MAXIMUS Federal Services

Case Number:	CM15-0060652		
Date Assigned:	04/06/2015	Date of Injury:	06/09/2011
Decision Date:	06/30/2015	UR Denial Date:	03/13/2015
Priority:	Standard	Application Received:	03/30/2015

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: Texas, California
Certification(s)/Specialty: Family Practice

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 is a 60 year old male patient, who sustained an industrial injury on June 9, 2011. He reported lifting a large TV with his right arm, when it slipped, and he felt a pop at the left shoulder followed by increased pain. The diagnosis includes status post left shoulder surgery August 15, 2013. Per the doctor's note dated 2/13/2015, he had complaints of left shoulder pain and neck pain with radiation to the left upper extremity. The physical examination revealed tenderness, spasm and decreased range of motion of the cervical spine; left shoulder- surgical scar, positive impingement test and trigger point over the left trapezius muscles. Per the note dated 2/17/2015, patient is status post left shoulder steroid injection and still having pain and stiffness. Per the note dated December 10, 2014, he reported his pain at 8/10, with pain level without medication was 9/10, and with medication it decreased to 4-5/10. Physical examination was noted to show tenderness to palpation along the subacromial region over the left shoulder and along the trapezius muscles over the left shoulder with spasms. The medications list includes norco, tramadol and omeprazole. He has undergone left shoulder surgery on 8/15/2013. He has had X-rays and MRI of left shoulder. He has had physical therapy, chiropractic treatments, home exercise program (HEP), and medication. He has had urine drug screen on 11/17/2014, 9/18/2014. The treatment plan was noted to include prescriptions for Percocet, Tramadol, Genicin, and Somnicin, with the addition of compounded topical medications, a urine drug screen (UDS), and recommendation for a six month trial of a TENS unit.

IMR ISSUES, DECISIONS AND RATIONALES

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

Somnicin #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Treatment in Workers Compensation, Online Edition; Chapter: Pain (Chronic) 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) Chapter: Pain (updated 06/15/15) Somnicin Medical foods.

Decision rationale: Per ODG guidelines, regarding Somnicin "Not recommended. Somnicin, a nutritional supplement, contains melatonin, magnesium oxide, oxitriptan (the L form of 5-hydroxytryptophan), 5-hydroxytryptophan, tryptophan and Vitamin B6 (pyridoxine). It is postulated as a treatment for insomnia, anxiety and depression. Melatonin appears to reduce sleep onset latency and is used for delayed sleep phase syndrome. This is considered a circadian abnormality. It is also used to treat rapid eye movement sleep disorders. It is not a hypnotic and treatment for chronic insomnia is inconclusive. It is available over-the-counter. See Melatonin. Magnesium oxide uses for which there is evidence favoring efficacy, include the following: (1) as a treatment for magnesium deficiency; (2) as a treatment for upset stomach and acid indigestion. There is no indication for magnesium oxide as a treatment for sleep disorders of any kind. (Micromedex, 2015) (Lexi Comp, 2015) (Clinical Pharmacology, 2015) For oxitriptan and 5-hydroxytriptophan, see Medical foods. Inconclusive evidence has been found for treatment for anxiety. There is some suggestion that 5-hydroxytryptophan can be used for treatment of depression, but at this point, this is only recommended for patients who are unable to take conventional antidepressants. With respect to Vitamin B 6 (pyridoxine), this vitamin 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. There is no indication for treatment for any sleep disorder. (Micromedex, 2015) (Lexi Comp, 2015) (Clinical Pharmacology, 2015) This can be purchased over-the-counter." Therefore these products still have limited scientific evidence for efficacy and safety profile for the management of pain. ACOEM and CA MTUS do not address these medications. The contents of these medical food products are not recommended by ODG. One of the contents of this nutritional supplement/ medical food is pyridoxine/ vitamin B6. Evidence of vitamin B6 deficiency in this patient is not specified in the records provided. According to the ODG guidelines, Medical food is "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." ODG quoting the FDA specifically states "To be considered the product must, at a minimum, meet the following criteria: (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements." The response to other pharmacological measures for treatment of pain, anxiety or insomnia is not specified in the records provided. There is no documented medical efficacy or benefit for these combinations or these doses when added to conventional medications. Therefore, there is no medical necessity for any medication containing

these food supplements. These products still have limited scientific evidence for efficacy and safety profile for the management of pain. Somnicin #30 is not medically necessary at this time.

Percocet 10/325mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CRITERIA FOR USE OF OPIOIDS Page(s): 76-80.

Decision rationale: This is a request for Percocet, which is an opioid analgesic. It contains acetaminophen and oxycodone. According to the cited guidelines, "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." The records provided do not specify that that patient has set goals regarding the use of opioid analgesic. The treatment failure with non-opioid analgesics is not specified in the records provided. Other criteria for ongoing management of opioids are: "The lowest possible dose should be prescribed to improve pain and function. Continuing review of overall situation with regard to non-opioid means of pain control. Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects...Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs." The records provided do not provide a documentation of response in regard to pain control and objective functional improvement to opioid analgesic for this patient. The continued review of the overall situation with regard to non-opioid means of pain control is not documented in the records provided. As recommended by the cited guidelines a documentation of pain relief, functional status, appropriate medication use, and side effects should be maintained for ongoing management of opioid analgesic, these are not specified in the records provided. This patient did not meet criteria for ongoing continued use of opioids analgesic. Percocet 10/325mg #90 is not medically necessary for this patient.

Tramadol 50mg #90: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page 75, Central acting analgesics Page 82, Opioids for neuropathic pain.

Decision rationale: Tramadol is a centrally acting synthetic opioid analgesic. According to MTUS guidelines "Central acting analgesics: an emerging fourth class of opiate analgesic that may be used to treat chronic pain. This small class of synthetic opioids (e.g., Tramadol) exhibits opioid activity and a mechanism of action that inhibits the reuptake of serotonin and nor epinephrine. Central analgesics drugs such as Tramadol (Ultram) are reported to be effective in managing neuropathic pain. (Kumar, 2003)" Cited guidelines also state that, "A recent consensus guideline stated that opioids could be considered first-line therapy for the following

circumstances: (1) prompt pain relief while titrating a first-line drug; (2) treatment of episodic exacerbations of severe pain; [&] (3) treatment of neuropathic cancer pain."Tramadol use is recommended for treatment of episodic exacerbations of severe pain." Per the records provided he had chronic neck and left shoulder pain with history of left shoulder surgery. He has had significant findings on physical examination; tenderness, spasm and decreased range of motion of the cervical spine; left shoulder, surgical scar, positive impingement test and trigger point over the left trapezius muscles. There was objective evidence of conditions that can cause chronic pain with episodic exacerbations. The request for Tramadol 50 mg #90 is medically appropriate and necessary to use as prn during acute exacerbations.

Genicin #90: 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 Glucosamine (and Chondroitin Sulfate) Page(s): 50 of 127.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines MTUS, Glucosamine (and Chondroitin Sulfate) is "Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. 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 knee pain in the study group overall; however, these may be effective in combination for patients with moderate-to-severe knee pain. Despite multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee), controversy on efficacy related to symptomatic improvement continues." Evidence of knee joint pain or arthritis is not specified in the records provided. An X-ray report demonstrating osteoarthritis is not specified in the records provided. Genicin #90 is not medically necessary at this time.