

Case Number:	CM15-0077613		
Date Assigned:	04/29/2015	Date of Injury:	04/07/2009
Decision Date:	08/24/2015	UR Denial Date:	03/27/2015
Priority:	Standard	Application Received:	04/23/2015

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: California
 Certification(s)/Specialty: Emergency 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 57-year-old male, who sustained an industrial injury on April 7, 2009. The injured worker has been treated for neck and back complaints. The diagnoses have included lumbar herniated nucleus pulposus, lumbar radiculitis, lumbar radiculopathy, neuropathic pain, myofascial syndrome, cervical sprain/strain, chronic pain syndrome, chronic pain-related depression, and chronic pain-related insomnia and tension headaches. Treatment to date has included medications, radiological studies, a neck brace and physical therapy. Current documentation dated March 5, 2015 notes that the injured worker reported severe low back pain that radiated to the mid back and bilateral lower extremities. He also noted discomfort on the top of both feet. Examination of the lumbar spine revealed tenderness, trigger points bilaterally and a painful and severely limited range of motion. The treating physician's plan of care included a request for the medications Prilosec, Theramine, Gabadone, Tramadol, Gabadone date of service (3/13/2015), Theramine date of service (3/13/2015), Flexeril/Flurbiprofen compound ointment and a drug screen.

IMR ISSUES, DECISIONS AND RATIONALES

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

Drug Screen: 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 Page(s): 78 of 127.

Decision rationale: The request is for a drug toxicology screen. This is usually performed in certain cases to identify patients who are taking drugs of abuse or not following the advised treatment regimen. Patients on prolonged courses of opioids are at risk for addiction. The MTUS guidelines state the following under the category of indications for ongoing management of the use of opioid medication: (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. In this case, there is inadequate documentation of issues of abuse or addiction necessitating a toxicology screen. As such, the request is not medically necessary.

Prilosec 20 mg Qty 30: 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 Page(s): 68 of 127.

Decision rationale: The request is for the use of a medication in the class of a proton pump inhibitor. This is usually given as an acid reducing medication for patients with esophageal reflux, gastritis, or peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatory for chronic pain. Unfortunately, they do have certain side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically. Criteria for risk are as follows: "(1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." Due to the fact the patient does not meet to above stated criteria, the request for use is not medically necessary.

Theramine Qty 120: 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) Theramine.

Decision rationale: The request is for the use of theramine. This is a compounded specialized formula that consists of: choline bitartrate, L-arginine, L-histidine HCL, L-glutamine, L-serine, GABA, griffonia seed (95% 5HTP), whey protein hydrolysate, grape seed extract (85% polyphenols), cinnamon, and cocoa extract (6% theobromine). It is used for the treatment of

chronic pain sometimes as an alternative to anti-inflammatory. The ODG guidelines state that its use is not recommended. The reason cited includes inadequate clinical trials showing efficacy beyond current standard treatments for chronic pain syndromes. As such, the request is not medically necessary.

Gabalone Qty 60: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 399.

Decision rationale: Gabalone is a homeopathic product, which contains multiple ingredients. This includes L-Glutamic Acid, 5-Hydroxytryptophan as Griffonia Seed Extract, Acetyl L-Carnitine HCL, Gamma Amino Butyric Acid, Choline Bitartrate, Hydrolyzed Whey Protein, Cocoa, Ginkgo Biloba, Valerian Root, and Grape Seed Extract. This product is marketed as a sleep aid. The request is for the use of a sleep aid. The need for this type of medication is varied and includes side effects of pharmaceuticals taken, stress, or even psychiatric conditions. Prior to use, a proper work-up is required delineating the etiology of the sleep disturbance. This may require a psychiatric evaluation. Further, restorative measures should initially include improving sleep hygiene, reducing caffeine intake and fat rich foods. In this case, the required evaluation and initial treatment measures are not seen. As such, the request is not medically necessary.

Flexeril/Flurbiprofen Compound ointment 240 gm, Qty 1: 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 Page(s): 111-113 of 127.

Decision rationale: The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients, which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the use of Flexeril is stated to be not indicated for use for the patient's condition. As such, the request is not medically necessary.

Tramadol 50 mg Qty 120 with 8 refills: 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 Page(s): 80, 80-83 of 127.

Decision rationale: Tramadol is a pain medication in the category of a centrally acting analgesic. They exhibit opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Centrally acting drugs are reported to be effective in managing neuropathic type pain although it is not recommended as first line therapy. The side effect profile is similar to opioids. For chronic back pain, it appears to be efficacious for short-term pain relief, but long term (>16 weeks) results are limited. They also did not appear to improve function. The use of Tramadol for osteoarthritis is indicated for short-term use only (<3 months) with poor long-term benefit. In this case, the patient does not meet the qualifying criteria or indications. As such, the request is not medically necessary.

Gabadone Qty 60 (retrospective DOS 03/13/15): Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 399.

Decision rationale: Gabadone is a homeopathic product, which contains multiple ingredients. This includes L-Glutamic Acid, 5-Hydroxytryptophan as Griffonia Seed Extract, Acetyl L-Carnitine HCL, Gamma Amino Butyric Acid, Choline Bitartrate, Hydrolyzed Whey Protein, Cocoa, Ginkgo Biloba, Valerian Root, and Grape Seed Extract. This product is marketed as a sleep aid. The request is for the use of a sleep aid. The need for this type of medication is varied and includes side effects of pharmaceuticals taken, stress, or even psychiatric conditions. Prior to use, a proper work-up is required delineating the etiology of the sleep disturbance. This may require a psychiatric evaluation. Further, restorative measures should initially include improving sleep hygiene, reducing caffeine intake and fat rich foods. In this case, the required evaluation and initial treatment measures are not seen. As such, the request is not medically necessary.

Theramine Qty 120 (retrospective DOS 03/13/15): 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) Theramine.

Decision rationale: The request is for the use of theramine. This is a compounded specialized formula that consists of: choline bitartrate, L-arginine, L-histidine HCL, L-glutamine, L-serine, GABA, griffonia seed (95% 5HTP), whey protein hydrolysate, grape seed extract (85% polyphenols), cinnamon, and cocoa extract (6% theobromine). It is used for the treatment of chronic pain sometimes as an alternative to anti-inflammatory. The ODG guidelines state that its use is not recommended. The reason cited includes inadequate clinical trials showing efficacy beyond current standard treatments for chronic pain syndromes. As such, the request is not medically necessary.