

Case Number:	CM14-0099240		
Date Assigned:	08/01/2014	Date of Injury:	08/06/2001
Decision Date:	10/16/2014	UR Denial Date:	05/29/2014
Priority:	Standard	Application Received:	06/27/2014

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 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 68-year-old male with an 8/6/01 date of injury. At the time (5/29/14) of the decision for Tabradol 1mg/ml oral suspension 250ml, 5 ml, (1tsp) 2-3 times a day, there is documentation of subjective (radiating low back pain) and objective (tenderness over the lumbar spine and decreased range of motion) findings, current diagnoses (lumbar disc displacement, lumbar radiculopathy, and internal derangement of the left knee), and treatment to date (medications).

IMR ISSUES, DECISIONS AND RATIONALES

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

Tabradol 1mg/ml oral suspension 250ml, 5 ml, (1tsp) 2-3 times a day: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 64.

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: The MTUS does not address the issue. The Official Disability Guidelines 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. Therefore, based on guidelines and a review of the evidence, the request for Tabradol 1mg/ml oral suspension 250ml, 5 ml, (1tsp) 2-3 times a day is not medically necessary.