

Case Number:	CM13-0001939		
Date Assigned:	11/27/2013	Date of Injury:	02/20/2009
Decision Date:	01/23/2014	UR Denial Date:	07/12/2013
Priority:	Standard	Application Received:	07/18/2013

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 and is licensed to practice in Illinois. 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 claimant is a 47-year-old male with a reported date of injury of 02/20/2009. The mechanism of injury is described as lifting up boxes when he injured his low back. On 08/26/2011, electrodiagnostic studies were performed, and the EMG was found to be unremarkable. There was no electrical evidence to support a presumptive diagnosis of lumbosacral radiculopathy. On 02/07/2012, medications in the form of Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine cream, and ketoprofen cream were prescribed for this claimant. On 05/29/2013, a drug screen revealed that there were no drugs detected, including opiates, benzodiazepines, or antidepressants. On 06/11/2013, medications in the form of compounded ketoprofen, compounded Cyclophene, Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex were prescribed. On 07/09/2013, a progress note revealed this claimant had burning back pain rated at 6/10 to 7/10 and he was referred for extracorporeal shockwave therapy procedure for his low back. He returned to clinic on 09/03/2013 with continued pain rated at 6/10 to 7/10, and a pain management consult was ordered as well as medications. Diagnoses at that time included lumbar spine herniated disc, lumbar spine degenerative disc disease, lumbar radiculopathy, and low back pain. Plan going forward was to prescribe physical therapy, chiropractic manipulation, shock wave therapy, ketoprofen cream, Cyclophene gel, Tabradol oral suspension, Deprizine oral suspension, Dicopanol oral suspension, Fanatrex oral suspension, and obtain a urine drug screen and prescribe Synapryn oral suspension.

IMR ISSUES, DECISIONS AND RATIONALES

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

Physical therapy 18 sessions for the lumbar spine: Upheld

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

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

Decision rationale: This request is for Physical therapy 18 sessions for lumbar spine. MTUS chronic pain guidelines state "The use of active treatment modalities (e.g., exercise, education, activity modification) instead of passive treatments is associated with substantially better clinical outcomes. In a large case series of patients with low back pain treated by physical therapists, those adhering to guidelines for active rather than passive treatments incurred fewer treatment visits, cost less, and had less pain and less disability." Furthermore, MTUS chronic pain guidelines state "Allow for fading of treatment frequency (from up to 3 visits per week to 1 or less), plus active self-directed home Physical Medicine. Myalgia and myositis, unspecified (ICD9 729.1): 9-10 visits over 8 weeks." Neuralgia, neuritis, and radiculitis, unspecified (ICD9 729.2) 8-10 visits over 4 weeks Reflex sympathetic dystrophy (CRPS) (ICD9 337.2): 24 visits over 16 weeks." This request exceeds current MTUS chronic pain guidelines. The records do not indicate at this time that this claimant had a home exercise program and/or is performing a home exercise program. The records do not demonstrate any significant functional deficits for which physical therapy would be reasonable. There are no stated strength deficits and there were no significant range of motion deficits. The request for physical therapy does not indicate whether this is for passive or active therapy, and MTUS chronic pain management guidelines favor active over passive. Additionally, the current status of this claimant is unknown as his most recent clinical note is dated 09/03/2013. As such, the records do not indicate if he has significant functional deficits for which physical therapy would be recommended. Therefore, this request is non-certified.

Chiropractic Manipulation 18 sessions for the lumbar spine: Upheld

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

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

Decision rationale: MTUS Chronic Pain Guidelines state " Manual Therapy is widely used in the treatment of musculoskeletal pain. The intended goal or effect of Manual Medicine 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. Manipulation is manual therapy that moves a joint beyond the physiologic range-of-motion but not beyond the anatomic range-of-motion." Low back: Recommended as an option. Therapeutic care - Trial of 6 visits over 2 weeks, with evidence of objective functional improvement, total of up to 18 visits over 6-8 weeks. Elective/maintenance care - Not medically necessary. Recurrences/flare-ups - Need to reevaluate treatment success, if RTW achieved then

1-2 visits every 4-6 months." The submitted medical records did not indicate that this claimant has the need for chiropractic manipulation at this time. The current status of this claimant is unknown as the medical records are silent after 09/03/2013. The request exceeds current guideline recommendations, as, for therapeutic care, guidelines recommend a trial of 6 visits over 2 weeks, and with evidence of objective functional improvement, a total of 18 visits would be supported. Therefore, this request is non-certified.

Shockwave therapy 6 treatments for the lumbar spine: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back-Lumbar and Thoracic (Acute & Chronic).

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 10 Elbow Disorders (Revised 2007) Page(s): 33-40.

Decision rationale: MTUS Chronic Pain Guidelines do discuss this treatment form, but in the elbow chapter. They do not discuss this specifically for the low back. They indicate that there is recommendation against using this therapy. The submitted records indicate this claimant has been prescribed extracorporeal shockwave therapy for the low back, and has undergone treatment in that form, but does not indicate that he has gotten any significant improvement from that treatment. As such, this request is non-certified.

Ketoprofen 20% in PLO Gel 120gm, #1: 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): 111-113.

Decision rationale: This request is for Ketoprofen 20% in PLO Gel 120grams, #1. MTUS chronic pain guidelines, in discussing topicals, state "Largely experimental in use with few randomized controlled trials to determine efficacy or safety...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." Furthermore, MTUS chronic pain guidelines, in discussing NSAIDs as topical agents, state "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." The records indicate this claimant has been prescribed this medication in the past, but he still rates his pain at 6/10 to 7/10 on the last clinical note of 09/03/2013. The current status of the claimant is unknown as the records are silent after 09/03/2013. MTUS chronic pain guidelines do not advocate use of this medication in this form. Efficacy of this medication has not been demonstrated. Furthermore, guidelines indicate that the efficacy of this medication is short lived for approximately only 2 weeks, and the claimant has been on this

medication for a significant length of time. As such, efficacy of this medication has not been documented by the records provided and this request is non-certified.

Cyclophene 5% in PLO gel 120gm, #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants and topical analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: This request is for Cyclophene 5% in PLO Gel 120 grams, #1. MTUS chronic pain guidelines, in discussing topicals, state "Largely experimental in use with few randomized controlled trials to determine efficacy or safety...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." In discussing cyclobenzaprine in particular, MTUS chronic pain guidelines state "There is no evidence for use of any other muscle relaxant as a topical product." The submitted records indicate this claimant has been on this medication previously, but he still rates his pain at 6/10 to 7/10. The efficacy of this medication, therefore, has not been demonstrated. The most current status of this claimant is unknown as the records are silent after 09/03/2013. Due to lack of support from guidelines and documentation of a specific need for this medication, this request is non-certified.

Tabradol 1mg/ml oral suspension 250ml, #1: 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, CRPS medications, DMSO Page(s): 41-42.

Decision rationale: This request is for Tabradol 1mg/ml oral suspension 250ml, QTY: 1.00. The records indicate this medication is also known as Cyclobenzaprine. MTUS chronic pain guidelines state, in discussing cyclobenzaprine, "The addition of cyclobenzaprine to other agents is not recommended." In discussing DMSO, as a medication for CRPS, MTUS chronic pain guidelines state "There is some evidence of efficacy for topical DMSO cream, IV bisphosphonates and limited courses of oral corticosteroids." The records do not indicate efficacy of this medication as the records indicate this claimant has been on this medication for a significant length of time and he still rates his pain at 6/10 to 7/10. The records do not indicate a medical reason for prescribing this medication in its current form, oral suspension, versus by mouth medication. Therefore, this request is non-certified.

Deprizine 15mg/ml oral suspension 250mg, #1: 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 NSAIDS, GI symptoms and cardiovascular risk Page(s): 68.

Decision rationale: This request is for Deprizine 15mg/ml oral suspension 250mg, #1. This medication is also known as an agent that would effectively control GI symptoms with use of nonsteroidal anti-inflammatories. MTUS chronic pain guidelines, in discussing NSAIDs and GI irritability, state "Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 µg four times daily) or (2) a Cox-2 selective agent." The medical records do not demonstrate this claimant has significant GI upset at this time, nor does he exhibit a past medical history significant for GERD or ulcers or other GI symptoms. The current status of this claimant is unknown as the records are silent after 09/03/2013. Therefore, this request is non-certified.

Dicopanol 5mg/ml oral suspension 150ml, #1: 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: PDR.

Decision rationale: This medication is Dicopanol 5mg/ml oral suspension 150ml, #1. MTUS/ACOEM/ODG do not discuss this medication. The Physician Desk Reference (PDR) states this is an "antihistamine used to treat a number of conditions including allergic symptoms and itchiness, the common cold, insomnia, motion sickness, and extrapyramidal symptoms." The records do not indicate this claimant currently has symptoms such as this as the records are silent after 09/03/2013. The records do not indicate a medical necessity for use of this medication before 09/03/2013 and/or its efficacy. Therefore, this request is non-certified.

Fanatrex (gabapentin) 25mg/ml oral suspension 420ml, #1: Upheld

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

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

Decision rationale: This medication is also known as Gabapentin. This is an oral suspension. The records do not indicate a rationale for oral suspension versus by mouth medications. MTUS chronic pain guidelines state "Gabapentin is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which 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. See Antiepilepsy drugs (AEDs) for general guidelines, as well as specific Gabapentin listing for more information and references." The records are silent as to the current status of this claimant as the records cease after 09/03/2013. Therefore, the records do not indicate current medical necessity for this medication. This request is, therefore, non-certified.

Urine drug screen: 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 drug screen, opioids Page(s): 43, 78.

Decision rationale: This request is for Urine drug Screen. MTUS chronic pain guidelines state "Recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs. For more information, see Opioids, criteria for use: (2) Steps to Take Before a Therapeutic Trial of Opioids & (4) On-Going Management; Opioids, differentiation: dependence & addiction; Opioids, screening for risk of addiction (tests); & Opioids, steps to avoid misuse/addiction." The records do not indicate, at this time, that the claimant is currently on medication for which a drug screen would be supported as the records are silent after 09/03/2013. The clinical note of 09/03/2013 does not indicate that the claimant was on any medications at that time for which a drug screen would be appropriate. Therefore, this request is not medically necessary.

Synapryn 10mg/1ml oral suspension 500ml: Upheld

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

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

Decision rationale: This request is for Synapryn 10mg/1ml oral suspension 500ml. Synapryn contains tramadol and glucosamine, as well as other proprietary agents. MTUS chronic pain guidelines state glucosamine is "Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride." Tramadol, per MTUS chronic pain guidelines is "a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. For more information and references, see Opioids. See also Opioids for neuropathic pain." The records indicate that this claimant was on this medication previously, but the efficacy of this medication was not demonstrated as he still rated pain at 6/10 to 7/10. The records do not indicate he has significant osteoarthritis of the knee for which glucosamine would be supported. Additionally, the records are silent after 09/03/2013 and, therefore, medical necessity for this medication has not been demonstrated. Tramadol is not recommended as a first line oral

analgesic and the records do not indicate that he has failed lesser medications in the most recent past. The records indicate this request is for an oral suspension of this medication and the records do not indicate rationale for an oral suspension versus by mouth medications. Therefore, this request is non-certified.