

Case Number:	CM15-0190174		
Date Assigned:	10/02/2015	Date of Injury:	03/07/2014
Decision Date:	12/08/2015	UR Denial Date:	09/01/2015
Priority:	Standard	Application Received:	09/29/2015

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 54 year old male who sustained an industrial injury on 3-7-14. A review of the medical records indicates he is undergoing treatment for status post right knee arthroscopy meniscectomy with residual pain, right knee medial meniscal tear, right knee internal derangement, right knee bursitis, right knee chondromalacia patella, right knee bone contusion, and right knee joint effusion. Medical records (1-6-15 to 7-14-15) indicate ongoing complaints of "residual" pain in the right knee, following a right knee arthroscopy. He rates his pain "4 out of 10" and describes it as "frequent to constant" and "moderate to severe". He reports the pain is aggravated by squatting, kneeling, ascending and descending stairs, as well as prolonged weight bearing, standing, and walking. The physical exam (7-14-15) reveals "1+ effusion", as well as patella-femoral crepitation and pain. He is noted to have pain with heel and toe walking. Tenderness is noted over the medial and lateral joint line. Decreased range of motion is noted. Decreased sensation is noted to pin prick and light touch at L4, L5, and S1 dermatomes in the right lower extremity. Motor strength is "4 out of 5". Diagnostic studies are not included in the reviewed records. Treatment has included medications. He is currently (7-14-15) receiving Deprizine, Dicoprofol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine, and Ketoprofen cream. He has been receiving these medications since, at least, 1-6-15. The utilization review (9-1-15) includes requests for authorization for Ketoprofen 20% cream 167gms, Cyclobenzaprine 5% cream 110gms, Synapryn 10mg per ml oral suspension 500ml, Tabradol 1mg per ml oral suspension 250ml, Deprizine 15 per ml oral suspension 250ml, Dicoprofol 5mg per ml oral suspension 150 ml, and Fanatrex 5mg per ml oral suspension 420ml. All requests were denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% cream, 167grams: 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 photocontact 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 explanation as to why the topical ketoprofen is prescribed despite MTUS recommendations against this formulation. It is not apparent if the worker has failed other forms of topical NSAIDs recommended by the CPMTG. Given this, this request is not medically necessary.

Cyclobenzaprine 5% cream 110grams: 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: This topical compound consists of topical cyclobenzaprine. 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.

Synapryn 10mg/ml oral suspension 500ml: 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): Glucosamine (and Chondroitin Sulfate), Opioids, criteria for use. Decision based on

Non-MTUS Citation US National Library of Medicine,
Synapryn <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22416>.

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: 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). Decision based on Non-MTUS Citation Medline, Tabradol <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=5d19ef8b-eef3-4d52-95f5-929765ca6dc7>.

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 indication of a failed trial of oral generic cyclobenzaprine or documentation of why this oral suspension is medically necessary (i.e., in cases of dysphagia). Furthermore, the compounding MSM is not provided in either the CA MTUS, ODG, or ACOEM. Given this, the currently requested Tabradol is not medically necessary.

Deprizine 15/ml oral suspension 250ml: 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): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/deprizine.html>.

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 or another indication for this medication. In light of the above issues, the currently requested Deprizine is not medically necessary.

Dicopanol (diphenhydramine) 5mg/ml oral suspension 150ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/diphenhydramine.html>.

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 suspension <http://www.drugs.com/pro/dicopanol.html>.

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. There are also "proprietary ingredients" in Dicopanol which have not been studied in peer reviewed studies. 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 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. It is not apparent in the records that the worker has failed a trial of generic diphenhydramine which has more extensive safety studies. Furthermore, this oral suspension also has "proprietary" ingredients which have not been subjected to peer reviewed research. Given this, the currently requested Dicopanol is not medically necessary.

Fanatrex (gabapentin) 5mg/ml oral suspension 420ml: 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): Antiepilepsy drugs (AEDs). Decision based on Non-MTUS Citation Drugs.com Listing of Fanatrex <http://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 antiepilepsy 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.