

Case Number:	CM15-0142281		
Date Assigned:	08/03/2015	Date of Injury:	07/01/2014
Decision Date:	09/03/2015	UR Denial Date:	06/25/2015
Priority:	Standard	Application Received:	07/22/2015

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: New York
 Certification(s)/Specialty: Anesthesiology

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 sustained an industrial injury on July 1, 2014. She reported pain in wrists and hands due to repetitive gripping, grasping, and fine hand movements required to perform her job duties. The injured worker was diagnosed as having cervical spine sprain-strain, thoracic spine sprain-strain, bilateral elbow sprain-strain, right triangular fibrocartilage complex (TFCC) tear, and bilateral carpal tunnel syndrome. Treatments and evaluations to date have included electromyography (EMG)-nerve conduction velocity (NCV), MRIs, bracing, splinting, x-rays, Toradol injection, physical therapy, home exercise program (HEP), and medication. Currently, the injured worker reports constant 8 out of 10 neck pain radiating to the left upper extremity with numbness and tingling, mid back pain, and bilateral upper extremity pain. The Primary Treating Physician's report dated May 26, 2015, noted the injured worker was not working, remaining on temporary total disability. Physical examination was noted to show restricted cervical right elbow, and right wrist range of motion (ROM). The treatment plan was noted to include a qualitative drug screen administered prescriptions for Cyclobenzaprine and Norco, compounded medications, and continuation of the home exercise program (HEP).

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective review of Terocin lotion, QTY: 240, DOS: 05/04/2015: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter, Topical analgesics, Salicylate topicals.

Decision rationale: The CA MTUS guidelines note topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed, and that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines note that these medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. The requested compound medication of Terocin patch contains the active ingredients of Lidocaine, Capsaicin, Methyl Salicylate, and Menthol. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain and is also used off-label for diabetic neuropathy. "No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain". The ODG states that Capsaicin is only recommended when other, conventional treatments have failed, and that an alert from the FDA warns that topical over-the-counter (OTC) pain relievers that contain menthol, methyl salicylate, or capsaicin may in rare instances cause serious burns. Any topical agent with Lidocaine is not recommended if it is not Lidoderm, therefore the Lidocaine in the Terocin patches is not recommended making the entire compounded medication not recommended. The treating physician's request did not include the site of application and as such, the prescription is not sufficient. Based on the MTUS guidelines, medical necessity for the requested topical medication was not established. The requested topical analgesic compound was not medically necessary.

Retrospective review of Genicin 500mg Capsule, DOS: 05/04/2015: Upheld

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

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

Decision rationale: According to the ODG, Genicin (glucosamine) is not recommended for the treatment of low back pain. Glucosamine is not significantly different from placebo for reducing pain-related disability or improving health-related quality of life in patients with chronic low back pain (LBP) and degenerative lumbar osteoarthritis, and it should not be recommended for patients with lower back pain. Glucosamine is a precursor molecule involved in building tendons, ligaments, and cartilage. It is hypothesized to restore cartilage and to have anti-inflammatory properties, and, despite conflicting data on its efficacy, has become widely used as a treatment for osteoarthritis. It has also become more widely used for LBP, including degenerative lumbar osteoarthritis. It is recommended as an option for patients with moderate

arthritis pain, especially knee arthritis. The physician prescribed Genicin for the treatment of arthritic pain without documentation of arthritic pain in the subjective or objective findings, nor was arthritis included in the listed diagnoses. The requested prescription did not include directions for use and as such the prescription is not sufficient. Medical necessity for the requested medication was not established. This medication was not medically necessary for the date of service of May 4, 2015.

Retrospective review of Flurb (NAP) Cream LA: Flurbipro pw, Lidocai pw, Amitript, pw, PCCA lipoderm base, QTY: 180, DOS: 05/04/2015: Upheld

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

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

Decision rationale: The CA MTUS guidelines note topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed, and that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines note that these medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. The requested topical compounded medication, Flurbi (NAP) cream, contains: Flurbiprofen, Amitriptyline, and Lidocaine. Flurbiprofen is a non-steroid anti-inflammatory drug (NSAID), indicated for use for osteoarthritis and tendinitis, particularly in the knee, elbow, or other joints that are amenable to topical treatment, not recommended for neuropathic pain nor FDA approved for topical application. Amitriptyline is a tricyclic antidepressant, not FDA approved for topical use. Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain and is also used off-label for diabetic neuropathy, and "no other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain". The treating physician's request did not include the site of application and as such, the prescription is not sufficient. The requested compounded topical analgesic contains drugs which are not recommended for topical use, therefore the entire compound is not recommended. Therefore, based on the guidelines, the request for a retrospective review of Flurbiprofen (NAP) Cream LA for the date of service of May 4, 2015, was not medically necessary.

Retrospective review of Somnicin caps QTY: 30, DOS: 05/04/2015: 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.

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, Somnicin.

Decision rationale: The MTUS is silent on the use of Somnicin. The Official Disability Guidelines (ODG) notes Somnicin is a nutritional supplement containing melatonin, magnesium oxide, oxitriptan, 5-hydroxytryptophan, tryptophan and Vitamin B6 (pyridoxine), and is not recommended. Somnicin as a treatment for chronic insomnia is inconclusive, with inconclusive evidence found for treatment of anxiety. Vitamin B6 is FDA approved 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, without any indication for treatment for any sleep disorder. The guidelines note that medical foods are not recommended for chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The physician prescribed the Somnicin for the treatment of insomnia, anxiety, and muscle relaxation, without documentation in the subjective or objective findings, or in the diagnoses, of insomnia, anxiety, or need for muscle relaxation. The treating physician's request did not include the directions for use and as such the prescription is not sufficient. Therefore, based on the guidelines, the request for Somnicin, for the date of service of May 4, 2015, was not medically necessary.

Retrospective review of Gabaclyotram: Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%, Lipoderm base, QTY: 180, DOS: 05/04/2015: Upheld

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

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

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines notes all chronic pain therapies are focused on the goal of functional restoration rather than merely the elimination of pain, and assessment of treatment efficacy is accomplished by reporting functional improvement. The guidelines indicates "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." The guidelines note topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed, and that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines note that these medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. The requested topical compounded cream contains: Gabapentin, Cyclobenzaprine, and Tramadol. Gabapentin is not recommended as a topical analgesic, and there is no peer-reviewed literature to support its use. Cyclobenzaprine is a muscle relaxant, and the guidelines note the addition to other agents is not recommended and there is no evidence for use as a topical agent. Tramadol is a synthetic opioid affecting the central nervous system. The treating physician's request did not include the site of application and as such, the prescription is not sufficient. The requested compounded topical analgesic contains drugs which are not recommended for topical use, therefore the entire compound is not recommended. Based on the guidelines, the request for Gabaclyotram, for the date of service of May 4, 2015, was not medically necessary.