

Case Number:	CM15-0178689		
Date Assigned:	09/21/2015	Date of Injury:	06/27/2003
Decision Date:	11/10/2015	UR Denial Date:	08/14/2015
Priority:	Standard	Application Received:	09/10/2015

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 is a 52 year old female, who sustained an industrial injury on June 27, 2003. The injured worker was being treated for status post right shoulder arthroscopic decompression, left shoulder impingement syndrome, tendonitis and bilateral carpal tunnel syndrome, cervical strain with disc lesion and radiculitis, right hand De Quervain's tenosynovitis, and status post right carpal tunnel release in 2011. Medical records (May 22, 2015 to June 26, 2015) indicate ongoing bilateral shoulder pain and stiffness. The medical records show the subjective pain rating is 7 out of 10 on June 26, 2015. The physical exam (May 22, 2015 to June 26, 2015) reveals unchanged right shoulder range of motion in all directions, except for a slight increase in flexion. There is decreased left shoulder flexion, extension, and abduction. The left shoulder adduction, internal rotation, and external rotation are unchanged. There are positive bilateral impingement tests, greater tuberosity tenderness of the humerus and rotator cuff muscles bilaterally, and subacromial grinding and clicking of the humerus bilaterally. There are multiple well-healed post arthroscopic scars and stitches at the right shoulder. On December 17, 2014, an MRI of the left shoulder revealed a partial tear of the supraspinatus tendon at its articular surface, supraspinatus and infraspinatus tendinosis, minimal subacromial and subscapularis bursitis, and osteoarthropathy of acromioclavicular joint. On December 17, 2014, an MR arthrogram of the right shoulder revealed interstitial tear supraspinatus and infraspinatus tendons, osteoarthropathy of acromioclavicular joint, and tear of superior glenoid labrum. Surgeries to date have included cervical epidural steroid injection and neuroplasty with segmental decompression at bilateral C3- C4 (cervical 3-cervical 4), C4-C5 (cervical 4-cervical 5), and C5-C6 (cervical 5-cervical 6) with facet blocks and posterior primary branch innervation block facet

joints at bilateral C4-C5 and C5-C6 on January 10, 2015 ; right shoulder arthroscopy in 2004, and right shoulder arthroscopic glenohumeral synovectomy, glenohumeral lysis of adhesions, glenohumeral debridement and edge tear of labrum, subacromial deltoid bursectomy and lysis of adhesions, partial anterior and lateral acromionectomy, acromioclavicular synovectomy and lysis of adhesions, and partial inferior and lateral claviculectomy on March 28, 2015. Treatment has included physical therapy, postoperative physical therapy for the right shoulder, a right wrist brace, a lumbar spine brace, a cane, left shoulder steroid injections, work and activity modifications, interferential-transcutaneous electrical nerve stimulation (TENS) unit, and medications including pain, muscle relaxant (Soma since at least October 2014), anti-epilepsy (Neurontin), hypnotic (Ambien 10 mg since at least October 2014), antianxiety (Xanax ER 0.5 mg since at least October 2014), antidepressant (Zoloft), proton pump inhibitor (Prilosec), and non-steroidal anti-inflammatory (Motrin). On August 6, 2015, the requested treatments included Soma 350 mg, Ambien 10 mg, Fiorinal #120, Ketoprofen 10-3-5% #1 tube, Flurbiprofen 10% #1 tube, Capsaicin 0.02%-Menthol 2%-Camphor 1% 30 gm, Xanax ER 0.5 mg #60. On August 14, 2015, the original utilization review non-certified a request for Soma 350 mg #90, Ambien 10 mg #30, Fiorinal #120, Ketoprofen 10-3-5% #1 tube, Flurbiprofen 10% #1 tube, and Capsaicin 0.02%-Menthol 2%-Camphor 1% 30 gm, and partially approved a request for Xanax ER 0.5 mg #50 (original request for #60) to allow for weaning.

IMR ISSUES, DECISIONS AND RATIONALES

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

Soma 350 mg #90: 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 rationale: The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long-term use, the request is not medically necessary.

Ambien 10 mg #30: 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).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental(stress)/ Zolpidem (Ambien).

Decision rationale: The request is for the use of zolpidem. The official disability guidelines state the following regarding the use of this medication: Not recommended for long-term use, but recommended for short-term use. See Insomnia treatment for zolpidem (brand names Ambien, Edluar, Intermezzo, Zolpimist). See also the Pain Chapter. Zolpidem is approved for the short-term (usually two to six weeks) treatment of insomnia. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. Ambien CR offers no significant clinical advantage over regular release zolpidem, and Ambien CR causes a greater frequency of dizziness, drowsiness, and headache compared to immediate release zolpidem. Due to adverse effects, FDA now requires lower doses for zolpidem. The ER product is still more risky than IR. Even at the lower dose of Ambien CR now recommended by the FDA, 15% of women and 5% of men still had high levels of the drug in their system in the morning. (Pain Chapter) Emergency department (ED) visits for adverse reactions related to zolpidem increased by almost 220% in a recent 5-year period, according to the Substance Abuse and Mental Health Services Administration (SAMHSA). Women and the elderly appear to be most prone to adverse reactions linked to zolpidem. Doctors should look at alternative strategies for treating insomnia such as sleep hygiene. By 2010 there were 64,175 ED visits involving zolpidem. The report stresses that zolpidem should be used safely for only a short period of time. (SAMHSA, 2013) Zolpidem (Ambien) increases the ability to remember images, but only those that have negative or highly arousing content. The findings have potential ramifications for patients prescribed zolpidem for relief of insomnia due to anxiety disorders, including posttraumatic stress disorder (PTSD). Physicians should watch out for this countertherapeutic effect in patients with anxiety disorders and PTSD, because these are people who already have heightened memory for negative and high-arousal memories. The study also identified sleep spindles as the mechanism that enables the brain to consolidate emotional memory. Sleep spindles are brief bursts of brain activity that occur primarily during non-rapid eye movement (REM) sleep. (Kaestner, 2013) New analysis from SAMHSA shows that overmedicating with zolpidem led to a near doubling of emergency department (ED) visits during the periods 2005-2006 and 2009-2010. (SAMHSA, 2014). In this case, zolpidem is not indicated. This is secondary to the prolonged duration of use. As such, the request is not medically necessary.

Fiorinal #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation FDA.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Barbiturate-containing analgesic agents.

Decision rationale: The request is for the use of a barbiturate containing analgesic medication. The MTUS states the following regarding this topic: Not recommended for chronic pain. The potential for drug dependence is high and no evidence exists to show a clinically important enhancement of analgesic efficacy of BCAs due to the barbiturate constituents. (McLean, 2000) There is a risk of medication overuse as well as rebound headache. (Friedman, 1987). In this case, as indicated above, the use of this medication is not recommended. Any barbiturate medication is not advised for chronic pain and has a high abuse potential. As such, the request is not medically necessary.

Ketoprofen 10/3/5% #1 tube: 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 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.

Flurbiprofen 10% #1 tube: 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 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.

Capsaicin 0.02%/ Menthol 2%/ Camphor 1% 30 gm: 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 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 compounded topical treatment contains Capsaicin. Qualifying factors for this product is indicated by the following per the guidelines: Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-BMJ, 2004) In this case, as stated above, the patient would not qualify for the use of capsaicin based on the diagnosis. There is also inadequate scientific evidence to support the use of menthol or camphor. As such, the request is not medically necessary.

Xanax ER 0.5 mg #60: 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): Benzodiazepines.

Decision rationale: The request is for the use of a medication in the category of benzodiazepines. It is usually indicated to treat anxiety disorders but has been used short-term as a muscle relaxant. The MTUS guidelines state the following: Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) In this case, a medication in this class would not be advised for continued use due to the duration of therapy. As such, the request is not medically necessary. All benzodiazepine medications should be titrated down slowly to prevent an acute withdrawal syndrome.