

Case Number:	CM15-0193839		
Date Assigned:	10/07/2015	Date of Injury:	06/14/2011
Decision Date:	11/19/2015	UR Denial Date:	09/23/2015
Priority:	Standard	Application Received:	10/02/2015

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, District of Columbia, Maryland
 Certification(s)/Specialty: Anesthesiology, 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 60 year old female, who sustained an industrial-work injury on 6-14-11. A review of the medical records indicates that the injured worker is undergoing treatment for right shoulder sprain and carpal tunnel syndrome. Treatment to date has included pain medication including Tylenol #3, Butrans patch, Gralise, Cymbalta, Duexis, Lidoderm patch, Prilosec, Neurontin, Fennipofen, Flexeril, Theramine, Sentra, Tramadol and Flexeril since at least 6-23-15, 2 shoulder surgeries, lumbar epidural steroid injection (ESI), physical therapy, psyche care and other modalities. Medical records dated (3-31-15 to 9-15-15) indicate that the injured worker complains of back, shoulder and left wrist pain. The back pain radiates to the right ankle and the right shoulder pain radiates to the entire right arm. She also reports numbness. The pain is rated 6-8 out of 10 on the pain scale and decreases to 3 out of 10 with medications. She reports that back and shoulder pain can get to 10 out of 10 on the pain scale and the topical creams are very helpful. Per the treating physician report dated 9-15-15 the work status is with restrictions. The physical exam dated 9-15-15 reveals bilateral tenderness and spasm of the cervical and trapezius muscles, decreased range of motion in the right shoulder, tenderness to palpation of the bilateral shoulders, positive Tinel's and Phalen's tests right wrist and right elbow medial aspect, and she walks with a slight limp. The treating physician indicates that the urine drug test result dated 8-1-15 was inconsistent with the medication prescribed. The requested services included Tramadol extended release 150mg quantity 30, Cyclobenzaprine 7.5mg quantity 60, and Exoten Cream #2. The original Utilization review dated 9-23-15 non-certified the request for Tramadol extended release 150mg quantity 30, Cyclobenzaprine 7.5mg quantity 60, and Exoten Cream #2 as not medically necessary.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol extended release 150mg quantity 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids, specific drug list.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

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 non-adherent) drug related behaviors. These domains have been summarized as the 4 A's (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 ongoing 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. It was noted that a UDS was performed 2/2015, however, the results were not stated. As MTUS recommends to discontinue opioids if there is no overall improvement in function, medical necessity cannot be affirmed.

Cyclobenzaprine 7.5mg quantity 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril), Muscle relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

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." Per p41 of the MTUS guidelines the effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment is recommended for the treatment of acute spasm limited to a maximum of 2-3 weeks. UDS that evaluate for cyclobenzaprine can provide additional data on whether the injured worker is compliant, however in this case there is no UDS testing for cyclobenzaprine. The documentation submitted for review indicates that the injured worker has been using this medication since at least 6/2015. There is no documentation of the patient's specific functional level or percent improvement with treatment with cyclobenzaprine. As it is recommended only for short-term use, medical necessity cannot be affirmed.

Exoten Cream #2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Salicylate topicals, Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Exoten-C lotion is capsaicin, menthol, and methyl salicylate. Per the MTUS guidelines, capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Capsaicin may have an indication for chronic lower back pain in this context. 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)." Exoten-C topical lotion contains 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, it would be optimal to trial each medication individually. The request is not medically necessary.