

Case Number:	CM14-0202302		
Date Assigned:	12/30/2014	Date of Injury:	04/08/2011
Decision Date:	02/25/2015	UR Denial Date:	11/05/2014
Priority:	Standard	Application Received:	12/03/2014

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Physical Medicine & Rehabn, Pain Management

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a patient with a date of injury of 4/8/11. A utilization review determination dated 11/5/14 recommends non-certification/modification of probiotics and Theratramadol. 1/6/15 medical report identifies abdominal pain in the RUQ and episodes of abdominal bloating. No abnormal exam findings are noted. Recommendations include Gaviscon, Citrucel, Simethecone, Amitiza, Dexilant, Probiotics, Sentra PTM, and tramadol.

IMR ISSUES, DECISIONS AND RATIONALES

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

(1) Prescription of Probiotics #60 with 2 refills: 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).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: http://cid.oxfordjournals.org/content/46/Supplement_2/S96.long

Decision rationale: Regarding the request for probiotics, CA MTUS and ODG do not address the issue. A search of the National Library of Medicine and other online resources reveals that "Proven benefits of probiotics include the treatment of acute and antibiotic-associated diarrhea; applications with substantial evidence include the prevention of atopic eczema and traveler's diarrhea; promising applications include the prevention of respiratory infections in children, prevention of dental caries, elimination of nasal pathogen carriage, prevention of relapsing *C. difficile*-induced gastroenteritis, and treatment of inflammatory bowel disease; and proposed future applications include the treatment of rheumatoid arthritis, treatment of irritable bowel syndrome, cancer prevention, prevention of ethanol-induced liver disease, treatment of diabetes, and prevention or treatment of graft-versus-host disease. The use of probiotics in medical practice is rapidly increasing, as are studies that demonstrate the efficacy of probiotics. A note of caution should be applied: negative findings are being reported, as would be expected as more studies are being performed and as more applications are being sought for the use of probiotics." Within the documentation available for review, there is no clear identification of the condition(s) for which the probiotics are being utilized and evidence-based support for the use of probiotics in the management of that/those condition(s). In the absence of clarity regarding the above issues, the currently requested probiotics are not medically necessary.

(1) Prescription of Theratramadol 90 co-pack #1 (3 month supply): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 44, 47, 75-79, 120 of 127.

Decision rationale: Theratramadol is a co-pack containing Theramine and tramadol. Regarding Theramine, California MTUS and ACOEM Guidelines do not contain criteria for the use of medical foods. ODG states Theramine is not recommended. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. Regarding the tramadol, California Pain Medical Treatment Guidelines note that it is an opiate pain medication. Due to high abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. Within the documentation available for review, there is no indication of efficacy from any prior use of opioids and there is no clear rationale for the use of an opioid in combination with Theramine given the lack of evidence-based support for its use in the management of the patient's cited conditions. In light of the above issues, the currently requested Theratramadol is not medically necessary.