

Case Number:	CM14-0147361		
Date Assigned:	09/15/2014	Date of Injury:	07/21/2000
Decision Date:	10/16/2014	UR Denial Date:	08/15/2014
Priority:	Standard	Application Received:	09/10/2014

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 Physical Medicine & Rehabilitation, has a subspecialty in Pain Medicine 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:

The injured worker is a 56-year-old female who reported an injury on 07/21/2000 due to a work related injury where she was getting out of the school bus, and her left extremity was caught in the school bus door. Following this, the driver started pulling away from the curb and she had to pull her arm out of the door, she then felt intense pain. The injured worker complained of upper extremity pain. The injured worker had a diagnosis of neuropathic pain with sympathetic component, severe myofascial pain, and complex regional syndrome. The past medical treatments included acupuncture, physical therapy, medications, internist, neurologist, orthopedist, chiropractic, and TENS unit. The diagnostics included an MRI to the upper extremity, CT scan, x-rays, and electromyograph. The physical examination dated 05/15/2014 of the extremities revealed hands slightly increased sweating, tenderness of the arms, very slight to palpation. Peripheral pulses in the upper extremities were 2+. The muscle examination revealed breakaway weakness in the flexors of the wrist bilaterally. Muscle strength was 5/5. Reflexes were 2+ to the upper extremities. Decreased pinprick and fine touch to the entire left side of the body. The injured worker rated her arm pain a 3/10 to 4/10 in severity and occasionally, a 9/10 to 10/10 in severity. The medications included Neurontin and nortriptyline. The treatment plan included medications. The Request for Authorization dated 09/15/2014 was submitted with documentation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Alendronate 35mg #4: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: The request for Alendronate 35mg #4 is not medically necessary. The California MTUS/ ACOEM does not address. The Official Disability Guidelines recommend treatment of bone resorption with bisphosphonate-type compounds as an option for patients with complex region pain syndrome Type I. Not recommended for other chronic pain conditions. The injured worker rated her arm pain a 3-4/10 in severity and 9/10 occasionally. The guidelines do not recommend for chronic pain use. The request did not address the frequency. As such, the request is not medically necessary.

Align 4mg #28: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pubmed/>

Decision rationale: The request for Align 4mg #28 is not medically necessary. The California MTUS/ACOEM or the Official Disability Guidelines do not address. The US Food and Drug Administration regulatory categorization indicates that probiotics are living microorganisms that, when consumed, have the potential to confer a beneficial health effect. Unfortunately for purveyors of probiotic products, the system of regulation delineated in the Food, Drug, and Cosmetic Act is anything but "one size fits all." How a probiotic product is used or is intended to be used will govern the regulatory category or categories that the US Food and Drug Administration (FDA) will assign to the product. The extent and nature of the restraints and data-collection requirements that may be imposed on the marketing of a product hinge on how a product is categorized under the Act. More specifically, the categorization of a product governs the respective regulatory burdens of an industry sponsor and the FDA. Pre-market systems, such as those for new drugs and biologics, place a heavy evidentiary burden on the sponsor of a product. Post-market systems, such as those for dietary supplements, place, at least initially, a higher regulatory evidentiary burden on the FDA than on the product sponsor. This article explains regulatory categorizations under the Food, Drug, and Cosmetic Act and their effects regarding the federal regulation of probiotic products. The request did not address the frequency. The clinical notes did not indicate an intestinal infection or history of intestinal issues that would warrant the use of probiotics. The guidelines do not address the probiotics. As such, the request is not medically necessary.

