

Case Number:	CM15-0036161		
Date Assigned:	03/04/2015	Date of Injury:	04/21/2007
Decision Date:	04/13/2015	UR Denial Date:	02/24/2014
Priority:	Standard	Application Received:	02/26/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 injured worker is a 50 year old male, who sustained an industrial injury on 4/21/2007. He has reported a back injury. The diagnoses have included irritable bowel syndrome (IBS), gastropathy secondary to chronic medication use and status post H. Pylori treatment, and also chronic pain syndrome, post laminectomy syndrome, low back pain, sciatica and lumbar/thoracic radiculopathy. Treatment to date has included medication therapy, physical therapy, Transcutaneous Electrical Nerve Stimulation (TENS), and steroid epidurals. Currently, the IW complains of back pain that radiated down bilateral legs, left greater than right. Pain was rated 7/10 with medication. The PR-2 dated 2/9/15, documented complaints of bloating, gas and constipation with no bleeding for one month. The physical examination from 1/8/15 documented tenderness throughout cervical, thoracic, and lumbar regions, positive lumbar facet loading maneuvers, decreased sensation to bilateral thighs, and positive left leg raise test. The physician documented Florsta was not helping and changed the medication to Bentyl. The plan of care included requesting authorization for a spinal cord stimulator trial, psychiatric evaluation for a spinal cord stimulator, and medication therapy. On 2/24/2015 Utilization Review non-certified Linzess 290mcg #30, Bentyl 10mg and Feldene ointment, noting the documentation did not support that prior diet and lifestyle modification were tried and failed. There were non- MTUS Guidelines were cited. On 2/26/2015, the injured worker submitted an application for IMR for review of Linzess 290mcg #30, Bentyl 10mg and Feldene ointment.

IMR ISSUES, DECISIONS AND RATIONALES

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

Linzess 290mcg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic) and on the National Collaborating Centre for Nursing and Supportive Care. Irritable bowel syndrome in adults. Diagnosis and management of irritable bowel syndrome in primary care. London (UK); National institute for Health and Clinical Excellence (NICE); 2008 Feb_ 27 p. (Clinical guideline; no. 61).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Up-to-date, Treatment of irritable bowel syndrome in adults.

Decision rationale: The MTUS and ODG are silent on the use of Bentyl. Other guidelines were used. "In patients with mild and intermittent symptoms that do not impair quality of life, we initially recommend lifestyle and dietary modification alone rather than specific pharmacologic agents. In patients with mild to moderate symptoms who fail to respond to initial management and in patients with moderate to severe symptoms that affect quality of life, we suggest pharmacological therapy as adjunctive treatment." The adjunctive medications recommended vary. In patients with IBS with constipation (IBS-C) who have failed a trial of soluble fiber (eg, psyllium/ispaghula), we suggest polyethylene glycol (PEG). We treat patients with persistent constipation despite treatment with PEG with lubiprostone or linaclotide. The medication in question, Linzess or Linaclotide is a guanylate cyclase agonist that stimulates intestinal fluid secretion and transit. As the long-term risks of linaclotide are unknown, its role in the treatment of IBS-C is limited to patients with persistent constipation despite treatment with PEG. In this case, the diagnosis of IBS-C has not been confirmed. Furthermore, the medical records fail to document failure of primary conservative therapies prior to medical therapy and failure of PEG. As such, the request for Linzess 290mcg #30 is not medically necessary.

Bentyl 10mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic) and on the National Collaborating Centre for Nursing and Supportive Care. Irritable bowel syndrome in adults. Diagnosis and management of irritable bowel syndrome in primary care. London (UK); National institute for Health and Clinical Excellence (NICE); 2008 Feb_ 27 p. (Clinical guideline; no. 61).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Up-to-date Treatment of irritable bowel syndrome in adults.

Decision rationale: The MTUS and ODG are silent on the use of Bentyl. Other guidelines were used. "In patients with mild and intermittent symptoms that do not impair quality of life, we initially recommend lifestyle and dietary modification alone rather than specific pharmacologic agents. In patients with mild to moderate symptoms who fail to respond to initial management

and in patients with moderate to severe symptoms that affect quality of life, we suggest pharmacological therapy as adjunctive treatment." In regards to antispasmodics like Bentyl or Dicyclomine, "Antispasmodics should be administered on an as needed basis and/or in anticipation of stressors with known exacerbating effects. Antispasmodics provide short-term relief in symptoms of abdominal pain in patients with IBS, but their long-term efficacy has not been established. Antispasmodic include those that directly affect intestinal smooth muscle relaxation (eg, mebeverine and pinaverine), and those that act via their anticholinergic or antimuscarinic properties (eg, dicyclomine and hyoscyamine). The selective inhibition of gastrointestinal smooth muscle by antispasmodics and peppermint oil reduce stimulated colonic motor activity and may be beneficial in patients with postprandial abdominal pain, gas, bloating, and fecal urgency. In a 2011 meta-analysis, antispasmodics were associated with a significant improvement in abdominal pain, global assessment and symptom score as compared with placebo. Subgroup analyses demonstrated statistically significant benefits for cimetropium/dicyclomine, peppermint oil, pinaverium, and trimebutine." In this case, the diagnosis of IBS-C has not been confirmed. Furthermore, the medical records fail to document failure of primary conservative therapies prior to medical therapy and failure of PEG. As such, the request for Benyl 10mg is not medically necessary.

Feldene ointment: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams.

Decision rationale: MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." NSAIDs (recommended in OA/tendinitis, not recommended for neuro) MTUS states regarding topical NSAIDs, "Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use." In this case, there is no indication that the medication is being used for osteoarthritis. As such, the request for Feldene ointment is not medically necessary.