

Case Number:	CM14-0181732		
Date Assigned:	11/06/2014	Date of Injury:	02/28/2014
Decision Date:	01/31/2015	UR Denial Date:	10/20/2014
Priority:	Standard	Application Received:	10/31/2014

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, has a subspecialty in Interventional spine 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:

This patient is a 44 year old male with an injury date of 2/28/14. Based on the 10/08/14 progress report, this patient complains of "constant, moderate to severe 7/10 pain" burning pain and muscle spasms in the low back and bilateral hips and knees, radiating to the feet. Exam of lumbar spine shows "palpable tenderness with spasms" at the paraspinal muscles and over the lumbosacral junction with tenderness at the anterior pubic area, gluteal and piriformis muscles, and over the medial joint line in the knees. Patient is positive bilaterally for the following tests: Tripod Sign, Flip-Test, Lasegue's Differential, Apley's Compression, and Patella Grinding Tests. There is some very slight to minor decreased range of motion of the lumbar spine, bilateral hips, and knees. Neurological exam shows slightly decreased sensation at the L4, L5 and S1, dermatomes bilaterally with 4/5 motor strength in bilateral lower extremities. Diagnoses for this patient are: 1. Low back pain 2. Radiculitis, lower extremity 3. Bilateral hip sprain/strain 4. Bilateral knee sprain/strain 5. Anxiety disorder 6. Mood disorder 7. Sleep disorder 8. Stress Work status was not addressed on the 10/08/14 progress report. The utilization review being challenged is dated 10/20/14. The request is for Fanatrex (Gabapentin) oral suspension 25mg/ml 420ml - take 5ml, three times a day. The request was non-certified due to the lack of documentation for the need of a compounded format of Gabapentin, as compounded medication is only supported if there is a failure of first-line FDA-approved medications. Also, the requested dosing is unlikely to provide any significant improvement as the therapeutic dose is usually a minimum of 900mg per day; often much higher at 1800-2400 mg/day. The requesting provider has provided reports from 4/10/14 to 10/08/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fanatrex (Gabapentin) Oral Suspension 25 mg/ml 420 ml- take 5 ml, three times a day:
Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Compounded Medications

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs), Medications for chronic pain Page(s): 16, 17, 60, and 61.

Decision rationale: This patient presents with chronic neuropathic pain and spasms from low back, to bilateral hips and knees. The treater requests Fanatrex (Gabapentin) oral suspension 25mg/ml 420ml - take 5ml, three times a day, per report dated 10/08/14. Regarding Gabapentin, MTUS guidelines page(s) 16-18, it is considered an anti-epilepsy drug and recommended for neuropathic pain, postherpetic neuralgia, central stroke pain, CRPS, fibromyalgia, lumbar spinal stenosis, and post-operative pain. However, there is insufficient evidence to recommend it for or against axial low back pain, osteoarthritic pain of the hip, and myofascial pain. MTUS guidelines, ODG, and ACOEM do not specifically address Fanatrex. According to Drugs.com (online), Fanatrex contains: 10.5 g Gabapentin and 420 mL oral suspension vehicle (water, banana flavor, N-acetyl-D-glucosamine, strawberry flavor, marshmallow flavor, glycerin, stevia powder, acesulfame potassium, xanthan gum, monoammonium glycyrrhizinate, sodium saccharin, sodium benzoate, potassium sorbate, dibasic sodium phosphate). Currently, it is categorized as "unapproved drug other." A review of submitted medical records document the history of Neurontin as follows: 4/10/14: Neurontin 300 mg, is increased from one to two by mouth, QHS. 7/09/14: Patient issued Fanatrex, oral suspension for his chronic, neuropathic pain. 8/06/14: Patient to continue taking Fanatrex. 8/24/14: Continue use of Fanatrex. 9/10/14: Continue use of Fanatrex. No clinical rationale is documented as to why this patient cannot take standard oral medications to warrant the use of an oral suspension that has not been FDA-approved (switched in July of 2014, from tablets to an oral suspension). Furthermore, there is an absence of documentation as required by MTUS page 60, which states, "A record of pain and function with the medication should be recorded." Given the absence of documentation of pain and function, use of an oral form which has not been FDA-approved, the request is not medically necessary.