

Case Number:	CM15-0160970		
Date Assigned:	08/27/2015	Date of Injury:	08/21/2012
Decision Date:	09/30/2015	UR Denial Date:	07/17/2015
Priority:	Standard	Application Received:	08/17/2015

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: Physical Medicine & Rehabilitation

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 an industrial injury on 08-21-2012. Mechanism of injury was not found in documentation provided for review. Diagnoses include cervical and lumbar disc protrusion, lumbar radiculopathy, lumbar spine status post-surgery in May of 2014, right shoulder bursitis, and left shoulder bicipital tenosynovitis. Treatment to date has included diagnostic studies, medications, and a home exercise program. An unofficial Magnetic Resonance Imaging of the right shoulder done on 03-17-2015 revealed Inferior aspect of the acromioclavicular joint causes minimal superior flattening of the distal SSM, and there is presence of subacromial-subdeltoid bursal fluid noted. Suspect SST tendonitis to explain bursal fluid. SST tears unlikely. The most recent physician progress note dated 05-05-2015 documents the injured worker complains of constant neck pain and upper extremity radicular pain with associated numbness and tingling rated 4 out of 10, constant low back pain which he rates as 5 out of 10 and radiating to her lower extremity, and constant bilateral shoulder pain rated 4 out of 10. Cervical spine range of motion is restricted and painful. Right shoulder is tender and there are spasms along the trapezius muscle on the right and impingement sign is positive on the right. Lumbar range of motion is restricted and there is tenderness over the lumbar spine and lumbar paraspinal muscles bilaterally. There are spasms present. There is decreased sensation to light touch over the C6 to C8 nerve root distribution over the left upper extremity. The treatment plan includes a request for an orthopedic evaluation for the right shoulder, a prescription for Norco, Sentra PM, Sentra AM, Gabadone, a follow up in 4-6 weeks, and continuation of her home exercise program. Treatment requested is for Theramine #180, and Lunesta 1mg, #30.

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 cite any medical evidence for its decision.

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, under Medical food.

Decision rationale: The patient presents with constant neck pain rated 4/10, upper extremity radicular pain with associated numbness and tingling rated 5/10, and bilateral shoulder pain rated 4/10. The request is for Theramine #180. The request for authorization is dated 07/09/15. Physical examination of the cervical spine reveals tenderness to palpation along the trapezius muscles bilaterally with palpable spasms. Spurling's test is negative bilaterally. Exam of right shoulder reveals tenderness noted over the subacromial segment. Tenderness and spasms along the trapezius muscle on the right. Impingement sign is positive on the right. Exam of lumbar spine reveals tenderness to palpation along the paravertebral muscles bilaterally. Straight leg raise is negative bilaterally. Sensory examination of the upper extremities reveals decreased sensation to light touch over the C6 to C8 nerve root distribution over the left upper extremity. Recommend for the patient to continue with a home exercise program. Patient's medications include Norco, Lunesta, Theramine, Sentra PM, Sentra AM, and Gabadone. Per progress report dated 05/05/15, the patient is temporarily totally disabled. MTUS and ACOEM guidelines are silent on medical foods. However, ODG Guidelines, Pain (Chronic) Chapter, under Medical food Section states, "Not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes". Per progress report dated 05/05/15, treater's reason for the request is "for chronic pain, fibromyalgia, neuropathic pain and inflammatory pain." This appears to be the initial trial prescription of Theramine. Theramine is a medical food containing a proprietary formulation of neurotransmitter precursors (L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine); polyphenolic antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory and immunomodulatory peptides (whey protein hydrolysate); and adenosine antagonists (cocoa, metabromine), as per <http://www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf>. While ODG guidelines do not discuss every ingredient found in Theramine, they state that L-arginine is "not indicated in current references for pain or inflammation;" Regarding L-serine; the Guidelines state "There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement". Regarding GABA, the guidelines state that "This supplement is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. Adverse reactions associated with treatment include hypertension, increased heart rate and anxiety". Furthermore, the guidelines do not recommend medical foods for the treatment of chronic pain. In this case, the treater has not provided a medical rationale to prescribe a medical food that contains ingredients not supported by ODG. Therefore, the request is not medically necessary.

Lunesta 1mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress Chapter, under Eszopicolone (Lunesta).

Decision rationale: The patient presents with constant neck pain rated 4/10, upper extremity radicular pain with associated numbness and tingling rated 5/10, and bilateral shoulder pain rated 4/10. The request is for LUNESTA 1MG #30. The request for authorization is dated 07/09/15. Physical examination of the cervical spine reveals tenderness to palpation along the trapezius muscles bilaterally with palpable spasms. Spurling's test is negative bilaterally. Exam of right shoulder reveals tenderness noted over the subacromial segment. Tenderness and spasms along the trapezius muscle on the right. Impingement sign is positive on the right. Exam of lumbar spine reveals tenderness to palpation along the paravertebral muscles bilaterally. Straight leg raise is negative bilaterally. Sensory examination of the upper extremities reveals decreased sensation to light touch over the C6 to C8 nerve root distribution over the left upper extremity. Recommend for the patient to continue with a home exercise program. Patient's medications include Norco, Lunesta, Theramine, Sentra PM, Sentra AM, and Gabadone. Per progress report dated 05/05/15, the patient is temporarily totally disabled. ODG Guidelines, Mental Illness & Stress Chapter, under Eszopicolone (Lunesta) Section states, "Not recommended for long-term use, but recommended for short-term use. See Insomnia treatment. See also the Pain Chapter. Recommend limiting use of hypnotics to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase... The FDA has lowered the recommended starting dose of eszopiclone (Lunesta) from 2 mg to 1 mg for both men and women." Per progress report dated 05/05/15, treater's reason for the request is "to be taken as needed for insomnia." The patient has been prescribed Lunesta since at least 03/10/15. In this case, the treater does not document or discuss the medication's efficacy and how the patient is doing with this medication. Furthermore, ODG recommendation limits the use of hypnotics to three weeks maximum in the first two month of injury. This request for additional Lunesta #30 would exceed MTUS recommendation and does not indicate intended short-term use of this medication. Therefore, the request is not medically necessary.