

Case Number:	CM14-0052425		
Date Assigned:	07/07/2014	Date of Injury:	03/25/1998
Decision Date:	08/26/2014	UR Denial Date:	04/18/2014
Priority:	Standard	Application Received:	04/21/2014

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 59-year-old male with a 3/25/98 date of injury. At the time (2/18/14) of request for authorization for Retrospective DOS: 2/18/14: Theracodophen-325 (Theramine-9) Qty: 1.00, there is documentation of subjective (back pain) and objective (negative straight leg raising test with decreased range of motion) findings, current diagnoses (lumbar sprain, sacroiliac sprain, and lumbar radiculalgia), and treatment to date (medications, physical therapy, and chiropractic therapy).

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective DOS: 2/18/14: Theracodophen-325 (Theramine-9) Qty: 1.00: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)- Pain Theramine.

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: An online search identifies that Theracodophen-325 is a convenience pack containing Theramine capsules and Hydrocodone/Acetaminophen tablets. The MTUS does not

address the issue. The 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. 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. 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 Retrospective Theracodophen-325 (Theramine-9) Qty: 1.00 is not medically necessary.