MAXIMUS Federal Services

Case Number:	CM15-0142694		
Date Assigned:	09/02/2015	Date of Injury:	08/01/2013
Decision Date:	10/22/2015	UR Denial Date:	06/30/2015
Priority:	Standard	Application Received:	07/23/2015

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: California
Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

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 61 year old male, who sustained an industrial injury on 8-1-13. The injured worker has complaints of headaches. The documentation noted that the injured worker is status post cervical fusion with residual pain. The pain is described as frequent to constant, moderate to severe that is aggravated by looking up, looking down and side to side as well as by repetitive motion of the head and neck. The documentation noted that the pain is associated with numbness and tingling of the bilateral upper extremities. The documentation noted bilateral hip pain and muscle spasms, bilateral knee pain and bilateral ankle pain. There is tenderness to palpation at the suboccipital region, trapezius muscles and over the sternocleidomastoid muscles and active range of motion is decreased. Straight leg raise is positive on the left and right. The diagnoses have included headaches; cervicalgia; cervical disc displacement; radiculopathy, cervical region and pain in thoracic spine. Treatment to date has included cervical fusion; terocin patches; deprizine; dicopanol; fanatrex ; synapryn; tabradol and topical compound creams. The request was for urine drug screen; bilateral magnetic resonance imaging (MRI) of the knees and ankles; bilateral platelet rich plasma injection for the knees; terocin patches; deprizine 5mg,ml oral suspension 250ml; dicopanol 5mg-ml oral suspension 150ml; fanatrex 25mg-ml oral suspension 420ml; synapryn 10-ml oral suspension 500ml; tabradol 1mg-ml oral suspension 250mg; topical compound cyclobenzaprine 5 percent cream 110gm; topical compound ketoprofen 20 percent cream 167gm; topical compound amitriptlyline 10 percent, gabapentin 1 percent, bupivacaine HCL 5 percent, hyaluronic acid 0.2 percent 240gram and

topical compound flurbiprofen 20%, baclofen 5%, camphor 2%, menthol 2%, dexamethason 0.2%, capsaicin 0.025%, hyaluronic acid 0.2% 240gram.

IMR ISSUES, DECISIONS AND RATIONALES

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

Urine drug screen: 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): Drug testing, Opioids, dealing with misuse & addiction, Opioids, differentiation: dependence & addiction, Opioids, steps to avoid misuse/addiction. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter, Urine Drug Testing.

Decision rationale: Regarding the request for a urine toxicology test, CA MTUS Chronic Pain Medical Treatment Guidelines state the drug testing is recommended as an option in patients on controlled substances. Guidelines go on to recommend monitoring for the occurrence of any potentially aberrant (or non-adherent) drug related behaviors. ODG recommends urine drug testing on a yearly basis for low risk patients, 2-3 times a year for moderate risk patients, and possibly once per month for high risk patients. Their risk stratification is an important component in assessing the necessity and frequency of urine drug testing. With the documentation available for review, there is documentation of prescription of controlled substances. The Synapryn suspension prescribed to this patient contains tramadol. However, there is no notation of when the last previous urine toxicology testing was done. No risk factor assessment, such as the utilization of the Opioid Risk Tool or SOAPP is apparent in the records, which would dictate the schedule of random periodic drug testing. Furthermore, as detailed below, the continuation of the Synapryn is not felt to be medically necessary. Given this, this request is not medically necessary.

Bilateral MRI of the knees: Upheld

Claims Administrator guideline: Decision based on MTUS Knee Complaints 2004.

MAXIMUS guideline: Decision based on MTUS Knee Complaints 2004, Section(s): Special Studies.

Decision rationale: Regarding the request for MRI of the bilateral knees, ACOEM Practice Guidelines state that reliance only on imaging studies to evaluate the source of knee symptoms may carry a significant risk of diagnostic confusion (false-positive test results) because of the possibility of identifying a problem that was present before symptoms began, and therefore has no temporal association with the current symptoms. The ODG Indications for MRI of the knee include the following: Acute trauma to the knee, including significant trauma (ie, motor vehicle accident), or if suspect posterior knee dislocation or ligament or cartilage disruption; Non-traumatic knee pain, child or adolescent: non-patellofemoral symptoms. Initial anteroposterior

and lateral radiographs non-diagnostic (demonstrate normal findings or a joint effusion) next study if clinically indicated. If additional study is needed; Non-traumatic knee pain, child or adult. Patellofemoral (anterior) symptoms. Initial anteroposterior, lateral, and axial radiographs non-diagnostic (demonstrate normal findings or a joint effusion). If additional imaging is necessary, and if internal derangement is suspected; Non-traumatic knee pain, adult. Non-trauma, non-tumor, non-localized pain. Initial anteroposterior and lateral radiographs non-diagnostic (demonstrate normal findings or a joint effusion). If additional studies are indicated, and if internal derangement is suspected; Non-traumatic knee pain, adult - non-trauma, non-tumor, non-localized pain. Initial anteroposterior and lateral radiographs demonstrate evidence of internal derangement (e.g., Peligrini Stieda disease, joint compartment widening). Within the medical information made available for review, there is documentation of non-traumatic knee pain. The progress note from 5/22/15 indicates that there is tenderness to palpation in the joint lines of both knees. There is restriction of AROM especially in flexion of the right more so than the left knee. There is documentation of positive McMurray's testing bilaterally. Stability testing is within normal limits. However, there is no documentation that radiographs are non-diagnostic or identification of any red flags signs. In the absence of such documentation, the currently requested MRI is not medically necessary.

Bilateral MRI of the ankles: Upheld

Claims Administrator guideline: Decision based on MTUS Ankle and Foot Complaints 2004.

MAXIMUS guideline: Decision based on MTUS Ankle and Foot Complaints 2004, Section(s): Special Studies. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ankle & Foot Chapter, Magnetic resonance imaging (MRI).

Decision rationale: Regarding the request for MRI of the ankle, ACOEM Practice Guidelines state that special studies are not usually needed until after conservative care, in the absence of red flag conditions. ODG states that the MRI provided more definitive visualization of soft tissue structures including ligaments, tendons, joints capsule, menisci, and joint cartilage structures. The ODG further stipulate the following indications for imaging after plain x-rays have been taken: Indications for imaging -- MRI (magnetic resonance imaging): suspected osteochondral injury, tendinopathy, pain of uncertain etiology, pain and tenderness over navicular tuberosity, and neural entrapment syndromes. In all cases, plain x-rays are the first recommended study. The guidelines also state that MRI has a very high specificity and positive predictive value in diagnosing tears of the anterior talofibular ligament, calcaneofibular ligament and osteochondral lesions. Within the documentation available for review, there is documentation of chronic ankle pain. A progress note from 5/22/15 indicates that there is 2+ tenderness to palpation over the medial and lateral malleolus bilaterally. There is also ATFL tenderness and slightly reduction in AROM, esp with bilateral eversion. However, there is no discussion of the outcome of plain films in the submitted records. Given this, the current request is not medically necessary.

Bilateral platelet rich plasma injection for the knees: 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), Knee & Leg (Acute & Chronic), Platelet-rich plasma.

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

Decision rationale: Regarding the request for platelet rich plasma injections of the knee, the CA MTUS does not address the issue. The ODG states that PRP for the knee is "recommended for limited, highly specific indications." The ODG Criteria for Platelet-rich plasma (PRP) intra-articular injection include: (1) Significantly symptomatic osteoarthritis: (a) Not responded adequately to recommended conservative non-pharmacologic (e.g., exercise) and pharmacologic treatments or are intolerant of these therapies (e.g., gastrointestinal problems related to anti-inflammatory medications), after at least 6 months; & (b) Documented symptomatic mild-moderate (not advanced) osteoarthritis of the knee; & (c) Under 50 years of age; & (d) Pain interferes with functional activities (e.g., ambulation, prolonged standing) and not attributed to other forms of joint disease; & (e) Failure to adequately respond to aspiration and injection of intra-articular steroids; & (f) Generally performed without fluoroscopic or ultrasound guidance; & (g) Single injection highly concentrated WBC-poor (filtered); & (h) Maximum once yearly if previous injection documented significant relief for over 6 months". In the case of this injured worker, the age require of < 50 year old is not met. Furthermore, PRP has still not had consistent supportive literature in trials regarding its use, and it is not covered by any major private or governmental insurance. Given this, this request is not medically necessary.

Terocin patches: 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: Terocin Patch is a topical formulation consisting of Methyl Salicylate 25%, Capsaicin 0.025%, Menthol 10%, and Lidocaine 2.50%. The Chronic Pain Medical Treatment Guidelines, on pages 111-113, specify that, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of topical non-steroidal anti-inflammatory, guidelines state that 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 1st 2 weeks of treatment of osteoarthritis, but either not afterwards, or with the diminishing effect over another two-week period. Regarding use of capsaicin, guidelines state that it is recommended only as an option for patients who did not respond to or are intolerant to other treatments. Regarding the use of topical lidocaine, guidelines the state that it is recommended for localized peripheral pain after there is evidence of a trial of first-line therapy. Guidelines further stipulate that no preparation of topical lidocaine except as Lidoderm patch is approved. Therefore, since this component is not recommended, the entire Terocin formulation is not recommended and the request is not medically necessary.

Deprizine 5mg/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): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: Regarding the request for Deprizine, this medication is not specifically described in the CA MTUS or ACOEM. Deprizine contains active and inactive bulk materials to compound a ranitidine hydrochloride oral suspension. California MTUS states that H2 antagonists such as ranitidine are appropriate for the treatment of dyspepsia secondary to NSAID therapy or for patients at risk for gastrointestinal events with NSAID use. Within the documentation available for review, there is no indication that the patient has trialed a conventional H2 antagonist such as ranitidine or famotidine in pill form. The worker also does not have clear documentation of complaints of dyspepsia secondary to NSAID use, a risk for gastrointestinal events with NSAID use, or another indication for this medication. In light of the above issues, the currently requested Deprizine 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 Chapter, Insomnia treatment and Other Medical Treatment Guidelines Drugs.com Listing of Dicopanol oral suspensionhttp://www.drugs.com/pro/dicopanol.htm.

Decision rationale: Regarding the request for Dicopanol, California MTUS guidelines are silent regarding this medication. Dicopanol contains active and inactive bulk materials to compound a diphenhydramine hydrochloride oral suspension. ODG states 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. They go on to state the failure of sleep disturbances to resolve in 7 to 10 days, may indicate a psychiatric or medical illness. Within the documentation available for review, there are no statements indicating how the patient has responded to treatment with Dicopanol despite the worker being on this medication for several months since at least April 21, 2015. There is no indication of why an oral suspension formulation is necessary, as opposed to a tablet form of this drug which is available as a generic. Given this, the currently requested Dicopanol 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.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs). Decision based on Non-MTUS Citation Drugs.com Listing of Fanatrexhttp://www.drugs.com/pro/fanatrex.html.

Decision rationale: Regarding the requested for Fanatrex, the CA MTUS does not specifically discuss this medication. Fanatrex contains active and inactive bulk materials to prepare 420 mL of a gabapentin oral suspension containing 25 mg/mL gabapentin. Per the MTUS, gabapentin is an anti-epileptic drug that is commonly used to treat neuropathic pain. The Chronic Pain Medical Treatment Guidelines state that anti-epilepsy drugs are recommended for neuropathic pain. They go on to state that a good outcome is defined as 50% reduction in pain and a moderate response is defined as 30% reduction in pain. Guidelines go on to state that 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. Within the documentation available for review, there is no identification of any specific analgesic benefit (in terms of percent reduction in pain or reduction of NRS), and no documentation of specific objective functional improvement. Additionally, there is no discussion as to why an oral suspension as opposed to a tablet form that is available as a generic is necessary in this case. Given this, the currently requested Fanatrex is not medically necessary.

Synapryn 10mg/ml 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): Glucosamine (and Chondroitin Sulfate), Opioids, criteria for use, Opioids for chronic pain, Opioids, specific drug list.

Decision rationale: Regarding the request for Synapryn, the CA MTUS does not specifically mention this drug. It is noted that this is a compounded medication containing tramadol and glucosamine, which are both separately discussed in the CPMTG. With regard to opioids such as tramadol, California MTUS Chronic Pain Medical Treatment Guidelines state that, due to high abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. With regard to glucosamine, it is recommended as an option in patients with moderate arthritis pain, especially for knee osteoarthritis. Within the documentation available for review, there is no indication that the medication is improving the patient's pain (in terms of percent reduction in pain or reduced NRS), and no discussion regarding aberrant use. There is also no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms (which is also the formulation recommended by the CA MTUS). In the absence of such documentation, the currently requested Synapryn 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): Muscle relaxants (for pain).

Decision rationale: Regarding the request for Tabradol, the CA MTUS does not address this specific drug/formulation. Tabradol contains cyclobenzaprine hydrochloride 1 mg/mL in oral suspension with MSM - compounding kit. Regarding cyclobenzaprine, Chronic Pain Medical Treatment Guidelines support the use of non-sedating muscle relaxants to be used with caution as a 2nd line option for the short-term treatment of acute exacerbations of pain. Guidelines go on to state that cyclobenzaprine specifically is recommended for a short course of therapy. Within the documentation available for review, there is no identification of a specific analgesic benefit or objective functional improvement as a result of the cyclobenzaprine. Additionally, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation, as recommended by guidelines. In the absence of such documentation, the currently requested Tabradol is not medically necessary.

Topical compound 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: Regarding the request for topical cyclobenzaprine, CA MTUS states that topical muscle relaxants are not recommended as there is no peer-reviewed literature to support the use of topical baclofen or any other muscle relaxant as a topical product. Furthermore, the same guidelines specify that if one component of a compounded medication is not recommended, then the entire formulation is not recommended. Given these guidelines, this request is not medically necessary.

Topical compound Ketoprofen 20% cream 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: The Chronic Pain Medical Treatment Guidelines on page 112 state the following: Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996).

Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000) Within the submitted documentation, there is no indications as to why the topical ketoprofen is recommend despite MTUS recommendations against this formulation. Given this, this request is not medically necessary.

Topical compound Flurbiprofen 20%, Baclofen 5%, Camphor 2%, Menthol 2%, Dexamethason 0.2%, Capsaicin 0.025%, Hyaluronic acid 0.2% 240g: 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: Regarding this request, one of the components requested is topical baclofen. Chronic Pain Medical Treatment Guidelines Page 113 of 127 states the following: "Topical Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline- Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen." Given these guidelines, the topical baclofen is not medically necessary. Since any formulation must have all components as recommended in order for the formulation to be medically necessary, this request is not medically necessary.

Topical compound Amitripyline 10%, Gabapentin 1%, Bupivacaine HCL 5%, Hylauronic acid 0.2% 240g: 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: With regard to this request for a topical compounded cream that contains gabapentin as a component, the CPMTG does not recommend topical gabapentin. On page 113 of the Chronic Pain Medical Treatment Guidelines, the following is stated: "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." The guidelines further state that if one drug or drug class of a compounded formulation is not recommended, then the entire compounded formulation is not recommended. Therefore, the topical gabapentin component is not recommended, and the entire formulation is not medically necessary.