

Case Number:	CM14-0047891		
Date Assigned:	07/02/2014	Date of Injury:	03/10/2011
Decision Date:	08/06/2014	UR Denial Date:	04/06/2014
Priority:	Standard	Application Received:	04/16/2014

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 50-year-old female with a 3/10/11 date of injury. At the time (4/6/14) of request for authorization for theracodophen 90 convenience pack 325 mg, there is documentation of subjective (right elbow pain) and objective (reduced cervical spine range of motion, right lateral elbow painful to palpation, right medial epicondyle painful to palpation, right olecranon painful to palpation; right knee medial joint line, superior patella, and inferior patella painful to palpation) findings, current diagnoses (cervical spondylosis, knee/lower leg pain, elbow pain, cervicgia, cervical radiculopathy, shoulder pain), 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:

Theracodophen 90 convenience pack 325mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG.

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: Theracodophen 90 convenience pack 325 mg contains medical food thiamine and generic drugs hydrocodone and acetaminophen. MTUS does not address the issue. ODG states 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 drugs are 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 theracodophen 90 convenience pack 325 mg is not medically necessary.