MAXIMUS Federal Services

Case Number:	CM15-0168585		
Date Assigned:	09/14/2015	Date of Injury:	01/30/2014
Decision Date:	11/02/2015	UR Denial Date:	07/24/2015
Priority:	Standard	Application Received:	08/27/2015

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 48 year old, male who sustained a work related injury on 10-28-14. The diagnoses have included right wrist scapholunate ligament tear with carpal instability and reconstruction surgery. Treatments have included right wrist-forearm surgery 1-30-15, 30 occupational therapy visits and oral medications. Medications he is currently taking include Duexis. In the occupational therapy notes, his pain level has varied from 2-7 out of 10, he has limited range of motion in right wrist and functional use of the right wrist on last visit was at 44%. In the progress notes dated 6-4-15, the injured worker reports improvement in right wrist function with occupational therapy. He is "frustrated by ongoing symptoms which have precluded him from golfing and mountain biking." He states Duexis is helping with his improvement. On physical exam, he has tape on his right arm. The swelling has decreased and his motion in wrist is improving. He is working regular duty. The treatment plan includes continued therapy and a refill of Duexis. In the Utilization Review, dated 8-26-15, Duexis is non- certified as it is not recommended as a first-line drug for pain control and it is unclear why the provider prescribed this medication.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine 90 mg 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: 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 entirely 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 mg Gabadone 60 is not medically necessary.

Sentralopram AM 10 #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 & (http://nutrientpharmacology.com/PDFs/copacks/SentraAM-SentralopramA_citalopram_10mg- co_pack.pdf).

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: Sentralopram 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 entirely 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. Sentralopram AM 10
#60 is not medically necessary.

Sentrazolpidem PM 5 #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: Sentrazolpidem 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 entirely 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. Sentrazolpidem PM 5 #60 is not medically necessary.

Genicin 90 & 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.

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: 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 does not have osteoarthritis and his injury is relatively new. Genicin 90 is not medically necessary. 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.

Ibuprofen 600mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: The MTUS recommends NSAIDs at the lowest dose for the shortest period in patients with moderate to severe pain. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence of long-term effectiveness for pain or function. The medical record contains no documentation of functional improvement. Guidelines recommend NSAIDs as an option for short term symptomatic relief. Ibuprofen 600mg #60 is not medically necessary.

Methocarbamol (Robaxin) 750mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: The MTUS states that muscle relaxants are recommended with caution only on a short-term basis. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. The patient has been taking the muscle relaxant for an extended period of time far longer than the short-term course recommended by the MTUS. Methocarbamol (Robaxin) 750mg #30 is not medically necessary.

Compound RX Capsaicin 0.25% Menthol 10% Lidocaine 2.5% Flurbiprofen 20% Lidocaine 5% Amitriptyline 4% and gabapentin 10% cyclobenzaprine 6% Tramadol 10%: 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. There is no evidence for use of any muscle relaxant as a topical product. Flurbiprofen topical is not supported by the MTUS. Compound RX Capsaicin 0.25% Menthol 10% Lidocaine 2.5% Flurbiprofen 20% Lidocaine 5% Amitriptyline 4% and gabapentin 10% cyclobenzaprine 6% Tramadol 10% is not medically necessary.