

Case Number:	CM14-0204911		
Date Assigned:	12/17/2014	Date of Injury:	07/16/2013
Decision Date:	02/06/2015	UR Denial Date:	11/20/2014
Priority:	Standard	Application Received:	12/08/2014

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 Physical Medicine Rehab 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:

According to the records made available for review, this is a 49-year-old female with a 7/16/13 date of injury. At the time (10/21/14) of request for authorization for Fanatrex 25mg/ml 420ml #1, there is documentation of subjective (left knee pain with muscle spasms rated as a 7 out of 10) and objective (1+ effusion noted in the left knee with tenderness to palpation over the medial and lateral joint lines, decreased left knee range of motion, positive Varus and McMurray's testing, and decreased strength and sensation in the bilateral lower extremities) findings, current diagnoses (rule out left knee internal derangement), and treatment to date (oral pain medications).

IMR ISSUES, DECISIONS AND RATIONALES

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

Fanatrex 25mg/ml 420ml #1: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Co-pack drugs and Other Medical Treatment Guideline or Medical Evidence: National Library of Medicine states.

Decision rationale: Medical Treatment Guideline identifies Fanatrex as gabapentin 25 mg/mL, in oral suspension - kit. MTUS does not address the issue. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for Fanatrex 25mg/ml 420ml #1 is not medically necessary.