MAXIMUS Federal Services

Case Number:	CM15-0129068		
Date Assigned:	07/31/2015	Date of Injury:	03/18/2013
Decision Date:	09/29/2015	UR Denial Date:	06/17/2015
Priority:	Standard	Application Received:	07/02/2015

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, California
Certification(s)/Specialty: Emergency 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 36-year-old female, who sustained an industrial injury on March 18, 2013. The injured worker's initial complaints and diagnoses are not included in the provided documentation. The injured worker was diagnosed as having headaches, cervical spine sprain-strain, cervical radiculopathy, thoracic spine sprain-strain, lumbar spine sprain-strain, lumbar radiculopathy, right shoulder osteoarthritis, status post right shoulder surgery, and right wrist sprain-strain. Diagnostic studies were not included in the provided medical records. Surgeries to date have included: a right shoulder arthroscopy with subacromial decompression. Treatment to date has included physical therapy, a home exercise program, and off work. There were no noted previous injuries or dates of injury, and no noted comorbidities. On March 26, 2015, the injured worker reported constant headaches, 6 out of 10; constant neck pain radiating to the upper extremities with numbness and tingling, 7 out of 10; constant mid back pain, 7 out of 10; constant low back pain radiating to the lower extremities with numbness and tingling, 7 out of 10; constant right shoulder pain, 7 out of 10; and constant right wrist pain with numbness and tingling, 7 out of 10. Her pain level: with medication = 5-6 out of 10 and without medication 8 out of 10. The physical exam revealed decreased cervical range of motion, negative bilateral Spurling's tests, and tenderness with spasms over the upper trapezius muscles. The right shoulder had decreased range of motion and tenderness to palpation along the trapezius muscles with palpable spasms. The right wrist had decreased range of motion and a positive Phalen's test. There was decreased range of motion of the thoracic spine. There was decreased lumbar range of motion, tenderness along the lumbar spine, and palpable spasms along the bilateral lumbar

paravertebral muscles. Her work status was described as permanent and stationary per the agreed medical evaluator and treating under future care. The treatment plan includes Somnicin, Terocin cream, Capsaicin 0.025%-Flurbi (NAP) cream-LA, Gabacyclotram cream,and Medical Food: Gabadone and Theramine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Somnicin Qty 30 (retrospective - dispensed 3/26/15): 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): Medical food; Somnicin.

Decision rationale: The California Medical Treatment Utilization Schedule (CMTUS) guidelines are silent with regard to Somnicin. The Official Disability Guidelines (ODG) does not recommend Somnicin, which is postulated as a treatment for insomnia, anxiety and depression. Somnicin contains melatonin, magnesium oxide, oxitriptan (the L form of 5-hydroxytryptophan), 5-hydroxytryptophan, tryptophan and Vitamin B6 (pyridoxine). Melatonin is used for delayed sleep phase syndrome and rapid eye movement sleep disorders. Magnesium oxide is used as treatment for magnesium deficiency and upset stomach and acid indigestion. Magnesium oxide has no indication for any kind of sleep disorders. There is inconclusive peer-reviewed evidence to support use Oxitriptan and 5-hydroxytriptophan for insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders (postulated to inhibit inflammation), anxiety and depression. Vitamin B 6 (pyridoxine) is FDA-labeled for treatment of pyridoxine deficiency, certain metabolic disorders, prevention of drug-induced neurotoxicity, and for the treatment of neuritis due to pyridoxine deficiency that is not drug-induced. Vitamin B 6 (pyridoxine) is not indication for treatment for any sleep disorder. There was lack of documentation of the injured worker having sleep difficulties, anxiety, or depression. There was lack of documentation of clear physician rationale for prescribing this medication. Therefore, the request for Somnicin is not medically necessary.

Terocin cream 120 mg (retrospective-dispensed 3/26/15): Upheld

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

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

Decision rationale: The treating physician has not discussed the ingredients of Terocin and the specific indications for this injured worker. Per the manufacturer, Terocin is Methyl Salicylate 25%, Menthol 10%, Capsaicin 0.025%, Lidocaine 2.5%, Aloe, Borage Oil, Boswelia Serrata,

and other inactive ingredients. Per page 60 of the MTUS, medications should be trialed one at a time. Regardless of any specific medication contraindications for this patient, the MTUS recommends against starting 3-7 medications simultaneously. Per the MTUS, any compounded product that contains at least one drug that is not recommended, is not recommended. Boswellia serrata resin and topical lidocaine other than Lidoderm are "not recommended" per the MTUS. Capsaicin alone in the standard formulation readily available OTC may be indicated for some patients. The indication in this case is unknown, as the patient has not failed adequate trials of other treatments. Capsaicin is also available OTC, and the reason for compounding the formula you have prescribed is not clear. Terocin is not medically necessary based on lack of specific medical indications, the MTUS, lack of medical evidence, FDA directives, and inappropriate prescribing. This request is not medically necessary.

Capsaicin 0.025%, Flurbi cream-LA 180 gms (retrospective - dispensed 3/26/15): Upheld

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

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

Decision rationale: The requested medication is Capsaicin 0.025%-Flurbi (NAP) cream-LA lotion. Flurbi (NAP) cream-LA is noted in the medical records as Flurbiprofen 20%-lidocaine 5%-Amitriptyline 4%. This compounded topical medication contains capsaicin 0.025%, flurbiprofen 20%, lidocaine 5%, and Amitriptyline 4%. The California Medical Treatment Utilization Schedule (CMTUS) guidelines primarily recommended topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. In addition, CMTUS does not recommend any compound product that contains at least one drug (or drug class) that is not recommended. The CMTUS recommends capsaicin only when other treatments have failed or the injured worker is unable to tolerate other treatments. Capsaicin is indicated for osteoarthritis, fibromyalgia, and chronic non-specific back pain. The CMTUS recommends topical non-steroidal anti-inflammatory drugs (NSAIDs) for "osteoarthritis and tendinitis in particular, that of the knee and elbow or other joints that are amenable to topical treatment". The treating physician did not discuss the failure of standard oral medications, including antidepressants and anticonvulsants. Therefore, the request for Capsaicin 0.025%-Flurbi (NAP) cream-LA is not medically necessary.

Gabacyclotram 180 mg cream (retrospective - dispensed 3/26/15): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Opioids Page(s): 111-113; 74-96.

Decision rationale: The requested medication is Gabacyclotram cream, is noted in the medical records as Gabapentin 10%-Cyclobenzaprine 6%-Tramadol 10%. The California Medical Treatment Utilization Schedule (CMTUS) guidelines primarily recommended topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. In addition, CMTUS does not recommend any compound product that contains at least one drug (or drug class) that is not recommended. The CMTUS does not recommended Gabapentin and Cyclobenzaprine for topical use as there is no peer-reviewed literature to support its use. The

CMTUS recommends Tramadol for oral use in the treatment of neuropathic pain. The treating physician did not discuss the failure of standard oral medications, including antidepressants and anticonvulsants. The injured worker was also prescribed an oral non-steroidal anti-inflammatory medication, which makes the topical non-steroidal anti-inflammatory medication redundant. Therefore, the request for Gabacyclotram cream is not medically necessary.

Medical Food: Gabadone Qty 60 (retrospective - dispensed 3/26/15): 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): Medical food; Gabadone.

Decision rationale: The California Medical Treatment Utilization Schedule (CMTUS) guidelines are silent with regard to Theramine. According to the Official Disability Guidelines (ODG), medical food is not recommended for chronic pain treatment, as they have not demonstrated meaningful benefits or improvements in functional outcomes. Medical food is defined as "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." Per the ODG, Gabadone is a medical food that is not recommended for the treatment of sleep disorders. Gabadone is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. Gabadone contains choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. There was lack of documentation of the injured worker having difficulty sleeping. Therefore, the requested Gabadone is not medically necessary.

Theramine Qty 180 (retrospective - dispensed 3/26/15): 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): Medical food; Theramine.

Decision rationale: The California Medical Treatment Utilization Schedule (CMTUS) guidelines are silent with regard to Theramine. According to the Official Disability Guidelines (ODG), medical food is not recommended for chronic pain treatment, as they have not demonstrated meaningful benefits or improvements in functional outcomes. Medical food is defined as "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." Per the ODG, Theramine is a medical food that is not recommended for the treatment of chronic pain. Theramine is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Theramine contains 5-hydroxytrytophan 95%, choline bitartrate, L- arginine, histidine, L-glutamine, L-serine,

gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). There was lack of documentation of the product as a food for oral or tube feeding, that it was labeled for dietary management of a specific medical disorder, disease, or condition for which distinctive nutritional requirements, and that it is used under medical supervision. Therefore, the requested Theramine is not medically necessary.