

Case Number:	CM13-0046302		
Date Assigned:	12/27/2013	Date of Injury:	09/14/1989
Decision Date:	04/23/2014	UR Denial Date:	10/08/2013
Priority:	Standard	Application Received:	11/12/2013

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 and Rehabilitation, 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 59 year-old female sustained a low back injury after lifting a case of paper off a pallet onto a dolly on 9/14/89 while employed by the [REDACTED]. Current diagnoses include status post lumbar hardware removal with revision decompression L3-4 on 5/16/13, partial corpectomy and fusion at L3-4 on 10/6/11, bilateral sacroilitis, and history of left lower extremity deep vein thrombosis. Conservative care has included cervical steroid injection, physical therapy, aquatic therapy, medications, and diagnostics. The report dated 8/20/13 noted the patient to have difficulty with ambulation since her May 2013 surgery. She has pain in the back and buttocks region, but does not have radiculopathy. Exam noted that the patient was using her brace and standing up better than before.

IMR ISSUES, DECISIONS AND RATIONALES

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

60 DONNATAL: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Berman DA, Porter RS, Graber M (2003). "The GI Cocktail is no more effective than plain liquid antacid: a randomized, double blind clinical trial." Journal of Emergency Medicine 25(3): 239-244.

Decision rationale: The MTUS, ACOEM, and ODG are silent on the use of Donnatal. Research review indicates that Donnatal is a proprietary combination medication for the treatment of intestinal cramping due to various causes including irritable bowel syndrome, often administered as part of a GI cocktail. It is classed as an anti cholinergic, antispasmodic drug. Donnatal is marketed by PBM Pharmaceuticals and is available as tablets, capsules, extended release tablets, and elixir. Active ingredients are listed as Phenobarbital, hyoscyamine, atropine, and scopolamine, the latter three ingredients being found in plants of the Solanaceae family. Recent clinical trials showed that Donnatal was no more effective than plain antacid in relieving the symptoms of dyspepsia; however, the active ingredients in Donnatal have been shown to be more effective than placebo in treating moderately severe symptoms of irritable bowel syndrome. Submitted reports have not adequately demonstrated the indication, clinical findings, or diagnoses for the treatment use of this medication. The request for Donnatal is not medically necessary and appropriate.