

Case Number:	CM15-0015112		
Date Assigned:	02/03/2015	Date of Injury:	02/09/2006
Decision Date:	03/24/2015	UR Denial Date:	01/23/2015
Priority:	Standard	Application Received:	01/27/2015

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: New York, Pennsylvania, Washington
 Certification(s)/Specialty: Internal Medicine, Geriatric Medicine

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 62 year old female with an industrial injury dated 02/09/2006 as the results of tripping and falling on uneven ground. Her diagnoses include myalgia and myositis, obstructive sleep apnea, diabetes mellitus without comp, and obesity. Recent diagnostic testing was not submitted. She has been treated with medications. In a progress note dated 12/15/2014, the treating physician reports total body pain, chronic fatigue, problems sleeping, and morning gel phenomenon. The objective examination revealed no new joint swelling, normal neurological exam, and no rheumatoid arthritis deformities. The treating physician is requesting multiple medications which were denied by the utilization review. On 01/23/2015, Utilization Review non-certified a prescription for Gabadone 2C at bed time. No rationale or guideline criteria was provided for this decision. On 01/23/2015, Utilization Review non-certified a prescription for Theramine 3C every day. No rationale or guideline criteria was provided for this decision. On 01/23/2015, Utilization Review non-certified a prescription for Flurbiprofen AAA twice daily. No rationale or guideline criteria was provided for this decision. On 01/23/2015, Utilization Review non-certified a prescription for Trepadone 3C every day. No rationale or guideline criteria was provided for this decision. On date IMR application was received, the injured worker submitted an application for IMR for review of Gabadone 2C at bed time, Theramine 3C every day, Flurbiprofen AAA twice daily, and Trepadone 3C every day.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabadone 2C HS: 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.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/> and uptodate: treatment of insomnia

Decision rationale: Gabadone is a Medical Food formulated to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) 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." The records do not substantiate improvement with medications or why a medical food is being used instead of or in addition to traditional medications. Additionally, patients with sleep disturbance should receive therapy for any medical condition, psychiatric illness, substance abuse, or sleep disorder that may cause the problem and be counseled regarding sleep hygiene. After this, cognitive behavioral therapy would be used prior to medications. In this injured worker, the sleep pattern, hygiene or level of insomnia is not addressed. She also has a history of obstructive sleep apnea which would not be treated with medications to target sleep. The documentation does not support the medical necessity for gabadone.

Theramine 3C QD: 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.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>

Decision rationale: Theramine is a medical food used to treat chronic pain syndromes and low back pain. The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) 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." The records do not substantiate improvement with medications or why a medical food is being used instead of or in addition to traditional medications. The medical necessity for theramine is not documented.

Flurbiprofen AAA BID: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 9792.26 Page(s): 111-112.

Decision rationale: Per the guidelines, topical analgesics are largely experimental with few randomized trials to determine efficacy or safety. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder and there is no evidence to support its use in neuropathic pain. There is no documentation of efficacy with regards to pain and functional status or a discussion of side effects specifically related to the topical analgesic. Regarding topical flurbiprofen in this injured worker, the records do not provide clinical evidence to support medical necessity.

Trepadone 3C QID: 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.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>

Decision rationale: Trepadone is intended for use in the management of joint disorders associated with pain and inflammation. The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) 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." The records do not substantiate improvement with medications or why a medical food is being used instead of or in addition to traditional medications. The medical necessity for trepadone is not documented.