

Case Number:	CM13-0042418		
Date Assigned:	03/03/2014	Date of Injury:	07/15/2009
Decision Date:	05/23/2014	UR Denial Date:	10/10/2013
Priority:	Standard	Application Received:	10/18/2013

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 Anesthesiology has a subspecialty in Pain Management 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:

According to the records made available for review, this is a 40-year-old male with a 7/15/09 date of injury. At the time (10/7/13) of request for authorization for Tabradol 1MG/ML PO suspension 250ML BID-TID #1, there is documentation of subjective (burning and radiating low back pain associated with muscle spasms, numbness, and tingling) and objective (tenderness to palpation over the lumbar paraspinal muscles and the quadratus lumborum muscles, decreased lumbar spine range of motion, and decreased sensation over the L4, L4, and S1 dermatomes) findings, current diagnoses (lumbago and lumbar radiculopathy), and treatment to date (medications (including ongoing treatment with Tabradol)). Medical report identifies a request for Tabradol which contains cyclobenzaprine, methylsulfonylmethane, and other proprietary ingredients.

IMR ISSUES, DECISIONS AND RATIONALES

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

TABRADOL 1MG/ML PO SUSPENSION 250ML BID-TID #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril®)..

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

Decision rationale: MTUS does not address the issue. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription; that while the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug; and that there are no high quality medical studies to evaluate co-packs on patient outcomes. Within the medical information available for review, there is documentation of diagnoses of lumbago and lumbar radiculopathy. In addition, there is documentation of a request for Tabradol which contains cyclobenzaprine, methylsulfonylmethane, and other proprietary ingredients. Therefore, based on guidelines and a review of the evidence, the request for Tabradol 1MG/ML PO suspension 250ML BID-TID #1 is not medically necessary.