

Case Number:	CM14-0119795		
Date Assigned:	08/06/2014	Date of Injury:	05/09/2013
Decision Date:	10/06/2014	UR Denial Date:	07/08/2014
Priority:	Standard	Application Received:	07/30/2014

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. The expert reviewer is Board Certified in Occupational Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 patient is a 37-year-old male who has submitted a claim for left bicipital tenosynovitis, and left shoulder sprain/strain associated with an industrial injury date 5/9/2013. Medical records from 2013 to 2014 were reviewed. The patient complained of frequent, moderate, upper mid/low back pain, associated with stiffness. The patient likewise complained of constant, moderate, sharp left shoulder pain and numbness, aggravated by repetitive movement, radiating to the left arm. Physical examination showed tenderness to the left shoulder and thoracic muscles. Left shoulder range of motion was restricted on all planes. X-ray of the left shoulder, undated, showed degenerative joint disease of the acromion. Treatment to date has included LINT procedure for lumbar spine, physical therapy, use of interferential unit, acupuncture, chiropractic care, and medications such as Tramadol, Orphenadrine, Etodolac, Theramine, Sentra, Gabadone, and topical creams (since June 2014). The patient was shown to benefit from physical therapy and acupuncture. Utilization review from 7/8/2014 denied the requests for Compounded Capsaicin 0.25%, Flurbiprofen 20%, Tramadol 15%, Menthol 12%, Camphor 2% 180gm, QTY: 1.00 and Compounded Gabapentin 10%, Lidocaine 5%, Tramadol 15% 180gm, QTY: 1.00 because of limited published studies concerning its efficacy and safety; denied 6 sessions of Acupuncture because of no documented objective functional improvement from previous sessions; denied 12 sessions of chiropractic treatment because there was no documentation of objective functional improvement from previous sessions; and denied the requests for Theramine, Gabadone, and Sentra because there was no evidence of distinctive nutritional requirements established by medical evaluation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compounded Capsaicin 0.25%, Flurbiprofen 20%, Tramadol 15%, Menthol 12%, Camphor 2% 180gm, QTY: 1.00: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin; Topical Analgesics Page(s): 28-29; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Topical Salicylates

Decision rationale: The California MTUS Chronic Pain Medical Treatment Guidelines identifies on page 28 that topical Capsaicin is only recommended as an option if there was failure to respond or intolerance to other treatments. The guideline states there is no current indication that an increase over a 0.025% formulation of Capsaicin would provide any further efficacy. In addition, there is little to no research as for the use of Flurbiprofen in compounded products. The topical formulation of Tramadol does not show consistent efficacy. Regarding the Menthol component, the California MTUS does not cite specific provisions, but the Official Disability Guidelines Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl salicylate, or Capsaicin, may in rare instances cause serious burns. The guidelines do not address Camphor. In this case, topical cream is prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains Flurbiprofen and Tramadol, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class, which is not recommended, is not recommended. Therefore, the request for Compounded Capsaicin 0.25%, Flurbiprofen 20%, Tramadol 15%, Menthol 12%, Camphor 2% 180gm, QTY: 1.00 is not medically necessary.

Compounded Gabapentin 10%, Lidocaine 5%, Tramadol 15% 180gm, QTY: 1.00: Upheld

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

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

Decision rationale: As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. The California MTUS does not support the use of opioid medications and Gabapentin in a topical formulation. Topical formulations of Lidocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. The topical formulation of Tramadol does not show consistent efficacy. In this case, topical cream is prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains Gabapentin, Lidocaine, and Tramadol, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug

class, which is not recommended, is not recommended. Therefore, the request for Compounded Gabapentin 10%, Lidocaine 5%, Tramadol 15% 180gm, QTY: 1.00 is not medically necessary.

6 sessions of Acupuncture: Upheld

Claims Administrator guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

Decision rationale: The California MTUS Acupuncture Medical Treatment Guidelines state that acupuncture is used as an option when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery. Acupuncture treatments may be extended if functional improvement is documented. The frequency and duration to produce functional improvement is 3 - 6 treatments, frequency of 1 - 3 times per week, and duration of 1 - 2 months. It may be extended if functional improvement is documented. In this case, patient has received acupuncture treatment in the past; however, the exact number of visits is not documented in the medical records submitted. There was no documentation stating the pain reduction, functional improvement or decreased medication-usage associated with the use of acupuncture. Moreover, body part to be treated is not specified. Therefore, the request for 6 sessions of acupuncture is not medically necessary.

12 sessions of Chiropractic treatment: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual Therapy & Manipulation Page(s): 58.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manipulation Therapy Page(s): 58-59.

Decision rationale: As stated on pages 58-59 of California MTUS Chronic Pain Medical Treatment Guidelines, several studies of manipulation have looked at duration of treatment, and they generally showed measured improvement within the first few weeks or 3-6 visits of chiropractic treatment, although improvement tapered off after the initial sessions. There should be some outward sign of subjective or objective improvement within the first 6 visits for continuing treatment. In this case previously underwent chiropractic care. However, the exact number of sessions attended and functional outcomes were not documented. The medical necessity cannot be established due to insufficient information. Moreover, body part to be treated is not specified. Therefore, the request for 12 sessions of chiropractic treatment is not medically necessary.

Theramine, QTY: 90.00: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, 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) Section, Theramine

Decision rationale: The California MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, Official Disability Guidelines, Pain section was used instead. The Official Disability Guidelines states that Theramine is a medical food that is a proprietary blend of GABA (gamma-aminobutyric acid) and choline bitartrate, L-arginine and L-serine that is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain and inflammatory pain. However, it remains not recommended by the guidelines. In this case, patient has been on Theramine since June 2014. However, there is no documentation concerning pain relief and functional improvement derived from its use. This medication is likewise not recommended as stated above. There is no discussion concerning need for variance from the guidelines. Therefore, the request for Theramine, #90 is not medically necessary.

Gabadone, QTY: 60.00: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, 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 chapter, GABAdone

Decision rationale: The California MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, Official Disability Guidelines was used instead. The Official Disability Guidelines also state that GABAdone is not recommended as it is a medical food. It is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep, and reducing snoring in patient who are experiencing anxiety related to sleep disorders. In this case, patient has been on Gabadone since June 2014. However, there is no documentation regarding sleep difficulties or nutritional deficiencies to support this request. The medical necessity cannot be established due to insufficient information. Therefore, the request for Gabadone #60 is not medically necessary.

Sentra AM, QTY: 60.00: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, 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 Chapter, Sentra

Decision rationale: The California MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Chapter was used instead. It states that Sentra is a medical food intended for use in management of sleep disorders associated with depression, which is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. 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. Glutamic Acid is used for treatment of hypochlohydria and achlorhydria including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. In this case, patient has been on Sentra since June 2014. However, there is no clear indication for Sentra due to lack evidence of insomnia and depression. The medical necessity cannot be established due to insufficient information. Therefore, the request for Sentra AM, #60 is not medically necessary.