MAXIMUS Federal Services

Case Number:	CM15-0129221		
Date Assigned:	07/22/2015	Date of Injury:	06/30/2014
Decision Date:	09/17/2015	UR Denial Date:	06/12/2015
Priority:	Standard	Application Received:	07/03/2015

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: Arizona, Michigan
Certification(s)/Specialty: Preventive Medicine, Occupational 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 51 year old male, who sustained an industrial injury on June 30, 2014 while working as a truck driver. The injury occurred while the injured worker was securing a load and slipped and fell six feet to the ground. The injured worker sustained injuries to the head, neck, right shoulder and low back. The diagnoses have included headaches, cervical spine sprain-strain, lumbar radiculopathy, lumbar spondylosis, lumbar spinal stenosis, lumbar disc protrusion, right shoulder sprain-strain, anxiety and depression. Treatment and evaluation to date has included medications, radiological studies, MRI, physical therapy, cortisone injections, a transcutaneous electrical nerve stimulation unit, home exercise program and right shoulder surgery on March 9, 2015. The injured worker was noted to be temporarily totally disabled. Current documentation dated May 7, 2015 notes that the injured worker reported occasional headaches and constant neck pain with radiation to the right upper extremity. Associated symptoms included numbness and tingling in the right arm. The injured worker also noted frequent low back pain and constant right shoulder pain rated a seven out of ten on the visual analogue scale. Examination of the cervical and lumbar spine revealed a decreased range of motion. Examination of the right shoulder revealed soreness, status-post surgery and a decreased range of motion. The injured worker also noted severe pain in the medial and lateral epicondyle along the right elbow. The treating physician's plan of care included requests for Terocin 120 ml, Capsaicin 0.025%- Flurbuprofen cream-LA 180 grams, Gabacyclotram 180 mgs, Genicin # 90, Somnicin # 30, Norco 10-325 mg # 30, Theramine # 90, Trepadone # 120 and an orthopedic evaluation for musculoskeletal symptoms.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin 120ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 28-29, 105, and 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesics Page(s): 105, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Compounded Topical Analgesics.

Decision rationale: Regarding the request for Terocin 120 ml (lidocaine/menthol/methyl salicylate) the California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines on topical analgesics, states that topical analgesics are largely experimental in use and are recommended for localized neuropathic pain after there is evidence of a trial of first line therapy, such as tri-cyclic anti-depressants and anti-epileptic medications. Lidocaine in the formulation of a dermal patch (Lidoderm) has been designated for neuropathic pain. Lidocaine in other formulations such as creams, lotions or gels is not recommended. The MTUS guidelines also state that any compounded product with at least one drug, which is not recommended, is not recommended. Salicylate topicals such as Ben-Gay and methyl salicylate are significantly better than a placebo in chronic pain. Salicylate topicals are recommended. The MTUS guidelines do not discuss Menthol therefore; the Official Disability Guidelines were referenced. The Official Disability Guidelines state that custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm. In this case, the injured worker was noted to have chronic neck, low back and right shoulder pain. There is lack of clinical evidence in this case that the injured worker failed a trial of anti-depressant medications and anticonvulsant therapy. The MTUS guidelines state that any compounded product with at least one drug, which is not recommended, is not recommended. Lidocaine in other formulations other than a Lidoderm patch is not recommended. Therefore, the request for Terocin lotion is not medically necessary.

Capsaicin 0.025%, Flurbi (NAP) cream-LA 180gms: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Capsaicin Topical Page(s): 28, 111-113.

Decision rationale: The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines on topical analgesics states that topical analgesics are largely experimental in use and are recommended for localized neuropathic pain after there is evidence of a trial of first line therapy, such as tri-cyclic anti-depressants and anti-epileptic

medications. Any compounded product that contains at least one drug that is not recommended is not recommended. Capsaicin is only recommended in injured workers who have not responded or are intolerant to other treatments. Flurbiprofen is a nonsteroidal anti-inflammatory drug (NSAID). Topical NSAIDS are indicated for osteoarthritis and tendinitis, in particular that of the knee and elbow or other joints that are amenable to topical treatment. Note that topical Flurbiprofen is not FDA approved and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. In this case, the injured worker was noted to have chronic neck, back and shoulder pain. The MTUS guidelines state that any compounded product with at least one drug, which is not recommended, is not recommended. Flurbuprofen is not FDA approved and is not medically necessary. Therefore, the request for Capsaicin 0.025%, Flurbuprofen cream-LA is not medically necessary.

Gabacyclotram 180mgs: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Opioids Page(s): 75, 111-113.

Decision rationale: The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines on topical analgesics, states that topical analgesics are largely experimental in use and are recommended for localized neuropathic pain after there is evidence of a trial of first line therapy, such as tri-cyclic anti-depressants and anti-epileptic medications. The MTUS guidelines recommend topical non-steroidal anti-inflammatory drugs for osteoarthritis and tendonitis of the knee, elbow and other joints amendable to topical non-steroidal anti-inflammatory drugs. It is recommended for short-term use of 4 to 12weeks. There is little evidence to support its use for the treatment of osteoarthritis of the shoulder, hip or spine. The MTUS guidelines also states that any compounded product with at least one drug which is not recommended is not recommended. Cyclobenzaprine is a muscle relaxant. The MTUS guidelines note that there is no evidence for use of muscle relaxants as topical products. Regarding Gabapentin, there is no peer-reviewed literature to supports its use. Tramadol is a central acting analgesic, which may be used to treat chronic pain. Central analgesics drugs such as Tramadol are reported to be effective in managing neuropathic pain. Side effects are similar to traditional opioids. In this case, the injured worker was noted to have chronic neck, low back and right shoulder pain. The MTUS guidelines state that any compounded product with at least one drug, which is not recommended, is not recommended. Cyclobenzaprine and Gabapentin are not recommended in topical form. Therefore, the request for Gabacyclotram is not medically necessary.

Genicin #90 capsules: Upheld

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

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

Decision rationale: The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines recommend Glucosamine as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride. Despite multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee), controversy on efficacy related to symptomatic improvement continues. In this case, the injured worker was noted to have chronic neck, low back and right shoulder pain. Genicin is recommended for arthritis pain, especially in the knee. There is lack of documentation of noted osteoarthritis or knee symptoms in the medical records. Therefore, the request for Glucosamine is not medically necessary.

Somnicin #30 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 (ODG), Pain Chapter, Somnicin.

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), Somnicin.

Decision rationale: The California Medical Treatment Utilization Schedule (MTUS) Guidelines do not address Somnicin. The Official Disability Guidelines do not recommend Somnicin. Somnicin is a nutritional supplement which 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. Somnicin is considered a medical food, which is not recommended for treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. 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. There is evidence that Magnesium oxide use is effective for the treatment of magnesium deficiency and treatment for upset stomach and acid indigestion. There is no indication for magnesium oxide as a treatment for sleep disorders of any kind. 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, and 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. In this case, the injured worker was noted to have chronic neck, low back and right shoulder pain. Somnicin is not recommended for chronic pain. There is lack of documentation of sleep complaints in this injured worker. The request for Somnicin is not medically necessary.

Norco 10/325mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 91.

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

Decision rationale: The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines "discourages long term usage unless there is evidence of ongoing review and documentation of pain relief, functional status and appropriate medication use and side effects. Pain assessment should include: current pain, the least reported pain over the period since last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief and how long the pain relief lasts. Satisfactory response to treatment may be indicated by the injured worker's decreased pain level, increased level of function or improved quality of life." The MTUS guidelines state that "functional improvement" is evidenced by a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment. In this case, the injured worker was noted to have chronic neck, low back and right shoulder pain. There was no documentation of improvement in specific activities of daily living as a result of use of Norco. There was no documentation of decrease in medication use or decrease in frequency of office visits as a result of use of Norco. Due to lack of a detailed pain assessment, lack of documentation of improvement in pain and lack of documentation of functional improvement, the request for Norco is not medically necessary.

Theramine #90 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 (ODG), Pain Chapter, Theramine.

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) Theramine.

Decision rationale: The California Medical Treatment Utilization Schedule (MTUS) Guidelines do not address Theramine. The Official Disability Guidelines does not recommend Theramine for chronic pain. Theramine is a medical food that 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%). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The proposed mechanism of action is that it increases the production of serotonin, nitric oxide, histamine, and gamma-aminobutyric acid by providing these precursors. The entries for 5-hydorxytryptophan, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine and GABA all indicate there is no role for these supplements as treatment for chronic pain. In this case, the injured worker was noted to have chronic neck, low back and right shoulder pain. Per the ODG Theramine is not recommended for chronic pain. Therefore, the request for Theramine is not medically necessary.

Trepadone #120 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 (ODG), Pain Chapter, Trepadone.

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), Trepadone.

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) Guidelines are silent on Treapadone. The Official Disability Guidelines do not recommended Trepadone. Trepadone is a medical food that is suggested for use in the management of joint disorders associated with pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, chondroitin and cocoa. The entries for 5-hydorxytryptophan, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine and GABA all indicate there is no role for these supplements as treatment for chronic pain. Current literature suggests omega-3 fatty acids for treatment of certain cardiovascular and lipid conditions, treatment of rheumatoid arthritis and for selected patients for depression (primarily those who are unable to take conventional antidepressants). There is insufficient evidence to support its use for osteoarthritis or for neuropathic pain. In this case, the injured worker was noted to have chronic neck, low back and right shoulder pain. Per the Official Disability Guidelines, Trepadone is not recommended for chronic pain. Therefore, the request for Trepadone is not medically necessary.

Orthopedic evaluation for musculoskeletal symptoms: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM Occupational Medicine Practice Guidelines, 2nd Edition, 2004, page 127.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 305.

Decision rationale: Per MTUS/ACOEM, referral for surgical consultation is indicated for patients who have: Severe and disabling lower leg symptoms in a distribution consistent with abnormalities on imaging studies (radiculopathy), preferably with accompanying objective signs of neural compromise, Activity limitations due to radiating leg pain for more than one month or extreme progression of lower leg symptoms, clear clinical, imaging, and electrophysiologic evidence of a lesion that has been shown to benefit in both the short and long term from surgical repair, failure of conservative treatment to resolve disabling radicular symptoms. With or without surgery, more than 80% of patients with apparent surgical indications eventually recover. Although surgery appears to speed short-to mid-term recovery, surgical morbidity (recovery and rehabilitation time and effects) and complications must be considered. Surgery benefits fewer than 40% of patients with questionable physiologic findings. Moreover, surgery increases the need for future surgical procedures with higher complication rates. A review of the injured workers medical records that are available to me do not reveal a clear rationale for this referral and medical necessity for orthopedic evaluation is not established from the information that is garnered, therefore the request for orthopedic evaluation for musculoskeletal symptoms is not medically necessary.