

Case Number:	CM14-0021718		
Date Assigned:	05/05/2014	Date of Injury:	02/21/2013
Decision Date:	07/23/2014	UR Denial Date:	01/29/2014
Priority:	Standard	Application Received:	02/20/2014

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 Physical Medicine and Rehabilitation, 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 injured worker is a 24-year-old female with a date of injury of 2/21/13. The mechanism of injury occurred when she had gone to the supermarket to purchase some supplies for the program and suddenly felt a sharp pain in her right ankle and foot. Her diagnoses include unspecified adjustment disorder and complex regional pain syndrome to the right lower extremity. Her previous treatments include physical therapy, a lumbar paravertebral sympathetic blockade, crutches, and medications. The progress note dated 11/26/13 reported that the injured worker complained of constant right ankle pain located in the lateral ankle that radiated to the calf and foot associated with popping, clicking, locking, giving way, weakness, swelling; it also turns purple with limited motion. The injured worker indicated the character of the pain was sharp, burning, and tingling and indicated the pain level at its best was 6/10 and the worst was 10/10; pain was relieved by heat and wearing her boot. The injured worker reported constant right foot pain located in the plantar region of the foot with no pain radiation. An MRI of the right foot/ankle was performed on 4/29/13; the impression was a normal MRI of the ankle and foot. A [REDACTED] Biosciences Narcotic Risk lab test was performed on 11/18/13; the results were noted to be genetic variations that may place the injured work at greater risk for substance dependence and/or tolerance, including centrally active prescription medications. The injured worker's medications include Tylenol No. 3, Norco, Terocin 240 mL, flurbi (NAP), gabacyclotram, Genicin, Somnicin, Theramine, Sentra a.m., Sentra p.m., and GABAdone.

IMR ISSUES, DECISIONS AND RATIONALES

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

MAGNETIC RESONANCE IMAGE OF RIGHT FOOT/ANKLE WITHOUT CONTRAS:
Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 14 Ankle and Foot Complaints Page(s): 372-374.

Decision rationale: The injured worker had a normal MRI of the right foot/ankle without contrast in April 2013. The California ACOEM guidelines state that disorders of soft tissue (such as tendinitis, metatarsalgia, fasciitis, and neuroma) yield negative radiographs and do not warrant other studies such as MRIs. The California ACOEM states that MRI may be helpful to clarify diagnoses such as osteochondritis dissecans in cases of delayed recovery. There is a lack of clinical findings that show a significant clinical change in pathology to warrant a repeat MRI. As such, the request is not medically necessary.

1 [REDACTED] BIOSCIENCES NARCOTIC RISK LAB TEST: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

Decision rationale: The injured worker had a [REDACTED] Biosciences Narcotic Risk lab test in November 2013. The Official Disability Guidelines do not recommend genetic testing for opioid abuse. The guidelines state that while there appears to be a strong genetic component to addictive behavior, current research is experimental in terms of testing for this. The guidelines state studies are inconsistent and inadequate statistics enlarge phenotype range. Additionally, there is a lack of evidence of aberrant drug-taking behavior to warrant this test. As such, the request is not medically necessary.

THERAMINE #90: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

Decision rationale: The injured worker was prescribed Theramine in November 2013. The Official Disability Guidelines do not recommend Theramine. The guidelines state that Theramine is a proprietary blend of gamma-aminobutyric acid, choline bitartrate, l-arginine, and l-serine. It is intended for the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The guidelines state that gamma-

aminobutyric acid does not have a high quality peer reviewed literature to suggest that it is indicated, choline has no known medical need for choline supplementation, l-arginine is not indicated in the current references for pain or inflammation, and l-serine does not have an indication. According to the guidelines, in the manufacturer's study comparing Theramine to naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. However, until there are higher quality studies of the ingredients in Theramine, it remains non-recommended. As such, the request is not medically necessary.

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.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

Decision rationale: The Sentra AM ingredients are l-Glutamic acid, choline bitartrate, cocoa extract, acetyl l-chronatine, hawthorn berry, ginkgo biloba, and dextrose. According to the Official Disability Guidelines, to be considered the product must meet the following criteria: the product must be a food for oral or tube feeding; the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be used under medical supervision. The Official Disability Guidelines state Glutamic acid is used to treat hypochlorhydria and achlorhydria, and is generally used for digestive disorders in complementary medicine. The guidelines state there is no known medical need for choline supplementation except in the case of long term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Cocoa extract, l-chronatine, hawthorn berry, ginkgo biloba, and dextrose are not listed in the guidelines for recommendation. Therefore, the guidelines do not recommend Sentra AM for use, and the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.

SENTRA 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.

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

Decision rationale: The Sentra PM ingredients are listed as choline bitartrate, glutamine, and 5-hydroxytryptophan. The guidelines state that Sentra PM is a medical food intended for use in management of sleep disorders associated with depression. The guidelines state that choline has no known medical need except for the case of long term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. The guidelines also state that 5-hydroxytryptophan is found to be possible effective in treatment of anxiety disorders,

fibromyalgia, obesity, sleep disorders, and possibly depression. The guidelines also state that Glutamic acid is a supplement used to treat hypochlorhydria and achlorhydria for impaired intestinal permeability, short bowel syndrome, cancer, or critical illness, and is generally used for digestive disorders in complementary medicine. The documentation provided did not show clinical findings in of insomnia or depression consistent with the Sentra PM supplementation. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.

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.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

Decision rationale: GABAdone consists of choline bitartrate, Glutamic acid, 5-hydroxytryptophan, and GABA. It is intended to meet nutritional requirements for reducing sleep, promoting restorative sleep, and reducing snoring in injured workers who are experiencing anxiety-related sleep disorders. The Guidelines state that 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. The guidelines also state that Glutamic acid is a supplement used to treat hypochlorhydria and achlorhydria, which is a treatment indicated for those with impaired intestinal permeability, short bowel syndrome, cancer, and critical illness and it is generally used for digestive disorders in complementary medicine. The guidelines state that 5-hydroxytryptophan is found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. It has also been found to be effective for depression. The guidelines state gamma-aminobutyric acid is a supplement indicated for epilepsy, spasticity, and tardive dyskinesia. There is no high quality peer reviewed literature that suggests that GABA is indicated for the treatment of insomnia. There is a lack of clinical findings regarding insomnia or anxiety-related sleep disorders to warrant this medication. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.

GENICIN #90 CAPSULES :GLUCOSAMINE SODIUM 500 MG AS DIRECTED: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50.

Decision rationale: The injured worker was prescribed this medication in November 2013. The Chronic Pain Medical Treatment Guidelines recommend glucosamine as an option given its low risk in injured workers with moderate arthritis pain, especially for knee arthritis. The guidelines state that studies have demonstrated highly significant efficacy for crystalline glucosamine

sulfate on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride. There is a lack of clinical findings to diagnose the injured worker with osteoarthritis. Therefore, the injured worker does not have a diagnosis to warrant this medication. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.

SOMNICIN #30 CAPSULES: MELATONIN 2MG-5HTP 50 MGTRYPTOPHAN 100 MG-PYRIDOXINE10 MG -MAGNESIUM 50 MG AS DIRECTED: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation napharm.com, and dailymed.nlm.nih.gov.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

Decision rationale: The injured worker was prescribed this medication in November 2013. The Official Disability Guidelines state that 5-hydroxytryptophan is a supplement to be found effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. It has also been found to be effective for depression. The Guidelines state it is an alternative medicine used for depression, anxiety, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches, and various pain disorders. The guidelines recommend melatonin to treat insomnia. The repeated administration of melatonin improves sleep and thereupon reduced anxiety, which leads to lower levels of pain. The documentation provided lacks clinical findings regarding insomnia or depression to warrant this medication. The guidelines do not address tryptophan, pyridoxine, or magnesium. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.

TEROCIN 240 MLS: CAPSAICIN 0.025%-METHYL SALICILATE 25%-MENTHOL 10%-LIDOCAINE2.5%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-114.

Decision rationale: The injured worker was prescribed this medication in November 2013. The California Chronic Pain Medical Treatment Guidelines state that double analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. The guidelines also state they are primarily recommended for neuropathic pain or when trials of antidepressants or anticonvulsants have failed. The guidelines state there is little to no research to support the use of any of these agents. Any compound or product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines state that lidocaine is recommended for neuropathic pain. The guidelines also state that topical lidocaine, in formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for

neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. The guidelines also state that no other commercially-approved formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. The guidelines recommend capsaicin only as an option in injured workers who have not responded or are intolerant to other treatments. Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily for postherpetic neuralgia, diabetic neuropathy, and post-mastectomy pain). There are positive randomized studies with capsaicin cream in injured workers with osteoarthritis, fibromyalgia, and chronic nonspecific back pain. Lidocaine is not recommended in a topical formulation other than the Lidoderm patch, and according to the guidelines any drug (or drug class) that is not recommended is not recommended in a compounded agent. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.

FLURBI(NAP) CREAM LA 180 GRAMS: FLUBIPROFEN 20%-LIDOCAINE 5%-AMITRIPTYLINE4%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-114.

Decision rationale: The injured worker was prescribed this medication in November 2013. The California Chronic Pain Medical Treatment Guidelines recommend topical analgesics primarily for neuropathic when trials of antidepressants and anticonvulsants have failed. The guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines state there is little to no research for the use for many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines state that lidocaine is indicated for neuropathic pain, but not non-neuropathic pain. The guidelines state topical lidocaine, in the form of dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. The guidelines also state that no other commercially-approved formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. The guidelines state that NSAID efficacy in clinical trials for topical analgesics have been inconsistent and most studies are small and of short duration. The Guidelines state that topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first two weeks of treatment for osteoarthritis, but not afterward, or with diminishing effect over another two week period. The Guidelines state topical analgesics are indicated for osteoarthritis or tendonitis particularly of the knee or elbow or other joints that are amenable to topical treatment. It is not recommended for topical use for neuropathic pain. The guidelines also state there is no use for a muscle relaxant as a topical product. Therefore, as lidocaine and amitriptyline are not recommended by the guidelines, and the guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.

GABACYCLOTRAM 180 GRAMS: GABAPANTIN10%-CYCLOBENZAPRINE 6%-TRAMADOL 10%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-114.

Decision rationale: The injured worker was prescribed this medication in November 2013. The California Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines also are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines state there is little to no research for the use for many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines do not recommend gabapentin as there is no peer reviewed research to support the use. The guidelines also state there is no evidence for use of muscle relaxants as a topical product. The guidelines state any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended and gabapentin and Cyclobenzaprine are not recommended. Additionally, the request failed to provide the frequency at which this medication is to be utilized. As such, the request is not medically necessary.