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| <b>Case Number:</b>   | CM15-0107540 |                              |            |
| <b>Date Assigned:</b> | 06/12/2015   | <b>Date of Injury:</b>       | 06/16/1999 |
| <b>Decision Date:</b> | 07/30/2015   | <b>UR Denial Date:</b>       | 05/04/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 06/04/2015 |

### 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 66 year old male who sustained an industrial injury on 06/16/99. Initial complaints and diagnoses are not available. Treatments to date include medications, radiofrequency ablations, and lumbar epidural steroid injections. Diagnostic studies include MRI of the cervical spine and brain. Current complaints include pain in the left side of his head, neck, shoulder and left arm. Current diagnoses include cervical and thoracic disc space degeneration, cervical and lumbar radiculopathy, bulging cervical and lumbar discs, annular tear L5-S1, cervical disc herniations, cervical stenosis, spondylosis, and cervical posterior osteophyte disc complex. In a progress note dated 04/23/15 the treating provider reports the plan of care as medications including Opana, Nortriptyline, Zanaflex, Zoloft, Trazodone, Omeprazole, and Topamax. The requested treatments include Nortriptyline, Zanaflex, Trazadone, Omeprazole, and Topamax.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Nortriptyline 10 mg Qty 100 with 3 refills:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-16.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants Page(s): 24, 80. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Antidepressants for chronic pain, Tricyclic antidepressants.

**Decision rationale:** Antidepressants for chronic pain are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Tricyclic antidepressants, such as Nortriptyline (Pamelor), are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. In addition, recent reviews recommended tricyclic antidepressants as a first-line option, especially if pain is accompanied by insomnia, anxiety, or depression. Indications in controlled trials have shown effectiveness in treating central post-stroke pain, post-herpetic neuralgia, painful diabetic and non-diabetic polyneuropathy, and post-mastectomy pain. Tricyclics are contraindicated in patients with cardiac conduction disturbances and/or decompensation (they can produce heart block and arrhythmias) as well as for those patients with epilepsy. For patients > 40 years old, a screening EKG is recommended prior to initiation of therapy. In this case, there is documentation of objective functional improvement as a result of this medication. There is documentation of medical need to continue the Nortriptyline. Medical necessity for the requested medication has been established. The requested medication is medically necessary.

**Zanaflex 4 mg Qty 30 with 3 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tizanidine (Zanaflex) Page(s): 66.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63, 66.

**Decision rationale:** Zanaflex (Tizanidine) is a centrally acting alpha<sub>2</sub>-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. It is indicated for the treatment of chronic myofascial pain and considered an adjunct treatment for fibromyalgia. According to CA MTUS Guidelines, muscle relaxants have not been considered any more effective than non-steroidal anti-inflammatory drugs (NSAIDs) for pain or overall improvement. There is no additional benefit shown in combination with NSAIDs. In addition, sedation is the most commonly reported adverse effect of muscle relaxant medications. In this case, the patient has no reported lumbar spasm on physical exam. In addition, there is no documented functional improvement from previous use of this medication. Medical necessity for the requested medication has not been established. Zanaflex is not medically necessary.

**Trazodone 50 mg Qty 90 with 3 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-16.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Insomnia treatment.

**Decision rationale:** Trazodone (Desyrel) is recommended as an option for insomnia, only for patients with potentially co-existing mild psychiatric symptoms such as depression or anxiety. It is unrelated to tricyclic or tetracyclic antidepressants and has some action as an anxiolytic. In this case, there is no documentation of a history of depression, anxiety or insomnia. Medical necessity of the requested medication has not been established. The requested medication is not medically necessary.

**Omeprazole DR (delayed release) 40 mg Qty 30 with 3 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain (chronic) - Proton pump inhibitor.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines PPIs Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) PPIs.

**Decision rationale:** According to the California MTUS (2009), Omeprazole (Prilosec), is proton pump inhibitor (PPI) that is recommended for patients taking NSAIDs, with documented GI distress symptoms, or at risk for gastrointestinal events. GI risk factors include: age >65, history of peptic ulcer, GI bleeding, or perforation; concurrent use of aspirin, corticosteroids, and/or anticoagulants, or high dose/multiple NSAIDs. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Based on the available information provided for review, the patient is not maintained on NSAIDs. The medical necessity for Omeprazole is not established. The requested medication is not medically necessary.

**Topamax 50 mg Qty 60 with 3 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) Page(s): 16-22. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain (chronic) - Topiramate.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDS) Page(s): 17-19. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) AEDs.

**Decision rationale:** Topiramate (Topamax) is an anticonvulsant (antiepilepsy) drug (AED). According to the CA MTUS and the ODG, AED's are recommended for neuropathic pain. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. The choice of specific agents depends on the balance

between effectiveness and adverse reactions. The guidelines cite the role of AEDs in the management of non-acute pain and chronic conditions such as, polyneuropathy, post-herpetic neuralgia, central pain, spinal cord injury, postoperative pain, migraine headaches, and chronic non-specific axial low back. Topiramate has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of "central" etiology. It is still considered for use for neuropathic pain when other AEDs fail. In this case, the records document that the patient has neuropathic pain related to his chronic low back condition. There is no documentation contraindicating the use of other AEDs, such as Gabapentin. Medical necessity for Topamax has not been established. The requested medication is not medically necessary.