

Case Number:	CM14-0010444		
Date Assigned:	02/21/2014	Date of Injury:	06/26/2007
Decision Date:	01/15/2015	UR Denial Date:	01/17/2014
Priority:	Standard	Application Received:	01/24/2014

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. The expert reviewer is Board Certified in Anesthesiology, has a subspecialty in Pain and Acupuncture and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 62 year old male who sustained a work injury on June 26, 2007 from lifting and straining, injuring his neck and right shoulder. Current work status was not found in the records. A consultation report dated February 8, 2011 states that the injured worker had bilateral neck pain with numbness and weakness of the right hand. The injured workers pain level was seven out of ten. Physical examination revealed a decreased range of motion of the neck in all directions. The documentation supports an MRI done on October 22, 2007 revealed a moderate right cervical-five neural foraminal stenosis and disc protrusion at cervical four-five level, central disc protrusion at cervical five-six level and cervical facet arthropathy. A physician's report dated September 20, 2013 notes that the injured worker complained of constant right shoulder pain which radiated down the arm to the fingertips. He also reported tension and spasms. The pain was rated at seven out of ten and increased with movement. The examination of the neck and upper extremities revealed decreased range of motion, decreased cervical sensation and decreased strength of the right upper extremity. Utilization Review documentation notes that the injured worker had a right rotator cuff repair performed on January 31, 2008 and fluoroscopically guided cervical facet joint medical branch blocks performed, dates unknown. Treatment also included diagnostic testing, neurodiagnostic testing, physical therapy treatments and a TENS unit. A physicians report dated January 8, 2014 notes that the injured worker had continued tenderness along the rotator cuff repair and weakness to resisted function was noted. The injured worker notes that the function of his right shoulder is worse lately. Current diagnoses include a right rotator cuff tear post decompression and rotator cuff repair and discogenic cervical condition with facet inflammation and radiculopathy along the right upper extremity. The treating physician requested prescriptions of Tramadol ER 150mg # 60, Terocin Patches # 60 and Flexeril 7.5 mg # 120. Utilization Review evaluated and denied the Terocin

Patches and modified the prescriptions for Tramadol ER 150 mg # 60 and Flexeril 7.5 mg # 60 on January 17, 2014. Utilization Review denied the Terocin Patches due to MTUS Chronic Pain Medical Treatment Guidelines which notes that topical medications have not been proven with regards to overall efficacy and safety. The Tramadol ER 150 mg and Flexeril 7.5 mg tablets were modified due to no documentation of a maintained increase in function or decrease in pain with the use of the medications. Therefore, the medications would not be indicated as medically necessary. However, the prescriptions were modified for a weaning process.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin Patches Qty:60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 25, 60, 105, 111-113.

Decision rationale: Terocin is capsaicin, lidocaine, menthol, methyl salicylate, and boswellia serrata. Per MTUS p 112 "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." Methyl salicylate may have an indication for chronic pain in this context. Per MTUS p105, "Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004)." However, the other ingredients in Terocin are not indicated. The preponderance of evidence indicates that overall this medication is not medically necessary. Regarding topical lidocaine, MTUS states (p112) "Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo." (Scudds, 1995). Per MTUS p25 Boswellia Serrata Resin is not recommended for chronic pain. Terocin patches contain menthol. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the

analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, Terocin Patches Qty: 60 are not medically necessary.

Tramadol 150 ER tablet Qty: 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 91.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78, 93.

Decision rationale: Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding ongoing management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug related behaviors. These domains have been summarized as the '4 As' (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Review of the available medical records reveals no documentation to support the medical necessity of tramadol nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for my review. As MTUS recommends to discontinue opioids if there is no overall improvement in function or screening for risk, medical necessity cannot be affirmed.

Flexeril 7.5mg tablets Qty:60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CYCLOBENZAPRINE (FLEXERIL) Page(s): 41, 64.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-64.

Decision rationale: With regard to muscle relaxants, the MTUS CPMTG states: "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most

LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement." Regarding Cyclobenzaprine: "Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects." There is no mention of lower back pain nor muscle spasm in the most recent medical record available for review. As such, the request is not medically necessary.