

Case Number:	CM14-0140122		
Date Assigned:	09/08/2014	Date of Injury:	09/18/2003
Decision Date:	10/06/2014	UR Denial Date:	08/26/2014
Priority:	Standard	Application Received:	08/29/2014

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 Preventative Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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 36 year old employee with date of injury of 9/18/2003. Medical records indicate the patient is undergoing treatment for s/p decompressive laminectomy at L5 with removal of large extruded disc (June 2004), neurogenic bladder secondary to L5-S1 disc disease. Subjective complaints include three epidural steroid injections which only decreased her pain level for a short period of time by diminishing the pain that would go into the perineum and down the left lower extremity. She does get a permanent benefit from the injection because her shooting pains have decreased over time. The injections have also diminished her numbness. She has constant low back pain that ranges from 4-8/10. The symptoms that are the most bothersome are shooting, sharp and stabbing pains. The pain shoots into her gluteal region, into pelvic floor, the vagina area and extends to the hips. The pain also shoots into the medial aspect of the left lower extremity, primarily her thighs but sometimes into her foot. This particular pain is severe and is rated 10/10. This pain occurs spontaneously and causes her to drop objects when the pain occurs. She has numbness in her groin area, mons pubis and perineal floor. She has no sensation in her rectum and vagina. Objective findings include restricted back motion, no spasm. Normal gait and she can toe and heel walk. She has diminution of pin in the gluteal region just past her sciatic notch. There is a decrease in pin in the posterior upper thigh, medial and lateral thigh on the left and lesser on the right. She has further decrease of pin in the left lower extremity sparing the gastroc medially, posteriorly and laterally. Light touch in the same distribution is diminished. Seated and supine straight leg raise is negative bilaterally. Hip flexion is negative bilaterally. Treatment has consisted of PT, three epidural steroid injections, ice packs, Lexapro, ibuprofen, lidocaine patch, Limbrel and Trazodone. The utilization review determination was rendered on 8/25/2014 recommending non-certification of 1 Prescription Limbrel 500mg #90 with 3 refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 Prescription Limbrel 500mg #90 with 3 refills: 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 (chronic)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Limbrel (flavocoxid)

Decision rationale: The ODG states, "Under study as an option for arthritis in patients at risk of adverse effects from NSAIDs. Limbrel is a botanical medical food, made from root and bark extracts from plants. It contains flavocoxid, a blend of two flavonoids (baicalin and catechins). It is thought to inhibit the conversion of arachidonic acid to both prostaglandins and leukotrienes. Medical foods do not require formal premarketing studies of safety and efficacy. As this product is made with botanical ingredients, variation can occur in concentration of substances. (Chalasan, 2012)Note: Limbrel is not included on the ODG Drug Formulary because it is not a drug. If Limbrel were covered on the Formulary, it would be an N drug, because it is not recommended as a first-line drug, but only after first-line drugs have been trialed and found to produce adverse effects or a history of adverse effects with use is obtained."While the patient does get moderate relief from Limbrel, it is a medical food and not regulated as a medical drug by the FDA. Limbrel has an increased risk of liver toxicity. The treating physician has not provided documentation of trials and failures of first line treatment and a clear medical rationale as to why Limbrel is needed at this time. As such the request for 1 Prescription Limbrel 500mg #90 with 3 refills is not medically necessary.