

<b>Case Number:</b>	CM15-0064300		
<b>Date Assigned:</b>	04/10/2015	<b>Date of Injury:</b>	06/19/2001
<b>Decision Date:</b>	05/13/2015	<b>UR Denial Date:</b>	04/01/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/05/2015

### 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: Ohio, North Carolina, Virginia  
 Certification(s)/Specialty: Family Practice

### 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 male, who sustained an industrial injury on June 19, 2001. The injured worker was diagnosed as having unspecified anxiety state, carpal tunnel syndrome, cervical postlaminectomy syndrome, lumbar postlaminectomy syndrome, cervicalgia, cervical radiculopathy, lumbago, and lumbar radiculopathy. Treatment to date has included MRI, electrodiagnostic studies, a transcutaneous electrical nerve stimulation (TENS) unit, a functional restoration program (FRP), pain psychology treatment, a back brace, and medications including pain, anti-epilepsy, proton pump inhibitor, muscle relaxant, anti-anxiety, melatonin, and non-steroidal anti-inflammatory. On March 26, 2015, the treating physician notes persistent and unchanged neck and low back pain. An EMG (electromyography) was done on the day prior. The injured worker asked about sleep hygiene, decreasing his use of medications, and quality of life improvement. He completed a functional restoration program, continues to do his home exercise program, breathing exercises, and meditation. The physical exam revealed no trigger point or muscle spasms of the lumbar/lumbosacral spine, a positive right supine straight leg raise, tenderness over the bilateral paraspinal muscles overlying the right-side facet joints and the right sacroiliac joint, and limited lumbar range of motion. There was decreased reflexes and muscle strength in the upper and lower extremities. Sensation was intact throughout. The treatment plan includes tapering and discontinuing his current sleep medication, and then replacing it with melatonin, continuing his proton pump inhibitor and non-steroidal anti-inflammatory medications, and a request for an extension of pain psychology for continued anxiety, sleep, and mood symptoms.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Pain Psychology, Quantity 6 sessions:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Psychological treatment Page(s): 101-102.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Psychological treatment Page(s): 101-102. Decision based on Non-MTUS Citation Official Disability Guidelines. Pain (Chronic) chapter. Cognitive therapy section.

**Decision rationale:** Psychological treatment is recommended for appropriately identified patients during treatment for chronic pain. Psychological intervention for chronic pain includes setting goals, determining appropriateness of treatment, conceptualizing a patient's pain beliefs and coping styles, assessing psychological and cognitive function, and addressing co-morbid mood disorders (such as depression, anxiety, panic disorder, and posttraumatic stress disorder). Cognitive behavioral therapy and self-regulatory treatments have been found to be particularly effective. Psychological treatment incorporated into pain treatment has been found to have a positive short-term effect on pain interference and long-term effect on return to work. The following "stepped-care" approach to pain management that involves psychological intervention has been suggested: Step 1: Identify and address specific concerns about pain and enhance interventions that emphasize self-management. The role of the psychologist at this point includes education and training of pain care providers in how to screen for patients that may need early psychological intervention. Step 2: Identify patients who continue to experience pain and disability after the usual time of recovery. At this point, a consultation with a psychologist allows for screening, assessment of goals, and further treatment options, including brief individual or group therapy. Step 3: Pain is sustained in spite of continued therapy (including the above psychological care). Intensive care may be required from mental health professions allowing for a multidisciplinary treatment approach. ODG Psychotherapy Guidelines: Up to 13-20 visits over 7-20 weeks (individual sessions), if progress is being made. (The provider should evaluate symptom improvement during the process, so treatment failures can be identified early and alternative treatment strategies can be pursued if appropriate.) In this instance, the injured worker attended cognitive therapy sessions as part of a 6-week functional restoration program, but the exact number of contact hours was unclear. At the conclusion of the functional restoration program, he rated a 'worse' score in seeking social supports, self-statements, relaxation, and talk persistence. While the documentation provided demonstrates that the injured worker had been taught a variety of self-management techniques, the above ratings showed no demonstrable progress. Therefore, the medical necessity for an additional 6 sessions of pain psychology is not medically necessary.

**Omeprazole 20 mg Quantity 120:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

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

**Decision rationale:** Proton pump inhibitors such as omeprazole are indicated for those at risk for gastrointestinal events such as gastric ulceration. Those risk factors include (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). In this instance, the injured worker has had rectal bleeding and abdominal pain associated with NSAID use for several months. Even if he were to discontinue all NSAIDS, a proton pump inhibitor will likely be required for an extended duration to help heal the associated damage. Omeprazole 20 mg #120 is medically necessary.

**Zorvolex 18 mg Quantity 360:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) - Diclofenac Sodium Page(s): 71.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines. Pain (Chronic) chapter. Zorvolex (diclofenac).

**Decision rationale:** Zorvolex is not recommended except as a second-line option, because diclofenac products are not recommended as first-line choices due to potential increased adverse effects. See Diclofenac. In late 2013 FDA approved diclofenac capsules (Zorvolex, Iroko Pharmaceuticals LLC) at 18-mg and 35-mg doses for the treatment of mild to moderate acute pain in adults. These dosages are 30% lower in strength than the 25-mg and 50-mg diclofenac products already on the market. The FDA also approved another lower-dose NSAID from Iroko Pharmaceuticals, indomethacin capsules (Tivorbex). While diclofenac has potent anti-inflammatory and analgesic properties, research has linked this drug to sometimes-serious adverse outcomes, including cardiovascular thrombotic events, myocardial infarction, stroke, gastrointestinal ulcers, gastrointestinal bleeding, and renal events (such as acute renal failure). (FDA, 2014) This new formulation of diclofenac does not present any apparent advantages versus other medications of the class. Zorvolex is pure acid versus salt in other formulations, resulting in faster dissolution using SoluMatrix Fine Particle Technology. However, it has the same side effect profile while more expensive than other NSAIDs that are available as generics. It is an expensive, brand name only, second-line medication with little to no place in the treatment of workers compensation injuries. In this instance, the injured worker was prescribed Zorvolex it seems on 3-26-2015. At that time, the medical record indicates that the injured worker continued to have unresolved rectal bleeding as authorization for upper and lower endoscopy was still pending. Zorvolex is associated with gastrointestinal ulcers and bleeding and is relatively contraindicated in this instance. Therefore, Zorvolex 18 mg #360 is not medically necessary.