

Case Number:	CM15-0185880		
Date Assigned:	10/20/2015	Date of Injury:	02/05/2007
Decision Date:	12/24/2015	UR Denial Date:	09/01/2015
Priority:	Standard	Application Received:	09/21/2015

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: Arizona, Michigan

Certification(s)/Specialty: Preventive Medicine, Occupational 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 53 year old male who sustained an industrial injury on 02/05/2007. Medical records indicated the worker was treated for cervical spine pain, radiculopathy, cervical region, cervical disc displacement, impingement syndrome of the bilateral shoulder, bilateral shoulder synovitis and tenosynovitis, low back pain, lumbar disc displacement, radiculopathy, lumbar region, anxiety disorder, mood disorder, sleep disorder, stress, and sexual dysfunction. In the provider notes of 08-27-2015, the injured worker complains of sharp, stabbing neck pain rated as a 5-6 on a scale of 0-10. His pain is frequent to constant, moderate to severe, and is aggravated by looking up, looking down, and side to side as well as by repetitive motions of the head and neck. The pain radiates to the bilateral upper extremities and is associated by numbness and tingling. He complains of sharp, burning bilateral shoulder pain that he rates in the right shoulder as a 6 on a scale of 0-10, and a 5-6 on a scale of 0-10. His pain is described as constant, moderate to severe and is aggravated by gripping, grasping, reaching, pulling, lifting, and doing work at or above the shoulder level. He has low back pain that is burning and sharp and rated as a 4-5 on a scale of 0-10. The pain is described as frequent to constant, moderate to severe and associated with numbness and tingling of the bilateral lower extremities. The pain is aggravated by prolonged positioning including, sitting, standing, walking, bending, arising from a sitting position, ascending or descending stairs and stooping. The pain is also aggravated by activities of daily living such as getting dressed and performing personal hygiene. He is experiencing symptoms of anxiety, insomnia, stress, sexual dysfunction and depression. Objective findings were a 2 = tenderness to palpation of the suboccipital, scalene and

sternocleidomastoid muscles, decreased range of motion in all planes of the cervical spine, tenderness to palpation of the rotator cuff attachment sight in the bilateral shoulders with tenderness to palpation at the subacromial space and at the AC joint. Range of motion of the shoulders was significantly diminished in all planes in the left, and diminished in all planes in the right. Neurologic exam showed slightly diminished sensation to pinprick and light touch over the C5-C8 and T1. Motor strength was 4 out of 5 in all represented muscle groups in the upper extremities. Deep tendon reflexes in the upper extremities were 2 = and normal. There was tenderness to palpation at the bilateral spinous processes from L2-L5 with bilateral lumbar paraspinal muscle guarding. Sensory exam of the lower extremities showed 4 out of 5 motor strength in all represented muscle groups of the lower extremities. Medications include Dicopanol, Deprizine, Fanatrex, Synapryn Tabradol, (all since at least 01-18-2015) and Cyclobenzaprine since 03-25-2015, and Ketapofren 20% cream since 04-23-2015. A request for authorization was submitted for: 1). Flurbiprofen 20%, Baclofen 10%, Dexamethasone micro 0.2%, Hyaluronic acid 0.2% cream base. 2). Amitriptyline 10%, Gabapentin 10%, Bupivacaine 5%, Hyaluronic acid 0.2%, 240gm. 3). Ketoprofen 20% 167gm. 4). Cyclobenzaprine 5% cream 110gm. 5). Synapryn 10mg/1ml oral suspension 500ml. 6). Tabradol 1mg/ml oral suspension 250ml. 7). Deprizine 15mg/ml oral suspension 250ml. 8). Dicopanol 5mg/ml oral suspension 150ml. 9). Fanatrex 25mg/ml oral suspension 420ml. 10). 6 Shockwave therapy sessions. 11). 1 Functional capacity evaluation. 12). 3 Sets of PRP treatments. 13). 1 Urine drug screen. (retrospective dos: 07/24/2015) 14). 18 Physical therapy visits. 15). 18 Chiropractic sessions. 16). 18 Acupuncture sessions. A utilization review decision 09/01/2015 Non-certified: Flurbiprofen 20%, Baclofen 10%, Dexamethasone micro 0.2%, Hyaluronic acid 0.2% cream base; Amitriptyline 10%, Gabapentin 10%, Bupivacaine 5%, Hyaluronic acid 0.2%, 240gm- Ketoprofen 20% 167gm; Cyclobenzaprine 5% cream 110gm; Synapryn 10mg/1ml oral suspension 500ml; Tabradol 1mg/ml oral suspension 250ml; Deprizine 15mg/ml oral suspension 250ml; Dicopanol 5mg/ml oral suspension 150ml; Fanatrex 25mg/ml oral suspension 420ml; 6 Shockwave therapy sessions; 1 Functional capacity evaluation; 3 Sets of PRP treatments; 1 Urine drug screen (retrospective dos: 07/24/2015) And conditionally non-certified; 18 Physical therapy visits; 18 Chiropractic sessions; 18 Acupuncture sessions

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 20%, Baclofen 10%, Dexamethasone micro 0.2%, Hyaluronic acid 0.2% cream base: 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: Per the MTUS, "topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and

anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. There is no peer-reviewed literature to support the use of topical baclofen". A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed, this compounded product is not supported by the guidelines, therefore the request for Flurbiprofen 20%, Baclofen 10%, Dexamethasone micro 0.2%, Hyaluronic acid 0.2% cream base is not medically necessary.

Amitriptyline 10%, Gabapentin 10%, Bupivacaine 5%, Hyaluronic acid 0.2%, 240gm:
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: Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. There is no peer-reviewed literature to support use of Gabapentin as a topical product. This compounded product is not supported by the guidelines. A review of the injured workers medical records that are available to me also does not show a trial of recommended first line agents that have failed, therefore the request for Amitriptyline 10%, Gabapentin 10%, Bupivacaine 5%, Hyaluronic acid 0.2%, 240gm is not medically necessary.

Ketoprofen 20% 167gm: 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: Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Ketoprofen is not currently FDA approved for a topical application, it has an extremely high incidence of photocontact dermatitis. A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed and there are no extenuating circumstances to warrant the use of

a topical product that is not FDA approved and not recommended by the MTUS, therefore the request for Ketoprofen 20% cream 167gm is not medically necessary.

Cyclobenzaprine 5% cream 110gm: 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: Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed and per the MTUS, cyclobenzaprine is a muscle relaxant and there is no evidence for use of any muscle relaxant as a topical product therefore the request for cyclobenzaprine 5% cream 110gm is not medically necessary.

Synapryn 10mg/1ml oral suspension 500ml: 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): Opioids, criteria for use, Opioids, specific drug list.

Decision rationale: The MTUS states that tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. Opioids are recommended for chronic pain, especially neuropathic pain that has not responded to first line recommendations like antidepressants and anticonvulsants. Long term users should be reassessed per specific guideline recommendations and the dose should not be lowered if it is working. Per the MTUS, Tramadol is indicated for moderate to severe pain. Synapryn contains tramadol. A review of the injured workers medical records do not show that he has difficulty swallowing or is unable to tolerate other recommended non liquid oral medications, there is also no documentation of pain, functional improvement and ongoing management actions for opioids as required by the guidelines, without this information the request for Synapryn 10mg/1ml oral suspension 500ml is not medically necessary.

Tabradol 1mg/ml oral suspension 250ml: 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): Topical Analgesics.

Decision rationale: Per the MTUS, Cyclobenzaprine is recommended as an option in the treatment of chronic pain using a short course of therapy. It is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment suggesting that shorter courses may be better. Treatment should be brief. It is not recommended for use for longer than 2-3 weeks. Tabradol contains cyclobenzaprine, however a review of the injured workers medical records do not show that he has difficulty swallowing or is unable to tolerate other recommended non liquid oral medications, there is also no documentation of ongoing muscle spasm or pain and functional improvement with the use of Tabradol, without this information Tabradol oral suspension is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml: 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): Topical Analgesics.

Decision rationale: Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria 1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Per the ODG, PPI's are "Recommended for patients at risk for gastrointestinal events. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)" However a review of the injured workers medical records do not reveal past or current gastrointestinal complaints that would indicate that the injured worker is at increased risk for a gastrointestinal event. The injured worker does not meet guideline criteria for prophylactic GI protection therefore the request for Deprizine 15mg/ml oral suspension 250ml is not medically necessary.

Dicopanol 5mg/ml oral suspension 150ml: 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 (chronic) / Insomnia, Insomnia treatment.

Decision rationale: The MTUS did not specifically address the treatment of insomnia in chronic pain; therefore, other guidelines were consulted. Per the ODG, correcting sleep deficits is recommended, as non-restorative sleep is one of the strongest predictors of pain. Sedating antihistamines have been suggested for sleep aids, for example, diphenhydramine, tolerance develops within a few days and next day sedation, impaired psychomotor and cognitive function have been noted. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness. Dicopanol is diphenhydramine and a review of the injured workers medical records did not reveal any difficulty swallowing or tolerating non-liquid oral medications without this information the request for Dicopanol 5mg/ml oral suspension 150ml is not medically necessary.

Fanatrex 25mg/ml oral suspension 420ml: Upheld

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

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

Decision rationale: Per the MTUS, antiepilepsy drugs are recommended for neuropathic pain. Gabapentin is considered first line treatment for neuropathic pain. The choice of specific agents will depend on the balance between effectiveness and adverse reactions. A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Fanatrex contains gabapentin. However, a review of the injured workers medical records do not reveal difficulty swallowing or tolerating non-liquid oral medications, there is also no documentation of pain and functional improvement with the use of this medication as required by the guidelines and without this information, the request is not medically necessary.

6 Shockwave therapy sessions: Upheld

Claims Administrator guideline: Decision based on MTUS Shoulder Complaints 2004. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back-Lumbar and Thoracic (Acute and Chronic), Shock wave therapy.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Shoulder / Extracorporeal Shock Wave Therapy (ESWT).

Decision rationale: The MTUS / ACOEM did not specifically address the use of shock wave therapy for the shoulder therefore other guidelines were consulted. Per the ODG, it is "recommended for calcifying tendinitis but not for other shoulder disorders. Criteria for the use of Extracorporeal Shock Wave Therapy (ESWT): 1) Patients whose pain from calcifying tendinitis of the shoulder has remained despite six months of standard treatment. 2) At least three conservative treatments have been performed prior to use of ESWT. These would include: a. Rest, b. Ice, c. NSAIDs, d. Orthotics, e. Physical Therapy, f. Injections (Cortisone). 3) Contraindicated in Pregnant women; Patients younger than 18 years of age; Patients with blood clotting diseases, infections, tumors, cervical compression, arthritis of the spine or arm, or nerve damage; Patients with cardiac pacemakers; Patients who had physical or occupational therapy within the past 4 weeks; Patients who received a local steroid injection within the past 6 weeks; Patients with bilateral pain; Patients who had previous surgery for the condition. 4) Maximum of 3 therapy sessions over 3 weeks." The rationale for the use of this treatment in this injured worker at this point is unclear; without this information, the request is not medically necessary.

1 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), Fitness for Duty, Functional capacity evaluation (FCE).

MAXIMUS guideline: Decision based on MTUS General Approaches 2004, Section(s): Prevention. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Fitness for Duty / Functional capacity evaluation (FCE).

Decision rationale: The MTUS states that to determine fitness for duty, it is often necessary to "medically" gauge the capacity of the individual compared with the objective physical requirements of the job based on the safety and performance needs of the employer and expressed as essential functions. Per the ODG, Guidelines for performing an FCE: Recommended prior to admission to a Work Hardening (WH) Program, with preference for assessments tailored to a specific task or job. If a worker is actively participating in determining the suitability of a particular job, the FCE is more likely to be successful. A FCE is not as effective when the referral is less collaborative and more directive. It is important to provide as much detail as possible about the potential job to the assessor. Job specific FCEs are more helpful than general assessments. The report should be accessible to all the return to work participants. Consider an FCE if 1) Case management is hampered by complex issues such as: a) Prior unsuccessful RTW attempts. b) Conflicting medical reporting on precautions and/or fitness for modified job. c) Injuries that require detailed exploration of a worker's abilities. 2)

Timing is appropriate: a) Close or at MMI/all key medical reports secured. b) Additional/secondary conditions clarified. Do not proceed with an FCE if: a) The sole purpose is to determine a worker's effort or compliance. b) The worker has returned to work and an ergonomic assessment has not been arranged. A review of the injured workers medical records that are available to me do not describe a purpose or goal for the evaluation and without this it is difficult to establish medical necessity based on the guidelines. Therefore, the request is not medically necessary.

3 Sets of PRP treatments: Upheld

Claims Administrator guideline: Decision based on MTUS Low Back Complaints 2004. Decision based on Non-MTUS Citation ACOEM (2007) Low Back Complaints: Injection therapies, pages 193-194, Official Disability Guidelines (ODG), Pain (Chronic), Platelet rich plasma (PRP).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Shoulder / Platelet-rich plasma (PRP).

Decision rationale: The MTUS did not address the use of this treatment modality, therefore other guidelines were consulted. Per the ODG, PRP is "under study as a solo treatment. Recommend PRP augmentation as an option in conjunction with arthroscopic repair for large to massive rotator cuff tears. (Jo, 2013) PRP looks promising, but it may not be ready for prime time as a solo treatment. PRP has become popular among professional athletes because it promises to enhance performance, but there is no science behind it yet. In a blinded, prospective, randomized trial of PRP vs. placebo in patients undergoing surgery to repair a torn rotator cuff, there was no difference in pain relief or in function. The only thing that was significantly different was the time it took to do the repair; it was longer if you put PRP in the joint. There were also no differences in residual defects on MRI. (AAOS, 2010) Platelet-rich plasma did not help patients recover from arthroscopic rotator cuff surgery in this study. (Jo, 2011) Platelet-rich fibrin matrix (PRFM) applied to the site of rotator cuff tendon repair does not improve healing, and in fact might impair it. There was a significantly higher failure rate in the PRFM group than in the control group for double-row/transosseous-equivalent repairs at 12 weeks. The PRFM used in the study was the Cascade Autologous Platelet System" Unfortunately the guidelines do not yet support this treatment and there are no extenuating circumstances that would warrant deviating from the guidelines, therefore the request for 3 Sets of PRP treatments is not medically necessary.

1 Urine drug screen (retrospective dos: 07/24/2015): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Urine drug testing (UDT).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Drug testing. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Urine Drug testing.

Decision rationale: Per the MTUS, Drug testing is recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs before a therapeutic trial of opioids, during ongoing management and to avoid misuse/ addiction. Per the ODG, frequency of urine drug testing should be based on documented evidence of risk stratification including use of a testing instrument. A review of the injured workers medical records did not reveal documentation of risk stratification and without this information medical necessity for urine drug test is not medically necessary.