

Case Number:	CM14-0075780		
Date Assigned:	07/21/2014	Date of Injury:	03/22/2006
Decision Date:	09/09/2014	UR Denial Date:	05/06/2014
Priority:	Standard	Application Received:	05/24/2014

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 Pain Medicine and Anesthesiology and is licensed to practice in Connecticut. 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:

After careful review of the medical records, this is a 53 year old male with complaints of low back pain and numbness and tingling bilateral lower extremities. The date of injury is 3/22/06 and the mechanism of injury is lifting heavy 400 pound beam resulting in his current symptoms. At the time of request for Fanatrex 25mg 420ml, there is subjective (low back pain, leg pain) and objective (tenderness to palpation lumbar paraspinal muscles, limited range of motion flexion/extension at the hips, positive straight leg raise bilateral, diminished sensory L4,L5,S1 dermatomes lower extremities) findings, imaging findings (MRI lumbar spine dated 6/6/14 shows grade I L3 on L4 retrolisthesis, posterior fixation device L5 to S1, interbody spacers L4/5 and L5/S1, anterior fixation instrumentation hardware L4 to S1, decompression laminectomy L4-5 level, L3/4 diffuse disc protrusion, L4/5 surgical fused with hypertrophy of facet joint on right side with neural foraminal narrowing, central canal patent), diagnoses (low back pain, lumbar disc displacement, radiculopathy, and s/p lumbar spine surgery with residual pain), and treatment to date (medications, surgery, physical therapy, acupuncture). Fanatrex, a formulation of gabapentin which is an anti-epileptic used to treat severe neuropathic pain, is non-FDA approved. Also, there is no documentation in any of the medical records provided of the efficacy of drug, analgesic response, functional changes, etc. or of a failed trial of Neurontin or generic gabapentin.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fanatrex 25mg 420ml (gabapentin and other proprietary ingredients): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines- Pain Chapter Compounded drugs.

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: Medication inserts prescribing information for Fanatrex.

Decision rationale: In thorough review, there are no guidelines for this specific drug. However, this particular formulation of gabapentin, which is an anti-epileptic used to treat severe neuropathic pain, is non-FDA approved. Also, there is no documentation in any of the medical records provided of the efficacy of drug, analgesic response, functional changes, etc. or of a failed trial of Neurontin or generic gabapentin. Therefore, the drug Fanatrex cannot be medically necessary.