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| <b>Case Number:</b>   | CM15-0102869 |                              |            |
| <b>Date Assigned:</b> | 06/05/2015   | <b>Date of Injury:</b>       | 03/19/2001 |
| <b>Decision Date:</b> | 07/07/2015   | <b>UR Denial Date:</b>       | 05/01/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 05/28/2015 |

### 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 Jersey, Alabama, California  
 Certification(s)/Specialty: Neurology, Neuromuscular 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 female who sustained an industrial injury on 3/19/01. The mechanism of injury is unclear. She currently complains of cervical and upper back pain with radiating pain into the upper extremities. Her pain level was 5-6/10. The low back pain and radicular pain to the lower extremities was controlled with the spinal cord stimulator. On physical exam there was significant trigger points and tenderness along the upper trapezius muscles with swelling over the neck and chest with decreased range of motion; the lumbar spine exhibits tenderness over the facets and sacroiliac joints but this is improved. She is having sleep difficulties. She has had functional improvement with spinal cord stimulator in the lumbar spine. Medications are Nucynta, Flexeril, Restoril, Acifex, Terocin patch. Diagnoses include cervicgia with bilateral radiculopathy; lumbago with bilateral radiculopathy; myofascial syndrome; cervicogenic headaches with intractable pain; reactive depression and anxiety; frequent falls. Treatments to date include permanent implantation of spinal cord stimulator (3/2/15); trigger point injections (4/9/15) upper back with improvement. In the progress note dated 4/9/15 the treating provider's plan of care includes requests for Aciphex, Flexeril and Restoril.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Aciphex 20 mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

**Decision rationale:** According to MTUS guidelines, Aciphex as well as other proton pump inhibitors are when NSAID are used in patients with intermediate or high risk for gastrointestinal events. The risk for gastrointestinal events are: (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). There is no documentation in the patient's chart supporting that she is at intermediate or high risk for developing gastrointestinal events. Therefore, the request for Aciphex 20mg #60 is not medically necessary.

**Flexeril 10 mg:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

**Decision rationale:** According to MTUS guidelines, Flexeril, a non sedating muscle relaxants, is recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic spasm and pain. Efficacy appears to diminish over time and prolonged use may cause dependence. The patient has been using Flexeril since at least December 2011 without documentation of pain and spasticity improvement. Therefore the request for Flexeril 10mg is not medically necessary.

**Restoril 15 mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

**Decision rationale:** According to ODG guidelines and in the treatment of insomnia section. "Recommend that treatment be based on the etiology, with the medications recommended below. See Insomnia. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. (Lexi-Comp, 2008) Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep

onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. Pharmacologic Treatment: There are four main categories of pharmacologic treatment: (1) Benzodiazepines; (2) Non-benzodiazepines; (3) Melatonin & melatonin receptor agonists; & (4) Over-the-counter medications. The majority of studies have only evaluated short-term treatment (i.e., 4 weeks) of insomnia; therefore more studies are necessary to evaluate the efficacy and safety of treatments for long-term treatment of insomnia. In 2007, the FDA requested that manufacturers of all sedative-hypnotic drugs strengthen product labeling regarding risks (i.e., severe allergic reactions and complex sleep-related behaviors, such as sleep driving). It is recommended that treatments for insomnia should reduce time to sleep onset, improve sleep maintenance, avoid residual effects and increase next-day functioning. (Morin, 2007) (Reeder, 2007) (1) Benzodiazepines: FDA-approved benzodiazepines for sleep maintenance insomnia include estazolam (ProSom), flurazepam (Dalmane), quazepam (Doral), and temazepam (Restoril). Triazolam (Halcion) is FDA-approved for sleep-onset insomnia. These medications are only recommended for short-term use due to risk of tolerance, dependence, and adverse events (daytime drowsiness, anterograde amnesia, next-day sedation, impaired cognition, impaired psychomotor function, and rebound insomnia). These drugs have been associated with sleep-related activities such as sleep driving, cooking and eating food, and making phone calls (all while asleep). Particular concern is noted for patients at risk for abuse or addiction. Withdrawal occurs with abrupt discontinuation or large decreases in dose. Decrease slowly and monitor for withdrawal symptoms. Benzodiazepines are similar in efficacy to benzodiazepine-receptor agonists; however, the less desirable side-effect profile limits their use as a first-line agent, particularly for long-term use". According to MTUS guidelines, benzodiazepines are not recommended for long term use for pain management because of unproven long term efficacy and because of the risk of dependence. Most guidelines limit their use to 4 weeks. The patient was using Restoril for long time without clear benefit. Therefore the prescription of Restoril 15mg #60 is not medically necessary.