

Case Number:	CM15-0163536		
Date Assigned:	09/09/2015	Date of Injury:	08/12/2014
Decision Date:	10/28/2015	UR Denial Date:	08/11/2015
Priority:	Standard	Application Received:	08/20/2015

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: New York

Certification(s)/Specialty: Internal Medicine

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 55 year old male who sustained an industrial injury on 8-12-14 resulting in bilateral shoulder injuries. Diagnoses include right shoulder sprain, strain; left shoulder sprain, strain; bilateral shoulder acromioclavicular arthrosis; left shoulder tendonitis; bilateral shoulder bicipital tenosynovitis; left shoulder labral tear; left shoulder joint effusion; bilateral shoulder rotator cuff tear; status post right shoulder surgery with residual pain (4-28-15). He currently complains of left shoulder discomfort; right shoulder discomfort that worsens with overhead activities. On physical exam of the right and left shoulder revealed tenderness to palpation of the lateral shoulder, Speed's causes pain on the right and left. Diagnostics included MRI of the right shoulder (6-11-15) showed osteoarthritis, supraspinatus tear, infraspinatus tear, tenosynovitis, joint capsule edema, effusion of synovium, bone cyst, fluid. Treatments to date include medications: ketoprofen 20% cream 187 grams; cyclobenzaprine 5% cream, 110 grams; Synapryn 10mg per milliliter, oral suspension, 500 milliliters; Tabradol 1 mg per milliliter, oral suspension, 250 milliliters; deprizine 15mg/ milliliter, oral suspension, 250 milliliters; dicopanol 5 mg per milliliter, oral suspension, 150 milliliters; Fanatrex 25mg per milliliter, oral suspension, 420 milliliters; status post shoulder surgery; subacromial injections without improvement; shockwave therapy; physiotherapy; chiropractic treatment; acupuncture. There was no indication of effectiveness of prior acupuncture, chiropractic care, shockwave therapy noted. In the progress note dated 5-27-15 the treating provider's plan of care included requests for ketoprofen 20% cream 187 grams; cyclobenzaprine 5% cream, 110 grams; Synapryn 10mg per milliliter, oral suspension, 500 milliliters; Tabradol 1 mg per milliliter, oral suspension, 250 milliliters;

deprizine 15mg/ milliliter, oral suspension, 250 milliliters; dicopanol 5 mg per milliliter, oral suspension, 150 milliliters; Fanatrex 25mg per milliliter, oral suspension, 420 milliliters; physiotherapy 3x8, right shoulder; chiropractic treatments 3x6, bilateral shoulders; acupuncture 3x6, bilateral shoulders; electromyography, nerve conduction study of bilateral upper extremities; shockwave therapy 3x6. The request for authorization for medications: ketoprofen 20% cream 187 grams; cyclobenzaprine 5% cream, 110 grams; Synapryn 10mg per milliliter, oral suspension, 500 milliliters; Tabradol 1 mg per milliliter, oral suspension, 250 milliliters; deprizine 15mg/ milliliter, oral suspension, 250 milliliters; dicopanol 5 mg per milliliter, oral suspension, 150 milliliters; Fanatrex 25mg per milliliter, oral suspension, 420 milliliters and physiotherapy 3x8, right shoulder; chiropractic treatments 3x6, bilateral shoulders; acupuncture 3x6, bilateral shoulders; electromyography, nerve conduction study of bilateral upper extremities; shockwave therapy 3x6 was dated 6-22-15. On 8-11-15 utilization review evaluated the following retrospective requests all with a date of service of 6-22-15 and all were non-certified: ketoprofen 20% cream 187 grams; cyclobenzaprine 5% cream, 110 grams; Synapryn 10mg per milliliter, oral suspension, 500 milliliters; Tabradol 1 mg per milliliter, oral suspension, 250 milliliters; deprizine 15mg/ milliliter, oral suspension, 250 milliliters; dicopanol 5 mg per milliliter, oral suspension, 150 milliliters; Fanatrex 25mg per milliliter, oral suspension, 420 milliliters; physiotherapy 3x8, right shoulder; chiropractic treatments 3x6, bilateral shoulders; acupuncture 3x6, bilateral shoulders; electromyography, nerve conduction study of bilateral upper extremities; shockwave therapy 3x6.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retro Ketoprofen 20% cream 167gm, DOS: 6/22/15: 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: The CA MTUS Chronic Pain Guidelines indicate that topical analgesics are "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." They are "largely experimental in use with few randomized controlled trials to determine effectiveness or safety." Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID). The MTUS indicates that topical NSAIDs may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Ketoprofen is not FDA approved for topical application. Non-FDA approved medications are not medically necessary. The only FDA-approved topical NSAIDs are diclofenac formulations. All other topical NSAIDs are not FDA approved. As per the MTUS medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. The prescribing physician dispensed multiple medications simultaneously without an adequate trial of each medication separately. The guidelines indicate that "Any compounded product that contains at least one drug (or drug class) that is not

recommended is not recommended." The requested treatment: Ketoprofen 20% cream 167gm is not medically necessary.

Retro Cyclobenzaprine 5% cream 110gm, DOS: 6/22/15: 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): Muscle relaxants (for pain), Topical Analgesics.

Decision rationale: As per the MTUS, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for this topical agent, it is not medically necessary on this basis at minimum. The prescribing physician dispensed multiple medications simultaneously without an adequate trial of each medication separately. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Analgesics are 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. There is little to no research to support the use of many of these agents. There have been no studies of topical cyclobenzaprine, and there is no recommendation for the topical use cyclobenzaprine. As such, the request for Cyclobenzaprine 5% cream 110gm is not medically necessary.

Retro Synapryn 10mg/1ml oral suspension 500ml, DOS: 6/22/15: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Compound drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Glucosamine (and Chondroitin Sulfate), Opioids, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC], Opioids for chronic pain.

Decision rationale: Synapryn 500ml (tramadol with glucosamine) oral suspension: The reason for combining these medications is not discussed in any physician report. Given that tramadol is generally a prn medication to be used as little as possible, and that glucosamine (assuming a valid indication) is to be taken regularly regardless of acute symptoms, the combination product is not indicated. Tramadol is prescribed without clear evidence of the considerations and expectations found in the MTUS and similar guidelines. Opioids are minimally indicated, if at all, for chronic back pain. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address the other recommendations in the MTUS. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial of non-opioid analgesics". The MTUS provides support for treating moderate arthritis pain, particularly knee OA, with glucosamine sulphate. Other forms of

glucosamine are not supported by good medical evidence. The treating physician in this case has not provided evidence of the form of glucosamine in Synapryn, and that it is the form recommended in the MTUS and supported by the best medical evidence. And should there be any indication for glucosamine in this case, it must be given as a single agent apart from other analgesics, particularly analgesics like tramadol which are habituating. Synapryn is not medically necessary based on the MTUS, lack of good medical evidence, and lack of a treatment plan for chronic opioid therapy consistent with the MTUS.

Retro Tabradol 1mg/ml oral suspension 250ml, DOS: 6/22/15: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Compound drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: Tabradol is cyclobenzaprine in an oral suspension. The MTUS for Chronic Pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short term exacerbations of chronic low back pain. This injured worker has chronic pain. The MTUS states that treatment with cyclobenzaprine should be brief, and that the addition of cyclobenzaprine to other agents is not recommended. In this case, cyclobenzaprine is added to other agents, and the oral suspension form plus topical is experimental and unproven. Multiple medications, including a topical muscle relaxant, were prescribed together without adequate trials of each. The Requested Treatment: Retro Tabradol 1mg/ml oral suspension 250ml is not medically necessary.

Retro Deprizine 15mg/ml oral suspension 250ml, DOS: 6/22/15: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Compound drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: Deprizine is ranitidine in an oral suspension. There is no documentation indicating the patient has any GI symptoms or GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. Cotherapy with an NSAID is not indicated in patients other than those at high risk. No reports describe the specific risk factors present in this injured worker. Medical necessity of the requested item has not been established. The Requested Treatment: Retro Deprizine 15mg/ml oral suspension 250ml is not medically necessary.

Retro Dicopanil (Diphenhydramine) 5mg/ml oral suspension 150ml, DOS: 6/22/15: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Compound drugs.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter: Insomnia Treatment.

Decision rationale: Dicopanol is diphenhydramine and other unnamed ingredients. Medical necessity cannot be determined for unspecified compounds, and unpublished ingredients cannot be assumed to be safe or effective. Dicopanol is not medically necessary on this basis alone. In addition, Dicopanol is stated to be for insomnia. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. Antihistamines are not indicated for long term use as tolerance develops quickly and that there are many, significant side effects. Dicopanol is not medically necessary based on lack of a sufficient analysis of the patient's condition, the ODG citation, and lack of information provided about the ingredients.

Retro Fanatrex (Gabapentin) 25mg/ml oral suspension 420ml, DOS: 6/22/15: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Compound drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

Decision rationale: As per MTUS, Fanatrex (gabapentin) is a compounded form of an anti-epilepsy drug (AEDs - also referred to as anti-convulsants). These drugs have been shown to be effective for treatment of diabetic painful neuropathy/polyneuropathy and postherpetic neuralgia and have been considered as a first-line treatment for neuropathic pain. FDA-approved drugs should be given adequate trial, if these are inadequate, ineffective or contraindicated in the individual patient, then compounded drugs with FDA-approved ingredients can be considered. The clinical documentation submitted for review does not indicate diagnoses of diabetic neuropathy or postherpetic neuralgia. There is no indication for the compounded oral suspension form of this drug in such a low dose (non-therapeutic dose) in comparison to the recommended dose of oral gabapentin in tablet form. In addition, there is no documented failed trial of the FDA-approved form of this drug, and no indication as to the reason that the FDA-approved form is contraindicated in this injured worker. As such, the request for Fanatrex (gabapentin) 25mg/ml oral suspension 420ml is not medically necessary.

Retro physiotherapy 3 x 6 for the right shoulder, DOS: 6/22/15: 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): Physical Medicine.

Decision rationale: MTUS recommends 1) Passive therapy (those treatment modalities that do not require energy expenditure on the part of the patient) can provide short term relief during the early phases of pain treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They can be used sparingly with active therapies to help control swelling, pain and inflammation during the rehabilitation process. 2) Active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy may require supervision from a therapist or medical provider such as verbal, visual and/or tactile instruction(s). Patients are instructed and expected to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices. The records are not clear about functional benefit from prior physical therapy visits. Also there is no mention of any significant change of symptoms or clinical findings, or acute flare up to support PT. The Requested Treatment: Retro physiotherapy 3 x 6 for the right shoulder is not medically necessary or appropriate.

Retro Chiropractic treatment 3 x 6 for the bilateral shoulders, DOS: 6/22/15: 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): Manual therapy & manipulation.

Decision rationale: Per MTUS guidelines it is recommended for chronic pain if caused by musculoskeletal conditions. 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. The Medical Records are not clear about the functional benefit, this injured worker had from prior Chiropractic visits. The request for Chiropractic therapy is not medically necessary or appropriate.

Retro Acupuncture 3 x 6 to the bilateral shoulders, DOS: 6/22/15: Upheld

Claims Administrator guideline: Decision based on MTUS Acupuncture Treatment 2007.

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment 2007.

Decision rationale: This prescription for acupuncture is evaluated in light of the MTUS recommendations for acupuncture. The MTUS recommends an initial trial of 3-6 visits of acupuncture. Per the MTUS, "acupuncture is used as an option when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery". Medical necessity for any further acupuncture is considered in light of "functional improvement". The records indicate no functional improvement from prior acupuncture therapy. There was no discussion by the treating physician regarding a decrease or intolerance to pain medications. Also 18 visits of acupuncture exceed the MTUS recommendation. Given the MTUS recommendations for use of acupuncture - Requested Treatment: Retro Acupuncture 3 x 6 to the bilateral shoulders is not medically necessary or appropriate.

Retro EMG/NCV of the bilateral upper extremities, DOS: 6/22/15: Upheld

Claims Administrator guideline: Decision based on MTUS Forearm, Wrist, and Hand Complaints 2004. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain.

MAXIMUS guideline: Decision based on MTUS Neck and Upper Back Complaints 2004, Section(s): Special Studies. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter-- Electrodiagnostic testing (EMG/NCS).

Decision rationale: The California MTUS/ACOEM Guidelines state, "Electromyography (EMG), including H-reflex tests, may be useful to identify subtle, focal neurologic dysfunction in patients with neck or arm symptoms, or both, lasting more than three or four weeks." The ODG regarding nerve conduction studies (NCS) states, "Not recommended". There is minimal justification for performing nerve conduction studies when a patient is presumed to have symptoms on the basis of radiculopathy. EMGs (electromyography) are recommended as an option (needle, not surface) to obtain unequivocal evidence of radiculopathy, after 1-month conservative therapy, but EMG's are not necessary if radiculopathy is already clinically obvious." The objective findings on examination did not include evidence of neurologic dysfunction such as sensory, reflex, or motor system change. The injured worker has no symptoms or findings that define evidence of a peripheral neuropathy. There was insufficient information provided by the attending health care provider to establish the medical necessity or rationale for the requested electrodiagnostic studies. The request for an EMG/NCV of the bilateral upper extremities is not medically necessary or appropriate.

Retro Shockwave therapy 3 x 6, DOS: 6/22/15: Upheld

Claims Administrator guideline: Decision based on MTUS Shoulder Complaints 2004. Decision based on Non-MTUS Citation Official Disability Guidelines, Shoulder.

MAXIMUS guideline: Decision based on MTUS Shoulder Complaints 2004, Section(s): Initial Care.

Decision rationale: As per MTUS/ACOEM Physical modalities, such as massage, diathermy, cutaneous laser treatment, ultrasound treatment, transcutaneous electrical neurostimulation

(TENS) units, and biofeedback are not supported by high-quality medical studies, but they may be useful in the initial conservative treatment of acute shoulder symptoms, depending on the experience of local physical therapists available for referral. Some medium quality evidence supports manual physical therapy, ultrasound, and high energy extracorporeal shock wave therapy for calcifying tendinitis of the shoulder. Patient's at-home applications of heat or cold packs may be used before or after exercises and are as effective as those performed by a therapist. Initial use of less-invasive techniques provides an opportunity for the clinician to monitor progress before referral to a specialist. Review of submitted Records indicates that this injured worker is complaining of discomfort in both shoulders that worsens with overhead activities. As per progress notes in the Medical Records, the injured worker does not appear to have any significant changes in her chronic symptoms, and there is no evidence of calcifying tendinitis. The requested treatment: Retro Shockwave therapy 3 x 6, DOS: 6/22/15 is not medically necessary or appropriate.