

Case Number:	CM15-0110956		
Date Assigned:	06/17/2015	Date of Injury:	09/24/2011
Decision Date:	10/02/2015	UR Denial Date:	06/03/2015
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:

The injured worker is a 50-year-old female who sustained an industrial injury on 09/24/2011. Mechanism of injury occurred when working as a correctional officer she fell from her chair while at work. Diagnoses include lumbar radiculopathy, chronic back pain, and status post lumbar interbody fusion with instrumentation on 04/20/2015. Additional diagnoses include rheumatoid arthritis, and hypertension. Treatment to date has included diagnostic studies, status post cervical fusion in 2007, spinal cord stimulator on 10/04/2012, S1 joint injections, status post anterior lumbar segmental spinal fixation lumbar fusion, and home exercise program. A physician progress note dated 05/08/2015 documents the injured worker continues to complain of constant low back pain radiating to the bilateral lower extremities with numbness and tingling and rates her pain as 5 out of 10. She is status post anterior lumbar fusion on 04/20/2015. Lumbar range of motion: flexion 25 degrees, extension 0 degrees, right and left lateral flexion is 5 degrees. The treatment plans includes, a sleep device consultation, continuation of home exercise program, and follow up in 4-6 weeks. Treatment requested is for Consult with orthopedic spine surgeon, Flurbi (NAP) cream-LA 180gm, Gabacyclotram 180gm, Genicin capsules 500mg #90, Home health care following lumbar surgery - 8 hours daily, Monday-Sunday, Opana ER 20mg #60, Orthosis - lumbar spine, Retrospective GABAdone #60, Retrospective Sentra AM #90, Retrospective Sentra PM #60, Retrospective Theramine #90, Somnicin capsules #30, Terocin 240ml, and Trepadone #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Genicin capsules 500mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) 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). This patient has sustained a lumbar injury and does not meet the above criteria in support of the use of Genicin. Therefore, the request is not medically necessary.

Somnicin capsules #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.

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) Chapter, 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. Therefore, the request is not medically necessary.

Opana ER 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-49, 115.

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

Decision rationale: According to the MTUS concerning medications for chronic pain, only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. Oxymorphone is indicated for the relief of moderate to severe pain and also as a preoperative medication to alleviate apprehension, maintain anesthesia and as an obstetric analgesic. This patient was approved for both Norco and OxyContin by the previous utilization reviewer. Therefore, the request is not medically necessary.

Flurbi (NAP) cream-LA 180gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment

Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

Decision rationale: According to the MTUS, there is little to no research to support the use of many of these Compounded Topical Analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Flurbiprofen topical is not supported by the MTUS. Therefore, the request is not medically necessary.

Gaba-Cyclo-Tram 180gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Gabapentin is not recommended. There is no peer-reviewed literature to support use. Therefore, the request is not medically necessary.

Terocin 240ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

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

Decision rationale: According to the MTUS, compounds containing lidocaine are not recommended for non-neuropathic pain. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. The patient's physical exam shows no evidence of radiculopathy or neuropathic pain. In addition, there is little to no research to support the use of many of these Compounded Topical Analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request is not medically necessary.

Orthosis - lumbar spine: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 301.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 301.

Decision rationale: It was noted in the PR-2 supplied for review that the patient was already given a back brace to aid in post-operative healing. Issue of another back brace would not be

medically appropriate. At present, based on the records provided, and the evidence-based guideline review, the request is not medically necessary.

Consult with orthopedic spine surgeon: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 305.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM Practice Guidelines, Chapter 7, Independent Medical Examinations and Consultations, page 132.

Decision rationale: According to available documentation, the patient does not meet the criteria for a surgical consultation. It was noted in the PR-2 associated with the request for authorization that the patient is status-post anterior L5-S1 interbody fusion with instrumentation on 04/20/2015. Therefore, the request is not medically necessary.

Home health care following lumbar surgery - 8 hours daily, Monday-Sunday: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 51.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic), Home Health Services.

Decision rationale: The Official Disability Guidelines recommend home health services only for recommended medical treatment for patients who are homebound, on a part-time or intermittent basis. Medical treatment does not include homemaker services like shopping, cleaning, and laundry, and personal care given by home health aides like bathing, dressing, and using the bathroom when this is the only care needed. The medical record does not contain documentation that the patient requires medical services to be provided at the home. Therefore, the request is not medically necessary.

Trepadone #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.

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: Trepadone is a medical food thought to help with the management and relief of pain and inflammation related to joint disorders. Medical food is defined in section 5(b) of the Orphan Drug Act 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. Therefore, the request is not medically

necessary.

Retrospective 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.

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 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. Therefore, the request is not medically necessary.

Retrospective Sentra AM #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.

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 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. Therefore, the request is not medically necessary.

Retrospective 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.

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 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. Therefore, the request is not medically necessary.

Retrospective 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.

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 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. Therefore, the request is not medically necessary.