

Case Number:	CM15-0189202		
Date Assigned:	10/01/2015	Date of Injury:	09/03/2009
Decision Date:	12/02/2015	UR Denial Date:	08/31/2015
Priority:	Standard	Application Received:	09/25/2015

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 50 year old female, who sustained an industrial injury on 9-03-2009. The injured worker is being treated for head pain, cervical sprain-strain, cervical spine disc protrusions, thoracic spine strain, lumbar spine disc protrusions, chronic back pain, bilateral shoulder sprain-strain, left shoulder tendinitis, bilateral shoulder lateral and medial epicondylitis, bilateral knee sprain-strain, left knee patellar tendinosis, right patellofemoral arthralgia, right ankle sprain-strain, NSAID induced gastropathy-Peptic Ulcer Disease, sleep disturbance and depression secondary to pain. Treatment to date has included diagnostics, surgical intervention of the lumbar spine in 2011, 2014 and 2015, epidural steroid injections, diagnostics and medications. Per the only medical record submitted, the Primary Treating Physician's Progress Report dated 7-27-2015, the injured worker reported headaches as well as pain in the neck, mid and upper back, bilateral shoulders, left elbow, and right ankle. Objective findings included tenderness over the cervical spine which has decreased and palpable spasm which remains the same. There was tenderness of the thoracic musculature which has increased and palpable spasm which remains the same. Lumbar spine tenderness has decreased, and there is restricted range of motion. Tenderness to palpation of the bilateral shoulders and elbows has remained the same since the last visit. Per the medical records dated 7-27-2015 there is no documentation of how many sessions of physical therapy the IW has received or any improvement in symptoms, increase in activities of daily living or decrease in pain level with the prior therapy. The notes from the provider do not document efficacy of the prescribed medications. Work status was temporary total disability. The plan of care included oral and topical medications and physical

therapy. Authorization was requested on 7-27-2015 for Norco 5-325mg #60, Theramine #90, Flurbi (NAP)-LA 180gm #1, Gaba-Cyclo-Tram 180gm #1 and 12 sessions (3x4) of physical therapy for the lumbar spine. On 8-31-2015, Utilization Review non-certified the request for Theramine #90, Flurbi (NAP)-LA 180gm #1, Gaba-Cyclo-Tram 180gm #1 and 12 sessions of physical therapy for the lumbar spine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #90: 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 (updated 04/15/12), Medical Food.

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 20% / Lidocaine 5% / Amitriptyline 5% 180gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

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 20% / Lidocaine 5% / Amitriptyline 5% 180gm in this injured worker, the records do not provide clinical evidence to support medical necessity.

Gabapentin 10% / Cyclobenzaprine 6% / Tramadol 10% 180gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

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 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 Gabapentin 10% / Cyclobenzaprine 6% / Tramadol 10% 180gm in this injured worker, the records do not provide clinical evidence to support medical necessity.

Physical therapy for the lumbar spine, 3 times a week for 4 weeks, quantity: 12 sessions:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Physical Medicine.

Decision rationale: Physical Medicine Guidelines allow for fading of treatment frequency from up to 3 visits per week to 1 or less, plus active self-directed home physical medicine. In this injured worker, physical therapy has already been used as a modality and a self-directed home program should be in place. The records do not support the medical necessity for additional physical therapy visits in this individual with chronic pain.