

<b>Case Number:</b>	CM15-0176070		
<b>Date Assigned:</b>	09/30/2015	<b>Date of Injury:</b>	08/11/2014
<b>Decision Date:</b>	12/01/2015	<b>UR Denial Date:</b>	08/10/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/08/2015

### 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 38 year old female who sustained an industrial injury on 8-11-14. The injured worker reported pain in the neck, bilateral shoulders and back. A review of the medical records indicates that the injured worker is undergoing treatments for cephalgia, cervical spine sprain strain, cervical radiculopathy, bilateral shoulder sprain strain, lumbar spine sprain strain and lumbar radiculopathy. Medical records dated 7-27-15 indicate pain rated at 6 out of 10. Treatment has included radiographic studies, lumbar spine magnetic resonance imaging, cervical spine magnetic resonance imaging, physical therapy, Hydrocodone, at least 24 sessions of chiropractic treatments, and acupuncture treatment. Objective findings dated 7-27-15 were notable for tenderness to palpation to the cervical and lumbar paraspinal muscles, the delto-pectoral groove, and decreased cervical and lumbar range of motion. The original utilization review (8-10-15) denied a request for Synapryn 10mg per 1ml oral suspension 500ml, 1 tsp BID- TID, Tabradol 1mg per ml oral suspension 250mg, 1 tsp BID-TID, Deprizine 15mg per ml oral suspension 250ml, 2 tsp once daily, Dicopanol (Diphenhydramine) 5mg per ml oral suspension 150ml, 1 ml HS, Fanatrex (Gabapentin) 25mg per ml oral suspension 420ml, 1 tsp TID, X-rays of the cervical spine, X-rays of the lumbar spine, X-rays of the bilateral shoulders, Physical therapy, 18 sessions for the affected body part, Chiropractic treatment, 18 sessions for the affected body part, Acupuncture, 18 sessions for the affected body part, Functional capacity evaluation, and MRI of the bilateral shoulders.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Synapryn 10mg/1ml oral suspension 500ml, 1 tsp BID-TID, (2-3 times a day): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Glucosamine (and Chondroitin Sulfate), Opioids for chronic pain.

**Decision rationale:** Synapryn is combination of tramadol and glucosamine. 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. If there is 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 oral suspension 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. The request is not medically necessary.

**Tabradol 1mg/ml oral suspension 250mg, 1 tsp BID-TID, (2-3 times a day): 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) Pain Chapter- Muscle relaxants.

**Decision rationale:** Tabradol is cyclobenzaprine in an oral suspension. According to the reviewed literature, Cyclobenzaprine (Flexeril) is not recommended for the long-term treatment of chronic pain. This medication has its greatest effect in the first four days of treatment. In addition, this medication is not recommended to be used for longer than 2-3 weeks. According to CA MTUS Guidelines, muscle relaxants are not considered any more effective than nonsteroidal anti-inflammatory medications alone. In this case, the available records are not clear if the injured worker has shown a documented benefit or any functional improvement from prior Cyclobenzaprine use. Based on the currently available information, the medical necessity for this muscle relaxant medication has not been established. The requested treatment: Tabradol 1mg/ml oral suspension 250mg, 1 tsp BID-TID is not medically necessary.

**Deprizine 15mg/ml oral suspension 250ml, 2 tsp once daily:** Upheld

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

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

**Decision rationale:** The prescription for Deprizine is evaluated in light of the MTUS recommendations. 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 over 65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. If Ranitidine is prescribed as co-therapy with an NSAID, Ranitidine is not the best drug. Co-therapy with an NSAID is not indicated in patients other than those at high risk. No reports describe the specific risk factors present in this case. Medical necessity of the requested item has not been established. The request is not medically necessary.

**Dicopanol (Diphenhydramine) 5mg/ml oral suspension 150ml, 1 ml HS, (at bedtime):** 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) Pain Chapter-Insomnia Treatment.

**Decision rationale:** Official Disability Guidelines (ODG) state Over-the-counter medications: Sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess, and tiredness. The treating physician has stated that Dicopanol is diphenhydramine and other proprietary 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. There is no evidence of that in this case. Official Disability Guidelines states that antihistamines are not indicated for long term use as tolerance develops quickly, and that there are many, significant side effects. MTUS states 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. Dicopanol (Diphenhydramine) 5mg/ml oral suspension is not medically necessary based on lack of a sufficient analysis of the patient's condition, and lack of information provided about the ingredients. The request is not medically necessary.

**Fanatrex (Gabapentin) 25mg/ml oral suspension 420ml, 1 tsp TID, (3 times a day): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter-Anti-epilepsy drugs (AEDs) for pain.

**Decision rationale:** Per the 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 post-herpetic neuralgia and has 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. Painful neuropathic symptoms were noted; however, 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 the injured worker. As such, the request for Fanatrex (Gabapentin) 25mg/ml 420ml, 1 tsp TID is not medically necessary and appropriate.

**X-rays of the cervical 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 (ODG), Cervical; Indications for imaging-X-rays.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck Chapter-Radiography (X-rays).

**Decision rationale:** As per ODG-criteria for imaging-Plain X-rays: Cervical spine trauma, unconscious-Cervical spine trauma, impaired sensorium (including alcohol and/or drugs)- Cervical spine trauma, multiple trauma and/or impaired sensorium- Cervical spine trauma (a serious bodily injury), neck pain, no neurological deficit - Cervical spine trauma, alert, cervical tenderness, paresthesias in hands or feet- Cervical spine trauma, alert, cervical tenderness - Chronic neck pain ( after 3 months conservative treatment), patient younger than 40, no history of trauma, first study - Chronic neck pain, patient younger than 40, history of remote trauma, first study - Chronic neck pain, patient older than 40, no history of trauma, first study - Chronic

neck pain, patient older than 40, history of remote trauma, first study - Chronic neck pain, patients of any age, history of previous malignancy, first study - Chronic neck pain, patients of any age, history of previous remote neck surgery, first study - Post-surgery: evaluate status of fusion. From the submitted Medical Records it is unclear how the X-ray will change the management. The injured worker has no progressive neurological deficits, no new red flags, and no recent acute injury. Without such evidence and based on guidelines cited, the request for X-ray Cervical spine is not medically necessary and appropriate.

**X-rays of 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 (ODG), Indications for imaging-Plain Xays.

**MAXIMUS guideline:** Decision based on MTUS Low Back Complaints 2004, Section(s): Special Studies. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic)- Radiography (X-rays).

**Decision rationale:** MTUS/ACOEM Guidelines state X-ray of Lumbar spine is not recommended in in patients with low back pain in the absence of red flags for serious spinal pathology, even if the pain has persisted has for at least six weeks. As per ODG -criteria for imaging-Plain X-rays: Lumbar spine trauma (a serious bodily injury): pain, tenderness; Lumbar spine trauma: trauma, neurological deficit; Lumbar spine trauma: seat belt (chance) fracture; Uncomplicated low back pain, trauma, steroids, osteoporosis, over 70; Uncomplicated low back pain, suspicion of cancer, infection; Myelopathy (neurological deficit related to the spinal cord), traumatic; Myelopathy, painful; Myelopathy, sudden onset; Myelopathy, infectious disease patient; Myelopathy, oncology patient; Post-surgery: evaluate status of fusion. From the submitted Medical Records it is unclear how the X-ray will change the management. The injured worker has no progressive neurological deficits, no new red flags, and no recent acute injury. Without such evidence and based on guidelines cited, the request for X-ray Lumbar spine is not medically necessary and appropriate.

**X-rays of the bilateral shoulders:** 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), Shoulder, Radiography.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Shoulder Chapter - X-rays.

**Decision rationale:** As per ODG-criteria for imaging-Plain X-rays: Acute shoulder trauma, rule out fracture or dislocation; Acute shoulder trauma, questionable bursitis. From the submitted Medical Records it is unclear how the X-ray will change the management. The injured worker has no new red flags, and no recent acute injury. The injured worker has no progressive neurological deficits, no new red flags, and no recent acute injury. Without such evidence and based on guidelines cited, the request for X-rays of the bilateral shoulders is not medically necessary and appropriate.

**Physical therapy, 18 sessions for the affected body part: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Physical Medicine.

**Decision rationale:** The prescription for Physical Therapy is evaluated in light of the MTUS recommendations for Physical Therapy. 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 do not indicate 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: Physical therapy, 18 sessions for the affected body part is not medically necessary and appropriate.

**Chiropractic treatment, 18 sessions for the affected body part: 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 do not indicate any functional benefit, this injured worker had from prior Chiropractic visits. The requested treatment: Chiropractic treatment, 18 sessions for the affected body part is not medically necessary and appropriate.

**Acupuncture, 18 sessions for the affected body part:** 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. There is evidence that this injured worker has received treatment with acupuncture before, however the records are not clear about its functional benefits. There was no discussion by the treating physician regarding a decrease or intolerance to pain medications. Also 18 sessions of acupuncture exceed the MTUS recommendation. Given the MTUS recommendations for use of acupuncture, the requested treatment: Acupuncture, 18 sessions for the affected body part is not medically necessary and appropriate.

**Functional capacity evaluation:** 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), Pain, FCE.

**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-Work conditioning, Work hardening.

**Decision rationale:** A number of functional assessment tools are available, including functional capacity exams and videotapes. Most assess general functioning, but modifications to test work-related functioning are under development or can be created by the clinician. ODG states valid Functional Capacity Evaluation (FCE) should be performed, administered and interpreted by a licensed medical professional. The results should indicate consistency with maximal effort, and demonstrate capacities below an employer verified physical demands analysis (PDA). Inconsistencies and/or indication that the patient has performed below maximal effort should be addressed prior to treatment in these programs. Within the medical information available for review, the injured worker has chronic pain and there is no indication the injured worker is close or at maximum-medical-improvement (MMI). There is no documentation of prior unsuccessful return-to-work (RTW) attempts. Medical records lack information about job description, physical demand level and specific work-related tasks. Also records do not document injured worker's return to work goals. The medical necessity of the requested treatment: Functional capacity evaluation has not been established. The request is not medically necessary.

**MRI of the bilateral shoulders:** 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), Shoulder, Indications for imaging-Magnetic resonance imaging (MRI).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Shoulder Chapter-Magnetic resonance imaging (MRI).

**Decision rationale:** As per ODG -criteria for MRI (magnetic resonance imaging): Acute shoulder trauma, suspect rotator cuff tear/impingement, over age 40, normal plain radiographs; Subacute shoulder pain, suspect instability/labral tear; Repeat MRI is not routinely recommended, and should be reserved for a significant change in symptoms and/or findings suggestive of significant pathology. Review of submitted Records indicates that injured worker is complaining of pain in the neck, bilateral shoulders and back. As per progress notes in the Medical Records, the injured worker does not appear to have significant changes in symptoms and signs. The records are not clear about neurological findings, and there are no red flags. Without such evidence and based on guidelines cited, the requested treatment: MRI of the bilateral shoulders is not medically necessary and appropriate.