

<b>Case Number:</b>	CM13-0057578		
<b>Date Assigned:</b>	06/09/2014	<b>Date of Injury:</b>	01/24/2005
<b>Decision Date:</b>	08/07/2014	<b>UR Denial Date:</b>	11/04/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/25/2013

### 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 Occupational Medicine 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:

The patient is a 60-year-old female who has filed a claim for discogenic cervical condition status post radiofrequency ablation associated with an industrial injury date of January 24, 2005. Review of progress notes indicates pain to the neck, bilateral shoulders, right elbow, and right wrist; numbness and tingling along the right fingertips; and sleep issues. Findings include tenderness over the cervical region, rotator cuff and biceps tendon, medial and lateral epicondyles, and CMC joint, and STT joints bilaterally. There is diffuse weakness of the upper extremities due to pain. Treatment to date has included topical analgesics, muscle relaxants, NSAIDs, TENS, hot/cold wrap, opioids, Gabapentin, Lyrica, antidepressants, trigger point injections, acupuncture, bracing to the right hand/wrist, and radiofrequency ablation to the neck, right shoulder surgery in 2007. Utilization review from November 04, 2013 denied the requests for functional restoration program evaluation as this is mainly for working individuals, and the patient has not yet seen a pain management specialist; Flexeril 7.5mg #60 as this is only recommended for short courses of therapy; Terocin patches #20 and Terocin lotion as these are not recommended for use; and Zantac 150mg #30 as this is not used for adverse effects from analgesics.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Functional Restoration Program Evaluation QTY: 1.00: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Program (FRP) Page(s): 49.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Programs (Functional Restoration Programs) Page(s): 30-32.

**Decision rationale:** According to pages 30-32 of the California MTUS Chronic Pain Medical Treatment Guidelines, functional restoration programs are recommended where there is access to programs with proven successful outcomes, for patients with conditions that put them at risk for delayed recovery. Patients should be motivated to improve and return to work. Criteria for use of multidisciplinary pain management programs include an adequate and thorough multidisciplinary evaluation has been made, unsuccessful attempts with conservative treatment options, significant loss of ability to function independently due to the chronic pain, and the patient is not a surgical candidate. Negative predictors of success include a negative relationship with the employer, poor work adjustment and satisfaction, negative outlook about future employment, high levels of psychosocial distress, involvement in financial disability disputes, greater rates of smoking, duration of pre-referral disability time, prevalence of opioid use, and pre-treatment levels of pain. In this case, the patient has retired from work for about 5 years. Although the patient has authorization to visit a pain management specialist, the patient refuses to do so. Also, there is no discussion regarding the desire to return to work. There is lack of support for enrollment in a functional restoration program at this time. Therefore, the request for functional restoration program evaluation was not medically necessary.

**Flexeril 7.5mg qty: 60.00:** 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 Cyclobenzaprine (Flexeril) Page(s): 41-42.

**Decision rationale:** CA MTUS Chronic Pain Medical Treatment Guidelines state that Cyclobenzaprine is a skeletal muscle relaxant and a CNS depressant that is recommended as a short-course therapy in the management of back pain. The effect is greatest in the first 4 days of treatment. Patient has been on this medication since at least April 2013. There is no documentation of acute exacerbation of pain, or of significant muscle spasms, in the latest progress note to support the continued use of this medication. Also, this medication is not recommended for chronic use. Therefore, the request for Flexeril 7.5mg #60 was not medically necessary.

**Terocin Patches qty: 20.00:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (Lidocaine Patch); Topical Analgesics, Lidocaine Page(s): 56-57; 112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Topical Salicylates.

**Decision rationale:** Terocin Patch contains 4% Lidocaine and 4% menthol. According to CA MTUS Chronic Pain Medical Treatment Guidelines, topical Lidocaine in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. In addition, topical Lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica). Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain Menthol, Methyl Salicylate, or Capsaicin, may in rare instances cause serious burns. In this case, patient's clinical manifestation of numbness and tingling sensation along the fingertips is consistent with neuropathic pain. Gabapentin was initially prescribed, however, persistence of symptoms prompted adjuvant therapy with a Terocin patch. Lidocaine in a transdermal formulation is a reasonable option at this time. Therefore, the request for Terocin patches #20 was medically necessary.

**Terocin Lotion 4OZ qty: 1.00: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 28-29, 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical; Salicylates Topical; Topical Analgesics Page(s): 28; 105; 111-112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Topical Salicylates.

**Decision rationale:** Terocin contains 4 active ingredients; Capsaicin in a 0.025% formulation, Lidocaine in a 2.50% formulation, Menthol in a 10% formulation, and Methyl Salicylate in a 25% formulation. California MTUS chronic pain medical treatment guidelines page 111 state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the Capsaicin component, CA MTUS Chronic Pain Medical Treatment Guidelines on page 28 states that topical Capsaicin is only recommended as an option when there is failure to respond or intolerance to other treatments; with the 0.025% formulation indicated for osteoarthritis. Regarding the Lidocaine component, CA MTUS Chronic Pain Medical Treatment Guidelines identify on page 112 that topical formulations of Lidocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain Menthol, Methyl Salicylate, or Capsaicin, may in rare instances cause serious burns. Regarding the Methyl Salicylate component, CA MTUS states on page 105 that Salicylate topicals are significantly better than placebo in chronic pain. In this case, there is no documentation regarding failure of or intolerance to other conventional oral pain medications. Lidocaine is likewise not approved for topical use. Therefore, the request for Terocin lotion 4oz was not medically necessary.

**Zantac 150MG qty: 30.00:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation PDR, Zantac (Ranitidine).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline Or Medical Evidence: FDA (Ranitidine).

**Decision rationale:** The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, and FDA was used instead. According to FDA, indications for ranitidine include short-term treatment and maintenance therapy of duodenal ulcer, short-term treatment and maintenance therapy for benign gastric ulcer, treatment of pathological hypersecretory conditions, treatment of GERD, and treatment and maintenance of erosive esophagitis. Patient has been on this medication since at least April 2013. In this case, there is mention that the patient has gastritis. However, there is no description of upper GI symptoms in the progress notes. The patient is also prescribed Prilosec, and there is no indication as to why two GI agents are necessary. Therefore, the request for Zantac 150mg #30 was not medically necessary.

**Retrospective Terocin Lotion 4oz qty: 1.00 (Dispensed 10/24/13):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 28-29, 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical; Salicylates Topical; Topical ANALGESICS Page(s): 28; 105; 111-112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Topical Salicylates.

**Decision rationale:** Terocin contains 4 active ingredients; Capsaicin in a 0.025% formulation, Lidocaine in a 2.50% formulation, Menthol in a 10% formulation, and Methyl Salicylate in a 25% formulation. California MTUS chronic pain medical treatment guidelines page 111 state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the Capsaicin component, CA MTUS Chronic Pain Medical Treatment Guidelines on page 28 states that topical Capsaicin is only recommended as an option when there is failure to respond or intolerance to other treatments; with the 0.025% formulation indicated for osteoarthritis. Regarding the Lidocaine component, CA MTUS Chronic Pain Medical Treatment Guidelines identify on page 112 that topical formulations of Lidocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain Menthol, Methyl Salicylate, or Capsaicin, may in rare instances cause serious burns. Regarding the Methyl Salicylate component, CA MTUS states on page 105 that Salicylate topicals are significantly better than placebo in chronic pain. In this case, there is no documentation regarding failure of or intolerance to other conventional oral pain medications. Lidocaine is likewise not approved for topical use.

Therefore, the retrospective request for Terocin lotion 4oz (DOS 10/24/13) was not medically necessary.

**Retrospective Terocin Patches qty: 20.00 (Dispensed 10/24/13): Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (Lidocaine Patch); Topical Analgesics, Lidocaine Page(s): 56-57; 112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Topical Salicylates.

**Decision rationale:** Terocin Patch contains 4% Lidocaine and 4% menthol. According to CA MTUS Chronic Pain Medical Treatment Guidelines, topical Lidocaine in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. In addition, topical Lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica). Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain Menthol, Methyl Salicylate, or Capsaicin, may in rare instances cause serious burns. In this case, patient's clinical manifestation of numbness and tingling sensation along the fingertips is consistent with neuropathic pain. Gabapentin was initially prescribed, however, persistence of symptoms prompted adjuvant therapy with a Terocin patch. Lidocaine in a transdermal formulation is a reasonable option at this time. Therefore, the retrospective request for Terocin patches #20 (DOS 10/24/13) was medically necessary.

**Retrospective Flexeril 7.5mg qty: 60.00 (Dispensed 10/24/13): 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 Cyclobenzaprine (Flexeril) Page(s): 41-42.

**Decision rationale:** CA MTUS Chronic Pain Medical Treatment Guidelines state that Cyclobenzaprine is a skeletal muscle relaxant and a CNS depressant that is recommended as a short-course therapy in the management of back pain. The effect is greatest in the first 4 days of treatment. Patient has been on this medication since at least April 2013. There is no documentation of acute exacerbation of low back pain to support the continued use of this medication. Also, this medication is not recommended for chronic use. Therefore, the retrospective request for Flexeril 7.5mg #60 (DOS 10/24/13) was not medically necessary.