

Case Number:	CM14-0044536		
Date Assigned:	07/23/2014	Date of Injury:	12/04/2013
Decision Date:	10/30/2014	UR Denial Date:	04/02/2014
Priority:	Standard	Application Received:	04/11/2014

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 Family Practice 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 injured worker is a 57 year old male who had a work related injury on 12/04/13. At the time of his injury he was trying to put a tractor on a ramp, and he fell backwards hitting his elbow against the ground and he sustained a right elbow fracture. He was under the care of [REDACTED] and received a course of occupational therapy to the elbow. Right elbow x-ray dated 07/24/14 no acute abnormality is demonstrated about the right elbow. Most recent clinical documentation submitted for review was dated 07/09/14 the injured worker was seen for routine follow up of work related injuries. He reported having constant, moderate severe pain in his right elbow with 4/10 in severity. On physical examination revealed that he was alert and oriented, coordination grossly intact. Speech was intact. Gait was normal. Right elbow was tender, range of motion with extension 180 degrees. No contracture. Grip strength on right was 40 pounds, left 70 pounds. The patient was using a TENS unit twice daily for pain management. Return to work was 06/02/14, but no job, patient was unemployed. Diagnosis lateral epicondylitis. Fracture of humerus, unspecified part. Prior utilization review on 04/02/14 modified the Zorvolex which was a generic diclofenac but denied the conzip, Terocin cream TENS rental for two months. Current request is for Conzip 100mg #30. Zorvolex 35mg #90. Terocin cream. TENS rental for two months.

IMR ISSUES, DECISIONS AND RATIONALES

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

CONZIP 100MG, #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [https://www.verticalpharma.com/sites/verticaliles/ConSip%20 Prescribing%20info.pdf](https://www.verticalpharma.com/sites/verticaliles/ConSip%20Prescribing%20info.pdf)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for Use of Opioids Page(s): 77.

Decision rationale: As noted on page 77 of the Chronic Pain Medical Treatment Guidelines, patients must demonstrate functional improvement in addition to appropriate documentation of ongoing pain relief to warrant the continued use of narcotic medications. There is no clear documentation regarding the functional benefits or any substantial functional improvement obtained with the continued use of narcotic medications. There are no documented VAS pain scores for this patient with or without medications. In addition, no recent opioid risk assessments regarding possible dependence or diversion were available for review. As the clinical documentation provided for review does not support an appropriate evaluation for the continued use of narcotics as well as establish the efficacy of narcotics, the medical necessity of this medication cannot be established at this time.

ZORVOLEX 35 MG, #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Diclofenac (Voltaren) Page(s): 43.

Decision rationale: As noted on page 43 of the Chronic Pain Medical Treatment Guidelines, diclofenac is not recommended as first line treatment due to increased risk profile. Post marketing surveillance has revealed that treatment with all oral and topical diclofenac products may increase liver dysfunction, and use has resulted in liver failure and death. The United States Federal Drug Administration advised physicians to measure transaminases periodically in patients receiving long-term therapy with diclofenac and issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium. With the lack of data to support superiority of diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or nonpharmacological therapy should be considered. As such, the request for this medication cannot be recommended as medically necessary.

TEROCIN CREAM: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymeddruginfo.cfm?id=31127>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

Decision rationale: As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Further, CAMTUS, Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. This compound contains: lidocaine which has not been approved for transdermal use. In addition, there is no evidence within the medical records submitted that substantiates the necessity of a transdermal versus oral route of administration. Therefore this compound cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.

TENS RENTAL X 2 MONTHS: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy Page(s): 116.

Decision rationale: As note on page 116 of the Chronic Pain Medical Treatment Guidelines, TENS use is not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration. Criteria for TENS use includes documentation of pain of at least three months duration; evidence that other appropriate pain modalities have been tried (including medication) and failed; a one-month trial period of the TENS unit should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) with documentation of how often the unit was used, as well as outcomes in terms of pain relief and function; rental would be preferred over purchase during this trial; other ongoing pain treatment should also be documented during the trial period including medication usage; and a treatment plan including the specific short- and long-term goals of treatment with the TENS unit should be submitted. There is no clinical documentation submitted that the patient has had a 1 month trial of TENS, therefore, medical necessity has not been established.