MAXIMUS Federal Services

Case Number:	CM15-0110955		
Date Assigned:	07/22/2015	Date of Injury:	09/10/2009
Decision Date:	09/24/2015	UR Denial Date:	06/02/2015
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: New York
Certification(s)/Specialty: Anesthesiology

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 47 year old male who sustained an industrial injury on 09/10/2009 resulting in injury to the neck, left shoulder and left upper extremity. Treatment provided to date has included: cervical fusion surgery (2010); physical therapy; acupuncture; cervical injections; medications (Pregabalin, Gabapentin, Tramadol, Lunesta, Omeprazole and current medications); and conservative therapies/care. Diagnostic tests performed include: MRI of the cervical spine (2013) showing multilevel one to two millimeter disc bulge, C5-6 desiccation, spurring and narrowing with a osteophyte and degenerative change, and multilevel orthopedic trans-surgical hardware at C7-T1 with mild desiccation; EMG/NCV (electromyography/nerve conduction velocity) testing of the left upper extremity (2010) which was within normal limits; and urine drug screen (04/2015). There were no noted comorbidities or other dates of injury noted. On 04/16/2015, physician progress report noted complaints of neck pain, shoulder pain (left greater than right), pain over the left scapula, and radiating pain down the left arm to the fingers in the left hand. The pain was rated 10/10 in severity without the use of medications and 7/10 with medications. The injured worker rated his daily function at a 5/10. Additional complaints included increased muscle spasm over the neck muscles and upper extremities. There were no changes from previous progress reports noted. Current medications include Norco, Fexmid, Ativan, Lexapro, Sentra PM, and topical analgesic creams with some relief of pain. The physical exam revealed an elevated blood pressure; limited range of motion in the cervical spine secondary to severe increased pain, tightness and stiffness; tenderness over the occipital nerves bilaterally; tenderness over the cervical spinal process and interspaces from C4 to C7; tenderness

over the facet joints from C4 to C7 bilaterally; positive provocation test with rotation and extension, tightness, tenderness and trigger points in the cervical paravertebral, trapezius, levator scapulae, supraspinatus, infraspinatus and rhomboid musculature bilaterally; tenderness over the left shoulder joint, and the supraspinatus and biceps tendons; tightness, tenderness and trigger points in the left shoulder girdle musculature; slightly diminished upper extremity reflexes at the left elbow and left wrist with numbness and burning sensation; diminished sensation to touch over the left medial and lateral distributions of the left upper extremity, decreased hand strength grip on the left and a positive Tinel's sign. The provider noted diagnoses of severe neck pain and stiffness, cervical radiculopathy, cervical disc bulging, cervical degenerative disc disease, cervical myofascial pain syndrome, left shoulder myofascial pain syndrome, and right shoulder pain. Plan of care includes Percura for nerve pain, massage therapy for increased muscle spasms, refill of current medications, and follow-up in one month. The injured worker's work status was not specified on this report. The request for authorization and IMR (independent medical review) includes retrospective requests: for Percura (medical food) every 6 hours with a date of service (DOS): 04/16/2015; Sentra PM #60 with a DOS: 04/16/2015; topical cream consisting of ketamine, Gabapentin, Tramadol and amitriptyline 180gm with a DOS: 04/16/2015; and a topical cream consisting of Tramadol and baclofen 180gm with a DOS; 04/16/2015.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retro: Pecura Q6H (medical food) between 4/16/2015 and 4/16/2015: 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. (2015).

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: Per Medscape, Percura, an amino acid mixture, is a medical food product indicated for clinical dietary management of the metabolic processes of pain, inflammation and loss of sensation due to peripheral neuropathy. According to the ODG guidelines, a medical food is not recommended for chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food 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." Medical necessity for the requested item was not established. The requested medical food was not medically necessary.

Retro: Sentra PM #60 between 4/16/2015 and 4/16/2015: 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): Sentra PM. (2015).

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 and Sentra PM.

Decision rationale: Sentra PM is a Medical food that is intended for use in the management of sleep disorders associated with depression. It is a proprietary blend of choline bitartate, glutamate, and 5-hydroxytryptophan. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. In this case, Sentra PM was prescribed by the physician without specifying its intended use. According to the ODG, "Sentra PM is not recommended." Medical necessity for the requested item has not been established. The requested medical food is not medically necessary.

Retro: Ketamine/Gabapentin/tramadol/Amitriptyline cream 180gm between 4/16/2015 and 4/16/2015: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics.

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

Decision rationale: According to the MTUS guidelines: Topical Analgesic are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The MTUS goes on to specify that Gabapentin is "not" recommended, as there is no peer-reviewed literature to support its use. Ketamine is not recommended except for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia with some positive results. There is no evidence for use of any other antiepilepsy drug, or opioid drugs in topical form. In regards to this topical compound analgesic, Gabapentin, topical opioids, and amitriptyline are not recommended. In addition, the treating physician's request did not include the concentration, quantity, site of application, or directions for use. Therefore, topical cream consisting of Ketamine, Gabapentin, Tramadol, and Amitriptyline 180gm (with DOS 04/16/2015) is not medically necessary.

Retro: Tramadol/baclofen cream 180gm between 4/16/2015 and 4/16/2015: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics.

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

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the topical compound contains Tramadol and Baclofen. These medications are not FDA approved for topical use. Medical necessity for the requested topical medications is not established. The requested topical cream is not medically necessary.