihistamine used to treat sneezing, runny nose, itching, hives, and other symptoms of allergies and the common cold. The submitted records do not indicate the rationale for prescribing this medication, as he has been prescribed this medication since at least July 17, 2013, and the records do not indicate he has exhibited any significant symptoms of allergies for which this medication would be supported. The patient does not have a cold for which this medication would be supported. The overall efficacy of this medication has not been demonstrated by the records provided. Additionally, the records do not indicate the medical necessity for an oral suspension versus by mouth medications. Therefore, this request is non-certified.

Fanatrex 25mg/mL: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 49, 16-22.

Decision rationale: This request is for Fanatrex 25 mg/mL oral suspension, 420 mL. Fanatrex contains gabapentin and other proprietary ingredients. The MTUS Chronic Pain Guidelines indicate that gabapentin is an anti-epilepsy drug and may be considered as a first-line treatment for neuropathic pain. The records indicate this patient has been on this medication since at least July 17, 2013, and the overall efficacy of this medication has not been demonstrated by the records. The records do not indicate a rationale for prescribing an oral suspension versus by mouth medications. The other proprietary ingredients are not specified. Therefore, medical necessity cannot be established at this time for this medication and this request is non-certified.

Functional Restoration Program with an unspecified frequency and duration: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Program Page(s): 49.

Decision rationale: The MTUS Chronic Pain Guidelines indicate that a functional restoration program is recommended, although research is still ongoing as to how to most appropriately screen for inclusion in these types of programs. Functional restoration programs, per MTUS Chronic Pain Guidelines, are a type of treatment included in the category of interdisciplinary pain programs that emphasize the importance of function over the elimination of pain. The submitted records do not indicate this patient currently is in significant pain, as his pain scale score has not been objectively documented by the records. The frequency and duration of this program has not been established by the records provided. Therefore, this request is not considered medically necessary and is non-certified

MRI of the Left Elbow: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 10 Elbow Disorders (Revised 2007) Page(s): 42-43.

Decision rationale: This request is for an MRI of the left elbow. The submitted records indicate this patient has been taken to surgery and had an MRI on November 26, 2012 of the left elbow. The most recent clinical exam of October 02, 2013 reveals range of motion is 115 degrees of flexion and extension is 0 to the left elbow. There is tenderness noted at the medial and lateral aspect of the elbow joint line. A pain score has not been objectively identified. The surgery was on April 01, 2013. The records do not indicate he sustained any significant pathology between the date of surgery and last clinical exam. The CA MTUS Elbow Chapter indicates that an MRI may be an appropriate consideration for patients whose limitations are due to consistent symptoms that have persisted for a month or more, when surgery is being considered for a specific anatomic defect or to further evaluate potentially serious pathology. At this time, the MRI is not considered medically necessary and is non-certified.

Physical Therapy with an unspecified frequency and duration: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine Page(s): 98-99.

Decision rationale: The request is for physical therapy, unspecified frequency and duration. The MTUS Chronic Pain Guidelines indicate that physical medicine guidelines allow for fading of treatment frequency from up to 3 visits per week to 1 or less plus active, self-directed home physical medicine. The records do not indicate he is on a home exercise program at this time. While guidelines do indicate that for myalgia and myositis, 9 to 10 visits over 8 weeks would be

considered reasonable, this request does not include the frequency or duration. Therefore, this request cannot be considered medically necessary at this time and is non-certified.

Chiropractic Sessions with an unspecified frequency and duration: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual Therapy and Manipulation Page(s): 58-60.

Decision rationale: The request is for chiropractic sessions, unspecified frequency and duration. The MTUS Chronic Pain Guidelines indicate that the goal of manual therapy is the achievement of positive symptomatic or objective measurable gains in functional improvement that facilitate progression in the patient's therapeutic exercise program and return to productive activities. Time to produce effect would be 4 to 6 treatments and a frequency of 1 to 2 times per week for the first 2 weeks as indicated by the severity of the condition. Chiropractic treatment to the forearm, wrist, and hand is not recommended. While this patient does have some limited range of motion of the left elbow, this may be more consistent with the usual postoperative phase of his treatment. At this time, the frequency and duration are not documented for the record. Therefore, this request is not considered medically necessary and is non-certified.