

Case Number:	CM15-0079766		
Date Assigned:	04/30/2015	Date of Injury:	09/24/2014
Decision Date:	06/03/2015	UR Denial Date:	04/09/2015
Priority:	Standard	Application Received:	04/27/2015

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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 46 year old female who sustained an industrial injury on 9/24/14 when she tried to sling an overfilled garbage can into a dumpster and injured her right shoulder. She was treated with medications (Tramadol and ibuprofen) which were not effective. She had an MRI (12/5/14) of the right shoulder, which showed a right supraspinatus tendon partial tear. She currently complains of severe, constant, tight, throbbing achy neck, shoulder, upper arm pain with radiation to her head which she describes as frequent headaches and radiation down the arm and into the hand. Her pain level is 5/10 with medications and 8/10 without medications and has been this over the past week. In addition she complains of sleep difficulties due to pain and stomach pain with constipation, diarrhea, nausea and vomiting) due to stress and current medications. Her activities of daily living are compromised in tasks where she needs to grasp using her right hand, reaching behind her back, lifting her right arm and some aspects of self-care. Medications are Tylenol #4, Toradol, Terocin Patch, gabadone, Theramine. Diagnoses include shoulder strain with pain; right elbow strain; tear of right shoulder rotator cuff; neck pain; pain related insomnia; myofascial syndrome; neuropathic pain. In the progress note dated 3/5/15 the treating provider's plan of care requests Voltaren for inflammation and joint pain; Sentra PM for insomnia; Theramine for neuropathic pain. In addition the Tylenol #4 and gabadone are discontinued. She is waiting for orthopedic consult regarding possible rotator cuff repair.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra PM: 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 (Chronic), 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, Medical food.

Decision rationale: MTUS is silent regarding Sentra PM. ODG states that Sentra PM is a medical food from [REDACTED], [REDACTED], intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. In addition ODG states that a medical food is Definition: 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 eternally 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. To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. ODG specifically states: Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Medical records do not indicate that the patient meets these criteria. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there is a component of this medication that is not recommended per guidelines. As such, the request for Sentra PM is not medically necessary.

Theramine: 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 Chapter, 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), Theramine and medical food.

Decision rationale: ODG states that a medical food is 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.

ODG comments on Theramine directly, Not recommended. Theramine is a medical food from [REDACTED], [REDACTED], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, There is no high quality peer-reviewed literature that suggests that GABA is indicated; Choline, where it says, There is no known medical need for choline supplementation; L-Arginine, where it says, This medication is not indicated in current references for pain or inflammation; & L-Serine, where it says, There is no indication for the use of this product. In this manufacturer study comparing Theramine to Naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The ODG guidelines do not support the use of Theramine. As such, the request for Theramine is not medically necessary.

Voltaren: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Voltaren (Diclofenac) Page(s): 43.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67.

Decision rationale: Based on California treatment guidelines, the use of anti-inflammatory medications is supported for individuals with arthritic or degenerative changes. The patient is documented as having nausea and abdominal pain, which may be due to her medications. Diclofenac has significant side effects of GI issues to include the ones above. There is mention that an MRI study documented documents a possible rotator cuff tear but no arthritis. The patient has been on ibuprofen with no documentation that this medication is not effective. As such, the request for Voltaren is not medically necessary.