

Case Number:	CM14-0049093		
Date Assigned:	07/07/2014	Date of Injury:	12/23/2008
Decision Date:	08/26/2014	UR Denial Date:	03/14/2014
Priority:	Standard	Application Received:	04/17/2014

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 Preventative Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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:

This patient is a 37 year old employee with date of injury of 12/23/2008. Medical records indicate the patient is undergoing treatment for low back, right knee and leg pain secondary to a right meniscal tear (status post repair); right knee sprain/strain; chronic pain syndrome, lumbar radiculitis and lumbar sprain/strain; chronic pain related anxiety, insomnia and depression. Subjective complaints include a pain level at 8/10 with medication and 9/10 without. Patient complained of feeling "too drugged" and thought it was due to the Gabapentin. Objective findings include the exam is positive for the right knee joint and negative for the left. The right knee shows no swelling or effusion but has a positive McMurray's test for the medial meniscus. The test is negative for the lateral meniscus. The range of motion is from 0" to 120". There is no instability for the collateral or cruciate ligaments. He has a slight limp on the right but does not use a cane. Treatment has consisted of Ketoflex compounded ointment, Norco, Floricet, Ultram, Zanaflex, Colace, Gabapentin and Trepadone. The provider replaced Gabapentin with Theramine, Sintralyne was discontinued and replaced with Gabadone and Cidaflex was discontinued. The utilization review determination was rendered on 3/14/2014 recommending non-certification of a Prospective request for 1 prescription of Trepadone #120, a Prospective request for 1 prescription of Gabadone #60 and a Prospective request for 1 prescription of Theramine #120.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prospective request for 1 prescription of Trepadone #120: 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 (Chronic) Medical food.

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

Decision rationale: MTUS is silent concerning Trepadone. ODG states that a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation". ODG comments on Trepadone directly, "Trepadone is a medical food from [REDACTED] that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gammaaminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. See Medical food, L-Arginine, Glutamic Acid, Choline, L-Serine, and Gamma-aminobutyric acid (GABA)." The ODG guidelines do not support the use of Trepadone. As such the request for Prospective request for 1 prescription of Trepadone #120 is not medically necessary.

Prospective request for 1 prescription of Gabadone #60: 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 (Chronic).

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

Decision rationale: MTUS is silent concerning Gabadone. ODG states that a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation". ODG comments on Gabadone directly, "Not recommended. Gabadone is a medical food from [REDACTED], that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. (Shell, 2009) See Medical food, Choline, Glutamic Acid, 5-hydroxytryptophan, and Gamma-aminobutyric acid (GABA)." The ODG guidelines do not support the use of Gabadone. As such the request for Prospective request for 1 prescription of Gabadone #60 is not medically necessary.

Prospective request for 1 prescription of Theramine #120: Upheld

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

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

Decision rationale: ODG states that a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation". ODG comments on Theramine directly, "Not recommended. Theramine is a medical food from [REDACTED], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for choline supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product." In this manufacturer study comparing Theramine to Naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended." In addition The ODG guidelines do not support the use of Theramine. As such the request for Prospective request for 1 prescription of Theramine #120 is not medically necessary.