

Case Number:	CM15-0169619		
Date Assigned:	09/14/2015	Date of Injury:	07/26/2002
Decision Date:	10/29/2015	UR Denial Date:	08/28/2015
Priority:	Standard	Application Received:	08/28/2015

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, Pain Management

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This 66 year old female sustained an industrial injury on 7-26-02. Documentation indicated that the injured worker was receiving treatment for cervical spine sprain and strain, lumbar spine sprain and strain and elevated blood pressure. Documentation indicated that recent treatment consisted of medication management. In a PR-2 dated 6-8-15, the injured worker complained of constant neck pain with radiation to the right upper extremity, rated 9 out of 10 on the visual analog scale and 10 out of 10 low back pain with radiation to the lower extremity associated with numbness and tingling. Physical exam was remarkable for cervical range of motion: flexion 40 degrees, extension 40 degrees, bilateral lateral flexion 25 degrees and bilateral rotation 60 degrees and tenderness to palpation along bilateral trapezius muscles. Lumbar spine range of motion had flexion 25 degrees, extension 0 degrees and bilateral lateral flexion 5 degrees and tenderness to palpation along the lumbar spine with positive bilateral straight leg raise. The treatment plan included requesting authorization for Cardio-respiratory testing - autonomic function assessment, pulmonary function testing and medications (Terocin, Gabacyclotram, Genicin, Somnicin, Cyclobenzaprine, Ibuprofen and Sentra AM. In a PR-2 dated 7-8-15, the injured worker complained of constant neck pain with radiation to the right upper extremity, rated 9 out of 10 on the visual analog scale and 10 out of 10 low back pain with radiation to the lower extremity associated with numbness and tingling. Physical exam was remarkable for cervical range of motion: flexion 35 degrees, extension 0 degrees, bilateral lateral flexion 5 degrees, bilateral rotation 60 degrees and lumbar spine range of motion: flexion 20 degrees, extension 0 degrees, bilateral lateral flexion 5 degrees and tenderness to palpation along the

lumbar spine and paraspinal musculature bilaterally with spasms and bilateral straight leg raise. The treatment plan included medications Cyclobenzaprine, Ibuprofen, Terocin, Gabacycltram, Genicin, Somnicin, Theramine, Sentra PM, Sentra AM and Gabadone. On 8-28-15, Utilization Review noncertified a request for of Ketoprofen 10% Gabapentin 6% Bupivacaine 5% Fluticasone 1% Baclofen 2% Cyclobenzaprine 2% Clonidine 0.2% Hyaluronic acid 0.2%, Theramine #180, Sentra AM #60, Sentra PM #60, GABAdone #60, Alpha lipoid 125mg, Folic acid .5mg, Hyaluronic acid-methylcobalamin 0.5mg, Pyridoxal-5 phosphate 35mg, Reservatrol 25mg, Ubquinol 50mg, Vitamin D3 500IU and Pentoxifyline 5%- Aminophylline 3%- Lidocaine 2.5%- Hyaluronic acid 1% 240gm.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 prescription of Ketoprofen 10% Gabapentin 6% Bupivacaine 5% Fluticasone 1% Baclofen 2% Cyclobenzaprine 2% Clonidine 0.2% Hyaluronic acid 0.2%: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: This topical compound consists in part of topical cyclobenzaprine. Regarding the request for topical cyclobenzaprine, CA MTUS states that topical muscle relaxants are not recommended, as there is no peer-reviewed literature to support the use of topical baclofen or any other muscle relaxant as a topical product. Similarly, the gabapentin component is not recommended by the CPMTG. Furthermore, the same guidelines specify that if one component of a compounded medication is not recommended, then the entire formulation is not recommended. Given these guidelines, this request is not medically necessary.

1 prescription of Theramine #180: Upheld

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

Decision rationale: Regarding the request for Theramine, California MTUS and ACOEM Guidelines do not contain criteria for the use of medical foods. ODG states that Theramine is not recommended. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. As such, the currently requested Theramine is not medically necessary.

1 prescription of Sentra AM #60: Upheld

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

Decision rationale: Regarding the request for Sentra AM, California MTUS does not address the issue. Per ODG, "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." Additionally, "Glutamic Acid" is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine. Within the documentation available for review, there is no documentation of a condition for which the components of Sentra AM would be supported. In the absence of such documentation, the currently requested Sentra AM is not medically necessary.

1 prescription of Senta PM #60: Upheld

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

Decision rationale: Regarding the request for Sentra PM, California MTUS does not address the issue. Per ODG, "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." Additionally, "Glutamic Acid" is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine. Within the documentation available for review, there is no documentation of a condition for which the components of Sentra PM would be supported. In the absence of such documentation, the currently requested Sentra PM is not medically necessary.

1 prescription of GABAdone #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) GABAdone (2015).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter, Medical Food.

Decision rationale: Regarding the request for GABAdone, the California MTUS and ACOEM guidelines do not contain criteria for the use of medical foods. The Official Disability Guidelines state that medical foods are recommended for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. Medical foods are not recommended for chronic pain by any evidence-based guidelines. Within the documentation available for review, the requesting physician has not indicated that this patient has any specific nutritional deficits. Additionally, there are no diagnoses, conditions, or medical disorders for which distinctive nutritional requirements are present. In the absence of such documentation, the currently requested GABAdone is not medically necessary.

1 prescription of Alpha lipoid acid 125mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Glenview (IL) : Wound , Ostomy, and Continence Nurses Society (WOCN); 2004. 57p (WOCN clinical practice guideline; no. 3).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation WebMD, Alpha Lipoid Acid Guo Y et al. Oral alpha-lipoic acid to prevent chemotherapy-induced peripheral neuropathy: a randomized, double-blind, placebo-controlled trial. Support Care Cancer. 2014 May;22(5):1223-31. Epub 2013 Dec 22.

Decision rationale: Alpha-lipoic acid is an anti-oxidant which has been suggested for the treatment of peripheral neuropathies, including diabetic and chemotherapy induced neuropathy. It is not addressed in the CA MTUS, ACOEM, or ODG. Alternate guidelines from WebMD and a scholar article are cited. Per WebMD, alpha-lipoic acid is "used for diabetes and nerve-related symptoms of diabetes including burning, pain, and numbness in the legs and arms. High doses of alpha-lipoic acid are approved in Germany for the treatment of these symptoms. Some people use alpha-lipoic acid for memory loss, chronic fatigue syndrome (CFS), HIV/AIDS, cancer, liver disease, diseases of the heart and blood vessels (including a disorder called cardiac autonomic neuropathy) and Lyme disease." An article by Guo Y et al failed to demonstrate any significant differences in an alpha lipoic acid treated group versus a control group in a small population of patients with chemotherapy-induced neuropathy. Given the paucity of evidence to support this medical supplement, this request is not medically necessary.

1 prescription of Folic acid .5mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) B vitamins & vitamin B complex (2015).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UptoDate Online, Folic Acid.

Decision rationale: Folic acid is a dietary supplement that is not specifically addressed by the CA MTUS, ACOEM, or ODG. Instead, UptoDate Online, an evidenced based database, is referenced. This website states that the indications for folic acid include anemia, for which the recommended dosage is 0.4 mg/day. It is also recommended for pregnant and lactating women at 0.8 mg/day. It has been linked to reduce the frequency of neural tube defects in pregnant mothers. Within the documentation submitted for review, it is unclear why folate is medically necessary, as the worker does not have any of these conditions above caused by the industrial injury. There is no documentation of folate deficiency. Given this, this request is not medically necessary.

1 prescription of Pyridoxal -5- phosphate 35mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) B vitamins & vitamin B complex (2015).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Uptodate Online, Pyridoxine.

Decision rationale: Regarding the request for pyridoxal 5 phosphate (also known as vitamin B6 or pyridoxine), the California MTUS, ODG, and ACOEM guidelines do not contain criteria for this. The alternative reference of Uptodate Online, an evidenced-based database, is cited. Uptodate Online specifies that this vitamin has a recommended daily allowance (RDA) that varies by gender and age. It can be utilized off-label in the following conditions: Dietary deficiency, Gyromitrin-containing mushroom (false morel) overdose/toxicity (treatment/prophylaxis), Nausea and vomiting of pregnancy (off-label use), and Neurological toxicities (ie, seizures, coma) associated with isoniazid overdose (prevention). Within the documentation available for review, the requesting physician has not indicated that this patient has any specific nutritional deficits or pyridoxine deficiency. Additionally, there are no diagnoses which warrant off-label use (such as INH toxicity), are present. Given this, the current request is not medically necessary.

1 prescription of Hyaluronic acid-methylcobalamin (B12) 0.5mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. CharFormat Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) B vitamins & vitamin B complex (2015).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain Chapter, Vitamin B.

Decision rationale: The methylcobalamin component of this combination is a B vitamin. Regarding the request for Vitamin B, the California MTUS guidelines do not contain criteria for its use. The ODG state that vitamin B is not recommended. They go on to state that when comparing vitamin B with placebo, there is no significant short-term benefit in pain intensity. The medical indication for this injection is when there is documentation of B12 deficiency on laboratory results, and there are symptoms of this present. There were no low B12 serum levels noted in the submitted records. As such, the current request is not medically necessary.

1 prescription of Resveratrol 25mg: 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 WebMD, Resveratrol.

Decision rationale: Regarding the request for resveratrol, the CA MTUS, ACOEM, and ODG do not address this. Instead, WebMD Online is cited, which states that this supplement "is a member of a group of plant compounds called polyphenols. These compounds are thought to have antioxidant properties, protecting the body against the kind of damage linked to increased risk for conditions such as cancer and heart disease. Resveratrol is found in the skin of red grapes, but other sources include peanuts and berries. Because resveratrol is thought to have so many health benefits, it is not surprising that a number of manufacturers have tried to capitalize by selling resveratrol supplements. Most resveratrol capsules sold in the U.S. contain extracts from the Japanese and Chinese knotweed plant *Polygonum cuspidatum*. Other resveratrol supplements are made from red wine or red grape extracts." Within the documentation available for review, it is not clear why this patient is being prescribed this medication. Furthermore, this supplement is not tied in with any industrially related injury in this case. Given this, this request is not medically necessary.

1 prescription of Ubiquinol (Co Q10) 50mg: 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 Uptodate Online, Coenzyme Q10.

Decision rationale: Regarding the request for coenzyme Q10 (aka ubiquinol), the CA MTUS, ACOEM, and ODG do not address this. Instead, Uptodate Online is cited, which states that this supplement is not recommended for statin myopathy. It does not appear that "administering Coenzyme Q10 (CoQ10) to try to improve or prevent statin-associated muscle events" is warranted given the lack of evidence. While "CoQ10 depletion may play a role in statin

myopathy... there is little published evidence showing benefit of CoQ10 for the treatment of myopathy." Within the documentation available for review, it is not clear why this patient is being prescribed this supplement. Furthermore, this supplement is not tied in with any industrially related injury in this case. Given this, this request is not medically necessary.

1 prescription of Vitamin D3 500 IU: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Vitamin D (cholecalciferol) (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 Chapter, Vitamin D (cholecalciferol).

Decision rationale: Regarding the request for Vitamin D3, the CA MTUS and ACOEM do not address this issue. The Official Disability Guidelines (ODG) state that, if necessary, vitamin D supplementation is recommended for consideration in chronic pain patients, but these same guidelines also note that Vitamin D deficiency is not considered a workers' compensation condition. Inadequate vitamin D may represent an under-recognized source of nociception and impaired neuromuscular functioning among patients with chronic pain. Physicians who care for patients with chronic, diffuse pain that seems musculoskeletal - and involves many areas of tenderness to palpation - should consider checking vitamin D level. For example, many patients who have been labeled with fibromyalgia may be suffering from symptomatic vitamin D inadequacy. There is also a correlation between inadequate vitamin D levels and the amount of narcotic medication taken by chronic pain patients. Within the documentation available for review, there is no indication of vitamin D deficiency noted by serum testing. Furthermore, even if such were the case, Vitamin D deficiency is not considered a workers' compensation condition. Given this, the current requested is not medically necessary.

1 prescription of Pentoxifyline 5%- Aminophylline 3%- Lidocaine 2.5%- Hyaluronic acid 1% 240gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: This compounded topical formulation contains lidocaine as one of its components. Regarding request for topical lidocaine, Chronic Pain Medical Treatment Guidelines recommend the use of topical lidocaine for localized peripheral pain after there has been evidence of a trial of the first line therapy such as tricyclic antidepressants, SNRIs, or antiepileptic drugs. Guidelines further stipulate that no commercially approved topical formulations of lidocaine cream, lotion, or gel are indicated for neuropathic pain. The CPMTG states that if one drug or drug class of compounded formulation is not recommended, then the entire formulation is not recommended. Given this guideline recommendation, the currently requested topical formulation which contains lidocaine is not medically necessary.