

<b>Case Number:</b>	CM14-0151010		
<b>Date Assigned:</b>	09/19/2014	<b>Date of Injury:</b>	01/09/2012
<b>Decision Date:</b>	10/20/2014	<b>UR Denial Date:</b>	09/04/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/16/2014

### 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. The expert reviewer is Board Certified in Physical Medicine & Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 62 year-old male with a date of injury of 1/9/2012. The patient's industrially related diagnoses include lumbar degenerative disc disease with radiculopathy and stenosis. The disputed issues are Tramadol 50mg #180, Prilosec 20mg #90, Trazodone 50mg #90, and Zanaflex 4mg #180. A utilization review determination on 9/4/2014 had non-certified Prilosec and Zanaflex and modified the certification of Tramadol to quantity #30 and Trazodone to quantity #30. The rationale for the denial of Tramadol was that the reports did not address the benefit and side effects of the requested medication. "There is no documentation of functional improvements in ADLs as a result of Tramadol use." The stated rationale for the denial of Prilosec 20mg was: "Use of Prilosec 20mg QTY: 90 as per MTUS is recommended for patients at intermediate risk for gastrointestinal events and non-selective NSAID use and these criteria are not met." Trazodone was denied because pain outcomes, function, change in use of other analgesic medication, and sleep quality and duration were not addressed. Lastly, Zanaflex was denied because "the efficacy and side effects and medical necessity for continued use are not addressed and long term use is not supported as per MTUS."

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Tramadol 50mg quantity requested: 180.00: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram) Page(s): 93-94 and 113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids and Tramadol Page(s): 76-80, 94.

**Decision rationale:** Tramadol is a synthetic opioid affecting the central nervous system. As of July 2014, the DEA changed the classification of Tramadol to a schedule IV controlled substance. Since Tramadol is an opioid, it is subject to the ongoing monitoring requirements as stated in the Chronic Pain Medical Treatment Guidelines: "The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the '4 A's' (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." In the progress report dated 8/7/2014, the treating physician documents that the injured worker had severe low back pain and no change in functional level. However, there was insufficient documentation addressing the 4 A's for ongoing monitoring. There was no documented reduction in pain level with medication use, no evaluation of side effects and no clinical evidence of functional improvement. According to the guidelines, opioids should be discontinued if there is no overall improvement in function. Therefore, due to lack of adequate documentation regarding the use of this opioid, medical necessity cannot be established for Tramadol 50mg. Therefore the request for Tramadol 50mg quantity 180 is not medically necessary and appropriate.

**Prilosec 20mg quantity 90.00:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS (Non-Steroidal Anti-Inflammatory Drugs) GI (Gastrointestina).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS and GI & cardiovascular risk Page(s): 68-69.

**Decision rationale:** Prilosec 20mg is a proton pump inhibitor (PPI). The Chronic Pain Medical Treatment Guidelines recommend that if a patient is at intermediate risk for gastrointestinal events and has no cardiovascular disease, then a non-selective NSAID with a PPI can be used. In the progress report dated 8/7/2014, there was no documentation that the injured worker was being prescribed or was taking an NSAID. No adverse effects with previous medication use were documented. The injured worker was diagnosed with "GI ICD-9 code 536.9" but there was no further documentation and no stated rationale for the request of Prilosec. Due to lack of documentation, medical necessity for Prilosec 20mg QTY: #90 could not be established. Therefore, the request for Prilosec 20mg quantity 90.00 is not medically necessary and appropriate.

**Trazodone 50mg quantity requested: 90.00:** Upheld

**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 Anti-Depressants Page(s): 13-17. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: [www.epocrates.com](http://www.epocrates.com) Trazodone

**Decision rationale:** Trazodone is a tetracyclic anti-depressant indicated for the treatment of major depressive disorder (MDD) and is similar to the SSRI (selective serotonin reuptake inhibitor) class of anti-depressants. It is sometimes used for insomnia. The Chronic Pain Medical Treatment Guidelines on pages 13-17 state the following regarding anti-depressants for use in pain management: "Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment." Long-term effectiveness of anti-depressants has not been established. For the diagnosis of low back pain, SSRIs have not been shown to be effective, but tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain. In regards to the diagnosis of radiculopathy, the guidelines state that anti-depressants can be an option, but no specific medications have been proven in high quality studies to be efficacious for treatment of lumbosacral radiculopathy. In the progress report dated 8/7/2014, the injured worker was diagnosed with lumbosacral radiculopathy and sleep disturbance. However, there was no documented assessment of treatment efficacy as recommended in the guidelines. Due to insufficient documentation, Trazodone is not medically necessary. Therefore, the request for Trazodone 50mg quantity 90 is not medically necessary and appropriate.

**Zanaflex 4mg quantity requested: 180.00: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tizanidine (Zanaflex) Page(s): 63-66.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-64.

**Decision rationale:** Zanaflex is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity but is used off-label for low back pain with multiple studies demonstrating efficacy for low back pain. Side effects include somnolence, dizziness, and hepatotoxicity. The Chronic Pain Medical Treatment Guidelines recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. In the progress report dated 8/7/2014, the treating physician documented that the injured worker had severe low back pain but did not document spasms. On physical exam the following statement was made: "no change in physical exam since last visit 7/11/2014." On the referenced progress report dated 7/11/2014, the treating physician documented physical findings of tenderness over the lumbar spine but no spasms (spasms were absent). Furthermore, there was no documentation of first-line options that were ineffective before prescribing Zanaflex. Therefore due to lack of documentation and no stated rationale for the request, Zanaflex 4mg #180 is not medically necessary.

