

Case Number:	CM15-0111515		
Date Assigned:	06/22/2015	Date of Injury:	05/19/2014
Decision Date:	10/05/2015	UR Denial Date:	05/27/2015
Priority:	Standard	Application Received:	06/09/2015

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: Preventive Medicine, Occupational 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:

This 43 year old male sustained an industrial injury on 5/19/14. He subsequently reported neck pain. Diagnoses include cervical disc protrusion, cervical disc degeneration, cervical spondylosis, stenosis and radiculopathy. Treatments to date include x-ray and MRI testing, injections and prescription pain medications. The injured worker continues to experience neck pain that radiates to the upper extremities and headaches. Upon examination, there was tenderness and spasm to palpation over the cervical spine and along the trapezius muscles bilaterally. Cervical range of motion was reduced. Spurling's test is negative bilaterally. A request for Theramine, Sentra AM, Sentra PM, Gabadone, Norco, Ambien, Omeprazole, Genicin, Colace and Somnicin medications was made by the treating physician.

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, 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), Medical food.

Decision rationale: Theramine is a Food and Drug Administration regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Theramine is thought to promote the production of the neurotransmitters that help manage and improve the sensory response to pain and inflammation. Medical food is defined in section 5 (b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as 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. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Theramine #90 is not medically necessary.

Sentra PM #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, 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), Medical food.

Decision rationale: Sentra is a medical food. Medical food is defined in section 5 (b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as 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. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Sentra PM #60 is not medically necessary.

Sentra AM #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, 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), Medical food.

Decision rationale: Sentra is a medical food. Medical food is defined in section 5 (b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as 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. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Sentra AM #60 is not medically necessary.

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, Compound drugs.

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), Medical food.

Decision rationale: Gabadone is a medical food. Medical food is defined in section 5 (b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as 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. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. GABAdone #60 is not medically necessary.

Norco 10/325mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-94.

Decision rationale: The Chronic Pain Medical Treatment Guidelines state that continued or long-term use of opioids should be based on documented pain relief and functional improvement or improved quality of life. Despite the long-term use of Norco, the patient has reported very little, if any, functional improvement or pain relief over the course of the last 6 months. A previous utilization review decision provided the patient with sufficient quantity of medication to be weaned slowly off of narcotic. Norco 10/325mg #30 is not medically necessary.

Ambien 10mg #15: Upheld

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

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), Zolpidem (Ambien).

Decision rationale: The Official Disability Guidelines do not recommend the use of sleeping pills for long-term use. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. The patient has been taking Ambien for longer than the 2-6 week period recommended by the ODG. A previous utilization review decision provided the patient with sufficient quantity of medication to be weaned slowly. Ambien 10mg #15 is not medically necessary.

Omeprazole 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67-68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines proton pump inhibitor, NSAID, gastrointestinal events Page(s): 68.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, prior to starting the patient on a proton pump inhibitor, physicians are asked to evaluate the patient and to determine if the patient is at risk for gastrointestinal events. Criteria used are: (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. There is no documentation that the patient has any of the risk factors needed to recommend the proton pump inhibitor omeprazole. Omeprazole 20mg #60 is not medically necessary.

Genicin #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, Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines glucosamine hydrochloride (GH) Page(s): 50.

Decision rationale: According to the MTUS, glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). At present, based on the records provided, and the evidence-based guideline review, the request is non-certified. Genicin #90 is not medically necessary.

Colace 100mg #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.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines prophylactic treatment of constipation Page(s): 77.

Decision rationale: The Chronic Pain Medical Treatment Guidelines makes provision for the prophylactic treatment of constipation secondary to chronic opiate use; however, the patient was previously provided with a sufficient quantity of narcotics to be weaned from opioids which makes a laxative not medically necessary. Colace 100mg #120 is not medically necessary.

Somnicin #30: 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.

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), Melatonin.

Decision rationale: The Official Disability Guidelines recommend a melatonin as a single agent to improve sleep. The repeated administration of melatonin improves sleep and thereby may reduce anxiety, which leads to lower levels of pain. Somnicin is a compounded medication. Melatonin compounded with other substances is not recommended. Somnicin #30 is not medically necessary.