MAXIMUS Federal Services

Case Number:	CM13-0005318		
Date Assigned:	06/06/2014	Date of Injury:	05/13/2003
Decision Date:	07/28/2014	UR Denial Date:	07/08/2013
Priority:	Standard	Application Received:	07/31/2013

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 Emergency Medicine and is licensed to practice in New York. 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:

The patient is a 53-year-old female who was injured on May 13, 2003. The patient continued to experience pain in her lower back and abdominal bloating. Physical examination was notable for normal gait, guarded lumbar range of motion, tenderness over the left L4-5 facet region, and moderate distention of the abdomen. Diagnoses included status post lumbar fusion. Treatment included medications and surgery. Request for authorization for donnatal was submitted for consideration.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETROSPECTIVE/ PROSPECTIVE REQUEST FOR DONNATAL: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult Drug Monograph last updated 02/11/2012.

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:UpToDate: Hyoscyamine, atropine, scopolamine, and phenobarbital; Treatment Guidelines from the Medical Letter, Issue 107: Drugs for Irritable Bowel Syndrome ; Treatment Guidelines from the Medical Letter, Issue 118: Advice for travellers; Treatment Guidelines from the Medical Letter, Issue 125: Drugs for Epilepsy.

Decision rationale: Donnatal is a compounded medication containing hyoscyamine, atropine, scopolamine, and phenobarbital. It is used for a gastrointestinal antispasmodic. Antispasmodics such as hyoscyamine are best used on an as-needed basis for acute attacks of abdominal pain or before meals in patients with postprandial symptoms. They induce intestinal smooth muscle relaxation through direct myorelaxant effects or anticholinergic mechanisms. They are commonly prescribed, often as adjuncts, for irritable bowel syndrome (IBS)-related abdominal pain and discomfort, but their efficacy is not well established. At higher doses, hyoscyamine can produce atropine-like effects including visual disturbances, dry mouth, urinary retention and constipation. Atropine is an anticholinergic drug sometimes used as a gastrointestinal antispasmodic. It is not indicated for abdominal bloating. Scopolamine is a cholinergic blocker used transdermally for the treatment of motion sickness. Phenobarbital is a barbiturate medication used in the treatment of seizures. It has a higher incidence of sedation that other antiepileptic medications. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. This medication contains drugs that are not recommended, therefore the medication is not medically necessary.