

Case Number:	CM15-0164375		
Date Assigned:	09/01/2015	Date of Injury:	05/26/2010
Decision Date:	10/20/2015	UR Denial Date:	07/21/2015
Priority:	Standard	Application Received:	08/21/2015

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: Pediatrics, Internal 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 45 year old female, who sustained an industrial injury on May 26, 2010. She reported that when lifting a heavy box she heard a "crack" and felt pain in the neck with pain in left shoulder. The injured worker was diagnosed as having cervical radiculopathy, cervical spinal stenosis, cervical disc degeneration, lumbar disc protrusion, lumbar spinal stenosis, lumbar radiculopathy, and right wrist carpal tunnel syndrome. Treatments and evaluations to date have included physical therapy, epidural steroid injections (ESIs), MRIs, x-rays, CT scan, and medication. Currently, the injured worker reports constant 9 out of 10 neck pain radiating into the upper extremities and constant 9 out of 10 low back pain radiating to the lower extremities. The Secondary Treating Physician's report dated May 14, 2015, noted the injured worker not working, remaining on temporary total disability. The physical examination was noted to show tenderness to palpation along the cervical spine and trapezius muscles bilaterally with palpable spasms. The lumbar spine was noted to have tenderness to palpation along the paravertebral muscles bilaterally with palpable spasms along the paravertebral muscles bilaterally. Straight leg raise was positive bilaterally in a seated position at 60 degrees. Decreased sensation to light touch and pinprick was noted over the median, ulnar, and radial nerves of the hands bilaterally. The treatment plan was noted to include the injured worker receiving an injection of Vitamin B12, and requests for authorization for an orthopedic spine evaluation, an orthopedic evaluation, and an internal medicine consultation, with recommendation for Lyrica, prescriptions for Norco, Zofran ODT, Omeprazole, and Ativan, dispensed Cyclobenzaprine, Theramine, Sentra PM, and Sentra AM, with compound medications, and Genicin and Somnicin sent out by the pharmacy.

IMR ISSUES, DECISIONS AND RATIONALES

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

Genicin #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.medications.com/?c=drugs&s-genocin>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.webmd.com/drugs/2/drug-159161/genicin-oral/details, healthy.kaiserpermanente.org/health/care/consumer/health-wellness/drugs-and-natural-medicines/drug-encyclopedia/medicine-information/!ut/p/a1/fc5BT4MwFAfwz7IDR-ljHaXz1rGIBWGYEcVeDJtdR8IoYd3Ivr2AeDBR3-29_N4_fyRQjkRdXEtVmFLXRTXsgrxnwDerlcMAHO4CT0OarCmdg4_RKwqRUJXejfjtaExzb4EFH-1FyXp_u2t0ayppLEBiuPE1y12y9AgMnNU7TBUSrTzIVrb2pe1ThozzGNJ1na20VpW09_pk_fpy1GeD8p-ybyX-Lw4TeAi3X2CzWFLgsf_o8yQCCLwJpAw4jcF1gGECnGQ48uLEgWAXAcD8eUwIUgK9jbLoZRIhgPk3-GMYoOZEb7i6Ph22vORsNvsEEXdvaw!!/dl5/d5/L2dBISEvZ0FBIS9nQSEh/.

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 MTUS and Official Disability Guidelines (ODG) are silent on the use of Genicin. Alternative guidelines note Genicin (Glucosamine) has been used for osteoarthritis. The FDA has not reviewed Genicin for safety or effectiveness. The physician notes to have 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 injured worker was noted to have been prescribed the Genicin since at least April 2015, without documentation of the efficacy of the medication. The treating physician's request did not include the directions for use and as such the prescription is not sufficient and not medically necessary. Therefore, based on the guidelines, the documentation provided did not support the medical necessity of the request for Genicin #90 and therefore is not medically necessary.

Somnicin #30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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, Somnicin.

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 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 injured worker was noted to have been prescribed Somnicin since at least April 2015 for the treatment of insomnia, anxiety, and muscle relaxation. The documentation provided did not identify the injured worker with insomnia or anxiety, nor was there documentation of improvement in the injured worker's function or of the efficacy of the Somnicin. The treating physician's request did not include the dosage, frequency, or directions for use and as such the prescription is not sufficient and not medically necessary. Therefore the request for Somnicin #30 is not medically necessary.

Zofran ODT 4mg: 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 section - Zofran.

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, Ondansetron (Zofran), Antiemetics (for opioid nausea).

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 MTUS Guidelines define functional improvement as "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 MTUS is silent on the use of Zofran. The Official Disability Guidelines (ODG)

notes antiemetics are not recommended for nausea and vomiting secondary to chronic opioid use. Zofran (Ondansetron) is FDA approved for nausea and vomiting secondary to chemotherapy and radiation treatment, and also for postoperative use and acute use for gastroenteritis. The injured worker was noted to have been prescribed Zofran since at least January 2015. The documentation provided did not identify the injured worker with complaints of nausea or vomiting. The injured worker was not noted to be undergoing radiation treatments or chemotherapy, nor had he undergone recent surgery. Therefore, based on the guidelines, the documentation provided did not support the medical necessity of the request for Zofran ODT 4mg.

Omeprazole 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter, Proton Pump Inhibitors (PPIs).

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 MTUS Chronic Pain Medical Treatment Guidelines note that co-therapy with a nonsteroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDs such as NSAID plus low dose aspirin). The guidelines are specific regarding the risk factors of history of peptic ulcer or GI bleeding or perforation, not just a GI history which could include many other GI issues. The Official Disability Guidelines (ODG) notes proton pump inhibitors (PPIs) are recommended for patients at risk for gastrointestinal (GI) events, with decision to use PPIs long term needs to be weighed against the risk. "The potential adverse effects of long-term PPI use include B12 deficiency; iron deficiency; hypomagnesemia; increased susceptibility to pneumonia, enteric infections, and fractures; hypergastrinemia and cancer; and more recently adverse cardiovascular effects. PPIs have a negative effect on vascular function, increasing the risk for myocardial infarction (MI)." The injured worker was noted to have been prescribed Omeprazole since at least March 2015 for treatment of gastrointestinal irritation, without documentation provided that indicated the injured worker was complaining of gastrointestinal (GI) symptoms, or was at risk for a gastrointestinal (GI) event as she was 45, without a documented history of a peptic ulcer or gastrointestinal (GI) bleed, nor was she prescribed concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose or multiple NSAIDs. Therefore, based on the guidelines, the documentation provided did not support the medical necessity of the request for Omeprazole 20mg #60.