

<b>Case Number:</b>	CM15-0146529		
<b>Date Assigned:</b>	08/07/2015	<b>Date of Injury:</b>	06/22/2012
<b>Decision Date:</b>	10/02/2015	<b>UR Denial Date:</b>	07/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/28/2015

### 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: Emergency 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 was a 45 year old female, who sustained an industrial injury, June 22, 2012. The injured worker previously received the following treatments bilateral wrist MRI in 2013, Ketoprofen cream, Cyclobenzaprine cream, Synapryn, Tabradol, Deprizine, Dicopanol and Fanatrex. The injured worker was diagnosed with right knee surgery on January 30, 2014, cervical spine pain, cervical spine radiculopathy, bilateral elbow pain, rule out bilateral elbow lateral epicondylitis, bilateral wrist pain, rule out wrist carpal tunnel syndrome, bilateral wrist De Quervain's tenosynovitis, low back pain, lumbar disc displacement, lumbar radiculopathy, bilateral knee pain, internal derangement, bilateral ankle and foot pain and rule out bilateral planter fasciitis. According to progress note of June 23, 2015, the injured worker's chief complaint was cervical spine, bilateral elbow, right knee and bilateral feet pain. The injured worker rated the pain in the cervical spine at 5 out of 10. The pain was described as intermittent ache which increased with movement. The bilateral elbow pain fluctuated from 3-6 out of 10. The bilateral wrist pain was 3-6 out of 10. The right knee pain was 6 out of 10. The lumbar spine required no further treatments. The injured worker was right hand dominate. The physical exam was documented as no change. The treatment plan included prescriptions for Ketoprofen cream, Cyclobenzaprine cream, Synapryn, Tabradol, Deprizine, Dicopanol and Fanatrex.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen (Rx 11/24/2014) 20% cream 165gm #1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 8 C.C.R. 9792.20 - 9792.26 (pages 111-112 of 127).

**Decision rationale:** The request is for the use of a topical NSAID for pain relief. There are specific criteria require for use based on the guidelines. The MTUS states the following: 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 first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the treatment duration. As such, the request is not medically necessary.

**Synapryn (Rx 11/24/2015) 10mg/ml 500ml #1: 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 chapter - Compounded drugs [www.dailymed.nlm.nih.gov](http://www.dailymed.nlm.nih.gov).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 8 C.C.R. 9792.20 - 9792.26 (pages 80-83 of 127).

**Decision rationale:** Tramadol is a pain medication in the category of a centrally acting analgesic. They exhibit opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Centrally acting drugs are reported to be effective in managing neuropathic type pain although it is not recommended as first line therapy. The side effect profile is similar to opioids. For chronic back pain, it appears to be efficacious for short term pain relief, but long term (>16 weeks) results are limited. It also did not appear to improve function. The use of tramadol for osteoarthritis is indicated for short term use only (<3 months) with poor long-term benefit. In this case, the patient does not meet the qualifying criteria. This is secondary to the duration of use, with this medication being indicated on a short-term basis only. As such, the request is not medically necessary.

**Deprizine (Rx 11/24/2015) 15mg/ml 250ml #1: 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 chapter - Compounded drugs [www.dailymed.nlm.nih.gov](http://www.dailymed.nlm.nih.gov).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 8 C.C.R. 9792.20 - 9792.26 (page 68 of 127).

**Decision rationale:** The request is for the use of a medication in the class of an acid reducing medication. The guidelines do not specifically address or advise the use of an H2 blocker but does make recommendations regarding medications in the same category classified as proton pump inhibitors. This is usually given for patients with esophageal reflux, gastritis, or peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain which have side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically with a proton pump inhibitor or Misoprostol. Criteria for risk are as follows: "(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)." Due to the fact the patient does not meet to above stated criteria, the request for use is not medically necessary.

**Fanatex (Rx 11/24/2015) 25mg/ml 420ml #1: 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 chapter - Compounded drugs [www.dailymed.nlm.nih.gov](http://www.dailymed.nlm.nih.gov).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 8 C.C.R. 9792.20 - 9792.26 (pages 16-17 of 127).

**Decision rationale:** The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. Their also should be documentation of functional improvement and side effects incurred with use. Disease states which prompt use of these medications include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, there is lack of documentation of adequate pain reduction for continued use. The records also do not reveal functional improvement or screening measures as required. As such, the request is not medically necessary.

**Cyclobenzaprine (Rx 11/24/2014) 5% cream 100gm #1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 8 C.C.R. 9792.20 - 9792.26 (pages 111 to 113 of 127).

**Decision rationale:** The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the use of the topical muscle relaxant is not indicated for use for the patient's condition. The MTUS states the following: "There is no evidence for use of any other muscle relaxant as a topical product." As such, the request is not medically necessary.

**Tabradol (Rx 11/24/2015) 1mg/ml 250ml #1: 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 chapter - Compounded drugs [www.dailymed.nlm.nih.gov](http://www.dailymed.nlm.nih.gov).

**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) NSAIDs, specific drug list & adverse effects.

**Decision rationale:** The request is for the use of ketorolac intramuscular injection for pain relief. The MTUS guidelines are silent regarding this issue. The ODG guidelines state the following: Ketorolac (Toradol, generic available): 10 mg. [Boxed Warning]: The oral form is only recommended for short-term (up to 5 days) in management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation following IV or IM dosing, if necessary. This medication is not indicated for minor or chronic painful conditions. Increasing doses beyond a daily maximum dose of 40 mg will not provide better efficacy, and will increase the risk of serious side effects. The FDA boxed warning would relegate this drug to second-line use unless there were no safer alternatives. Dosing: Acute pain (transition from IV or IM) for adults < 65 years of age: 20mg PO followed by 10mg PO every 4 to 6 hours (max 40 mg/day). An oral formulation should not be given as an initial dose. (Toradol Package Insert) The FDA has approved a nasal formulation of ketorolac (Sprix) for short-term pain management. (FDA, 2010) As indicated above, this patient does not qualify for the use of ketorolac. This is secondary to the duration of use with the guidelines stating that it is not to be given for chronic painful conditions. As such, the request is not medically necessary.

**Dicopanol (Rx 11/24/2015) 5mg/ml 150ml #1: 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 chapter - Compounded drugs [www.dailymed.nlm.nih.gov](http://www.dailymed.nlm.nih.gov).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness and Stress Diphenhydramine (Benadryl).

**Decision rationale:** The request is for the use of Diphenhydramine medication. The ODG guidelines advise the following regarding its use: Not recommended. See Insomnia treatment, where sedating antihistamines are not recommended for long-term insomnia treatment. The AGS updated Beers criteria for inappropriate medication use includes diphenhydramine. (AGS, 2012) Anti-cholinergic drugs, including diphenhydramine, may increase the risk for dementia by 50% in older adults. There is an obvious dose-response relationship between anticholinergic drug use and risk of developing dementia, but chronic use, even at low doses, would be in the highest risk category. While there is awareness that these drugs may cause short-term drowsiness or confusion, which is included in the prescribing information, there is no mention of long-term effects on cognition, and generally awareness of this issue is very low, and both the public and doctors need to be encouraged to use alternative treatments where possible. (Gray, 2015) As stated above, the use of this medication is not indicated. This is secondary to poor clinical evidence regarding its safe and effective use. As such, the request is not medically necessary.