

Case Number:	CM15-0067459		
Date Assigned:	04/15/2015	Date of Injury:	01/29/2014
Decision Date:	05/28/2015	UR Denial Date:	03/09/2015
Priority:	Standard	Application Received:	04/09/2015

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

Certification(s)/Specialty: Internal Medicine

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 46 year old female, who sustained an industrial injury on 1/29/14. The injured worker has complaints of right ankle pain. The diagnoses have included pain in joint, ankle and foot; stiffness of joint, not elsewhere classified ankle and foot and effusion of joint, ankle and foot. Treatment to date has included fractured her right tibia with surgery; status post removal external fixator; right ankle X-ray; cast; ankle-foot orthosis (AFO) soft interface valgus correction and heel lift; therapeutic exercises; physical therapy and hydrocodone for pain. The request was for xartemis #120.

IMR ISSUES, DECISIONS AND RATIONALES

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

Xartemis #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-80, 92, 124.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-48, Chronic Pain Treatment Guidelines Opioids Page 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Xartemis

XR. FDA Prescribing Information Xartemis <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfmsetid=efcb1e8b-c0be-47ee-b09e-7a6b41e64bdd>.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address opioids. The lowest possible dose should be prescribed to improve pain and function. 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 aberrant drug-taking behaviors). Frequent evaluation of clinical history and frequent review of medications are recommended. Periodic review of the ongoing chronic pain treatment plan for the injured worker is essential. Patients with pain who are managed with controlled substances should be seen regularly. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) Chapter 3 states that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal symptoms. Opioids should be used only if needed for severe pain and only for a short time. Official Disability Guidelines (ODG) indicates that Xartemis XR is not recommended as a first-line choice. The FDA has approved an extended-release combination of Oxycodone and Acetaminophen (Xartemis XR), for patients for whom alternative treatment options are ineffective, not tolerated, or would otherwise be inadequate. The drug has both immediate and extended-release components to allow pain relief within an hour, with twice-daily dosing. Oxycodone exposes patients to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. This product is not recommended as a first-line treatment and still carries the same risk of abuse and addiction as Oxycontin. The need for an extended-release opioid in the acute setting is questionable and should be considered with caution. FDA Prescribing Information documents that Xartemis XR is indicated for the management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate. Because of the risks of addiction, abuse, misuse, overdose, and death with opioids, even at recommended doses, reserve Xartemis XR for use in patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate. Medical records document the long-term use of opioids. Per MTUS, the lowest possible dose of opioid should be prescribed. The date of injury was 01-29-2014. Per ACOEM, opioids should be used only if needed for severe pain and only for a short time. The request for authorization (RFA) was dated 3/2/15 documented a request for Xartemis XR #120. The progress report dated 3/2/15 documented a history of right foot closed tibia-fibula fracture status post TSF transarticular screw fixation fracture stabilization. Norco 7.5/325 was documented in the 3/2/15 progress report. The patient is taking two pain pills daily. The lower extremity physical examination demonstrated pain-free full range of motion of the ankle. There is no documentation that treatment options are inadequate in the 3/2/15 progress report. Per ODG, Xartemis XR is not recommended as a first-line choice. MTUS, ACOEM, and ODG guidelines do not support the request for Xartemis XR. Therefore, the request for Xartemis XR is not medically necessary.