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| <b>Case Number:</b>   | CM15-0116295 |                              |            |
| <b>Date Assigned:</b> | 06/24/2015   | <b>Date of Injury:</b>       | 12/19/2007 |
| <b>Decision Date:</b> | 08/18/2015   | <b>UR Denial Date:</b>       | 05/18/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 06/16/2015 |

### 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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 49 year old female, who sustained an industrial injury on 12/19/07. The injured worker was diagnosed as having cervical radiculopathy, lumbar radiculopathy, and shoulder impingement. Treatment to date has included medication. On 5/13/15, pain was rated as 6/10. The injured worker had been taking Tramadol since at least 2/9/15. The injured worker had been taking Carisoprodol, Aciphex, and Gabapentin since at least 11/3/14. A physician's report dated 3/24/15 noted gastritis aggravated by side effects of medication. Currently, the injured worker complains of right shoulder pain with numbness and burning in the hands. The treating physician requested authorization for Carisoprodol 350mg #60 with 2 refills, Aciphex DR 20mg #60, Gabapentin 300mg #90, and Tramadol 50mg #34.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Carisoprodol 350mg #60 with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma) and Muscle relaxants (for pain) Page(s): 29, 63-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Soma (Carisoprodol).

**Decision rationale:** MTUS states regarding Carisoprodol, "Not recommended. This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers, the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs." ODG States that Soma is "Not recommended. This medication is FDA-approved for symptomatic relief of discomfort associated with acute pain in musculoskeletal conditions as an adjunct to rest and physical therapy (AHFS, 2008). This medication is not indicated for long-term use." The patient has been on the medication since in excess of guideline recommendations. Guidelines do not recommend long-term usage of SOMA. Treating physician does not detail circumstances that would warrant extended usage. As such, the request for Carisoprodol 350mg #60 with 2 refills is not medically necessary.

**AcipHex DR 20mg #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol. 2013 Mar; 108(3):308-28.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** MTUS states "Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease : (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg Omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." ODG states "If a PPI is used, Omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), Omeprazole (Prilosec), Pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of Omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs

appeared to be similarly effective. (AHRQ, 2011)." The medical documents provided do not establish the patient has having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. Additionally, there is no evidence of functional improvement with the use of this medication. As such, the request for AcipHex DR 20mg #60 is not medically necessary.

**Gabapentin 300mg #90: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs Page(s): 16-22. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Anti-epilepsy drugs (AEDs) for pain, Gabapentin (Neurontin).

**Decision rationale:** The MTUS considers Gabapentin as a first-line treatment for neuropathic pain and effective for the treatment of spinal cord injury, lumbar spinal stenosis, and post op pain. MTUS also recommends a trial of Gabapentin for complex regional pain syndrome. ODG states "Recommended Trial Period: One recommendation for an adequate trial with Gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. (Dworkin, 2003) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggests that if inadequate control of pain is found, a switch to another first-line drug is recommended." Additionally, ODG states that Gabapentin "has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain". The medical documentation provided does not indicate any objective functional improvement with the use of this medication. As such, the request for Gabapentin 300mg #90 is not medically necessary.

**Tramadol 50mg #34: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol, Ultram Page(s): 74-96, 113, 123. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram).

**Decision rationale:** Tramadol is classified as a central acting synthetic opioids. MTUS states regarding Tramadol that "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." ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/ acetaminophen." The treating physician did not

provide sufficient documentation that the patient has failed a trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of Tramadol prior to the initiation of this medication. MTUS states that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such, the request for Tramadol 50mg #34 is not medically necessary.