MAXIMUS Federal Services

Case Number:	CM13-0051721		
Date Assigned:	12/27/2013	Date of Injury:	05/13/2010
Decision Date:	06/04/2014	UR Denial Date:	10/30/2013
Priority:	Standard	Application Received:	11/14/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician 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 physician 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 47 year old female who reported a work-related injury on 11/4/10. The mechanism of injury was related to repetitive activities in the workplace. Per the clinical note dated 7/25/13, the injured worker had an EMG of the lower extremities that was normal and an NCV of the lower extremities that was also normal. Per the clinical note dated 8/6/13, the injured worker received two epidural steroid injections on 7/26/13, at L4-L5 and L5-S1. The injured worker also had a myelogram of the spine at that time. Per the x-ray dated 7/31/13, the injured worker had an anterior fusion of C5-C7 that was intact with no compression fractures, and intact spinous processes. Diagnoses included lumbosacral radiculitis, displacement of lumbar intervertebral disc without myelopathy, lumbosacral spondylosis, and spinal stenosis of the lumbar region.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin lotion, 240gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-112.

Decision rationale: The California MTUS guidelines state that topical NSAIDs are recommended for the short-term treatment of osteoarthritis and tendinitis affecting joints that are amenable to topical treatment; however, this does not include the spine, shoulders, or hips. Capsaicin, an ingredient in Terocin, is recommended only as an option in patients who have not responded or are intolerant to other treatments. Lidocaine, another ingredient in Terocin lotion, is not indicated for neuropathic pain in any form other than the Lidoderm patch. The MTUS guidelines state that any compounded product that contains at least one drug or drug class that is not recommended is not recommended. As such, the request is not medically necessary.

Gaba 10%/Cyclo 6%/Tram 10%, 180gm: Upheld

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

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

Decision rationale: Per the California MTUS guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety, and any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Gabapentin is not recommended as a topical. There is also no evidence for use of Cyclobenzaprine, or any other muscle relaxant, as a topical product. As such, the request is not medically necessary.

Flurbiprofen (NAP) cream-LA, 180gm: 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.

Decision rationale: Per the California MTUS guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety, and any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first two weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another two-week period. The use of Flurbiprofen, an NSAID, would not be recommended for topical application, then. As such, the request is not medically necessary.

90 Genicin 500mg: 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 based on Non-MTUS Citation National Institutes of Health.

Decision rationale: Per the California MTUS guidelines, Glucosamine is recommended as an option for patients with moderate arthritis pain, especially for knee osteoarthritis. However, the Glucosamine Chondroitin Arthritis Intervention Trial (GAIT) funded by the National Institutes of Health concluded that glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing non-arthritic knee pain. There is a lack of documentation in the medical reacords provided for review stating that the injured worker's pain is related to arthritis. Therefore the request is not medically necessary.

30 Somnicin capsules: 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, RxList, National Institutes of Health, Office of Dietary Supplements, and the U.S. Department of Health and Human Services.

Decision rationale: The requested medication is a compound containing Melatonin, 5-HTP, L-tryptophan, pyridoxine, and magnesium. Melatonin plays an important role in sleep regulation, and disruption of melatonin production has been linked to sleep disorders, including sleep apnea, insomnia, and delayed sleep phase syndrome, which are in turn linked to headache. Melatonin (N-acetyl-5-methoxytryptamine) is a neurohormone that is primarily produced by the pineal gland, located behind the third ventricle in the brain. In the synthesis of melatonin, tryptophan is hydroxylated to 5-hydroxytryptophan, which in turn is decarboxylated to 5-hydroxytryptamine (serotonin). Serotonin is converted to the melatonin precursor and metabolite Nacetylserotonin by the enzyme N-acetyl transferase. N-Nacetylserotonin is methylated via the enzyme hydroxyindole-o-methyltransferase to produce melatonin. 5-HTP works by increasing the production of the chemical serotonin. Serotonin can affect sleep, appetite, temperature, sexual behavior, and pain sensation. There is insufficient evidence to rate the effectiveness for L-tryptophan for depression, anxiety, seasonal affective disorder, attention deficit-hyperactivity disorder (ADHD), sleep disorders, and/or other conditions. Pyridoxine (vitamin B6) in coenzyme forms performs a wide variety of functions in the body and is extremely versatile, with involvement in more than 100 enzyme reactions, mostly concerned with protein metabolism. Magnesium is required for energy production, oxidative phosphorylation, and glycolysis. It contributes to the structural development of bone and is required for the synthesis of DNA, RNA, and the antioxidant glutathione. Magnesium also plays a role in the active transport of calcium and potassium ions across cell membranes, a process that is important to nerve impulse conduction, muscle contraction, and normal heart rhythm. The medical records provided for review show that this compounded medication was requested to treat insomnia and anxiety, and to relax muscles. Per clinical research, only two of the ingredients in this compound are effective for insomnia; none are effective as muscle relaxants. MTUS guidelines state that any if any

ingredient in a compounded medication is not recommended, the entire compound must not be recommended. As such, the request is not medically necessary.