

Case Number:	CM14-0003150		
Date Assigned:	04/04/2014	Date of Injury:	12/12/2007
Decision Date:	05/27/2014	UR Denial Date:	12/18/2013
Priority:	Standard	Application Received:	01/09/2014

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 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 expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records: Patient is an employee of [REDACTED] who filed a claim of cervical disc syndrome, cervical spondylosis, bilateral shoulder rotator cuff syndrome and bilateral wrist carpal tunnel syndrome associated with industrial injury date of 12/12/2007. Treatment to date includes physical therapy and chiropractic treatments, endoscopy which showed gastritis and duodenitis and positive for H.Pylori, ultrasound of abdomen which revealed fatty infiltration of liver and cholelithiasis. Medications include Dexilant #30, Gaviscon one bottle, Simethicone #60, Probiotic #60 for her gastrointestinal symptoms, Tramadol 50mg, topical creams (TGHOT), Flurbiprofen which were prescribed since 05/21/2013. Utilization review dated 12/18/2013 denied the request for TGHOT (Tramadol 8%/Gabapentin 10%/ Menthol 2%/Camphor 2%/Capsaicin 0.05%, Flurflex (Flurbiprofen 10%/Cyclobenzaprine 10%) and Ultram 50 mg because the requested compounded topical creams contain at least one drug that is not recommended. As for Ultram (Tramadol) it was denied because this is not the first line oral analgesic. Medical records from 2011 to 2013 revealed constant pain in her neck, shoulders, hands and low back which radiates into her legs with a pain scale of 8/10. Her neck pain is associated with headaches which radiates toward her upper arms. She also complained of abdominal pain and a burning sensation pointing to her epigastric region not related to meals. With regards to activities of daily living, she has difficulty brushing her teeth, combing her hair, bathing and dressing herself due to pain in her wrists and hands. She also reported that she has difficulty in standing, sitting, reclining, walking and climbing stairs as well as grasping, lifting and tactile discrimination. She has difficulty sleeping and experiences insomnia due to pain, depression and anxiety. Physical examination revealed positive watson test bilaterally. Wrist dorsiflexion is 60 degrees, palmar flexion is 60 degrees, abduction 20 degrees, adduction is 30

degrees. Upper extremity motor exam showed MMT of 5/5 in shoulder abduction, shoulder flexion, wrist extension, elbow extension, finger abduction and abductor pollicis brevis. Phalen's and Tinel's test were both positive.

IMR ISSUES, DECISIONS AND RATIONALES

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

TGHOT (TRAMADOL 8% / GABAPENTIN 10% / MENTHOL 2% / CAMPHOR 2% / CAPSAICIN 0.05%), 180GM: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, , 111-113, Topical Analgesics.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, 9792.24.2, 111-113, as well as Official Disability Guidelines (ODG) Pain Chapter; Salicylate Topicals.

Decision rationale: As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. TGHOT contains 5 active ingredients namely Tramadol in a 8% formulation, Gabapentin in a 10% formulation, Menthol in a 2% formulation, Camphor in a 2% formulation and Capsaicin in a 0.05% formulation. Regarding the Tramadol 8% formulation, there is little to no research to support the use of this agent and is not recommended. Regarding the Gabapentin component, CA MTUS does not recommend the use of this as a topical medication. There is no peer-reviewed literature to support use. Regarding the Capsaicin component, CA MTUS Chronic Pain Medical Treatment Guidelines identifies on page 28 that topical Capsaicin is only recommended as an option when there was failure to respond or intolerance to other treatments. 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, there is no evidence of failure of oral medications and there is no discussion concerning the need for variance from the guidelines given the adverse recommendation for this topical medication. Therefore, the request for TGHOT is not recommended.

FLURFLEX (FLURBIPROFEN 10% / CYCLOBENZAPRINE 10%), 180GM JAR:
Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, , 111-113.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, , 111-113.

Decision rationale: Flurflex contains 2 active ingredients namely Flurbiprofen 10% and Cyclobenzaprine 10%. As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. The California MTUS supports a limited list of NSAID topicals, which does not include Flurbiprofen. Regarding Cyclobenzaprine 6%, CA MTUS does not recommend muscle relaxants in topical formulations. CA MTUS also stated that any compounded product that contains at least one drug that is not recommended is not recommended. In this case, there is no evidence of failure of oral medications and there is no discussion concerning the need for variance from the guidelines given the adverse recommendation for this topical medication. Therefore, the request for Flurflex is not medically necessary.

ULTRAM 50MG, #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, , 113 Tramadol.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, 9792.20-9792.26, 78.

Decision rationale: Ultram is a brand name of Tramadol. Page 78 of the CA MTUS Chronic Pain Medical Treatment Guidelines state that ongoing opioid treatment should include monitoring of analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors; these outcomes over time should affect the therapeutic decisions for continuation. In this case, the patient has been using Tramadol since May 2013. However, there is no documentation of objective measures of analgesia or functional gains in terms of ability to perform activities of daily living. Therefore, the request for Ultram (tramadol) is not medically necessary.