

Case Number:	CM15-0188299		
Date Assigned:	10/01/2015	Date of Injury:	07/01/2014
Decision Date:	12/01/2015	UR Denial Date:	08/28/2015
Priority:	Standard	Application Received:	09/24/2015

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 68 year old female, who sustained an industrial injury on 7-01-2014. The injured worker is being treated for left shoulder rotator cuff syndrome. Treatment to date has included diagnostics and medications. Per the Primary Treating Physician's Progress Report dated 8-17-2015, the injured worker reported no change in her shoulder symptoms since the last time she was seen. She reported constant left shoulder pain rated as 5 out of 10. Objective findings included tenderness to palpation along the acromioclavicular joint and the trapezius muscles bilaterally with palpable spasms. Per the medical record dated 6-30-2015, she reported constant shoulder pain rated as 5 out of 10. She is working and performing full duty. Per the medical records dated 6-30-2015 to 8-17-2015 there is no documentation of improvement in symptoms, increase in activities of daily living or decrease in pain level with the current treatment. The notes from the provider do not document efficacy of the prescribed medications. Work status was temporarily totally disabled on 8-17-2015 and the plan of care included oral and topical medications. Authorization was requested on 8-21-2015 for Theramine #180, Sentra AM #60, Sentra PM 360, Gabadone #60, App Trim #120, and Ketoprofen 10%-Gabapentin 6%-Bupivacaine 5%- Fluticasone 1%-Baclofen 2%-Cyclobenzaprine 2%- Clonidine 0.2%- hyaluronic acid 0.2%-alpha lipoic acid 125mg-folic acid 0.5mg-hyaluronic acid-methyl cobalamin (B12) 0.5mg-Pyridoxal 5-phosphate 35mg-Reservatrol 25mg-CoQ10 50mg-VitaminD3 500IU and Pentoxifyline 5%-aminophylline 3%-lidocaine 2.5%- hyaluronic acid 1% #240gm. On 8-28-2015, Utilization Review non-certified the request for Theramine #180, Sentra AM #60, Sentra PM 360, Gabadone #60, App Trim #120, and Ketoprofen 10%-

Gabapentin 6%- Bupivacaine 5%- Fluticasone 1%-Baclofen 2%-Cyclobenzaprine 2%- Clonidine 0.2%- hyaluronic acid 0.2%-alpha lipoic acid 125mg-folic acid 0.5mg-hyaluronic acid-methyl cobalamin (B12) 0.5mg-Pyridoxal 5-phosphate 35mg-Reservatrol 25mg-CoQ10 50mg- VitaminD3 500IU and Pentoxifyline 5%-aminophylline 3%-lidocaine 2.5%- hyaluronic acid 1% #240gm.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #180: 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 (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 #180 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.

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 AM 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.

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 PM 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.

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 (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.

App Trim#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: 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: App Trim 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. App Trim#120 is not medically necessary.

Ketoprofen- 10% gabapentin, 6% bupivacaine, 5% flutiasone, 1% baclofen, 2% cyclobenzaprine, 2% clonidine, 0.2% hyaluronic acid, and 5% pentoxifyline, aminophylline 3%, 2.5% lidocaine, 1% hyaluonic acid 240 grams: 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: 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. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Ketoprofen agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Ketoprofen, 10% gabapentin, 6% bupivacaine, 5% flutiasone, 1% baclofen, 2% cyclobenzaprine, 2% clonidine, 0.2% hyaluronic acid, and 5% pentoxifyline, aminophylline 3%, 2.5% lidocaine, 1% hyaluonic acid 240 grams is not medically necessary.

Alpha lipoic acid 125mg, Folic acid 0.5mg. Hyaluronic Acid Methylcobalamin (B12) 0.5mg Pyridoxal 5-Phosphate 35mg-Resveratrol 25mg-Ubiquinol (CoQ10) 50 mg-Vitamin D3 500IU: 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 Medical Treatment 2009, Section(s): Topical Analgesics.

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. Topical analgesics are

largely experimental in use with few randomized controlled trials to determine efficacy or safety. Alpha lipoic acid 125mg, Folic acid 0.5mg. Hyaluronic Acid Methylcobalamin (B12) 0.5mg Pyridoxal 5-Phosphate 35mg-Resveratrol 25mg-Ubiquinol (CoQ10) 50 mg-Vitamin D3 500IU is not medically necessary.