

<b>Case Number:</b>	CM15-0083454		
<b>Date Assigned:</b>	05/05/2015	<b>Date of Injury:</b>	11/14/2012
<b>Decision Date:</b>	06/05/2015	<b>UR Denial Date:</b>	04/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/30/2015

### 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 54 year old female who sustained an industrial injury on 11/14/2012. The injured worker was diagnosed with lumbar degenerative disc disease, right lower extremity radiculopathy and chronic low back pain. The injured worker has a history of gastroesophageal reflux disorder (GERD) like symptoms. Treatment to date includes diagnostic testing, conservative measures, physical therapy, pain psychological sessions and medications. According to the primary treating physician's progress report on April 1, 2015, the injured worker reports an increase in pain in the lower back. Examination of the lumbar spine demonstrated normal alignment with tenderness to palpation over the paraspinal muscles at the facet joints and sacroiliac (SI) joints bilaterally with limited range of motion due to pain. Examination noted positive radicular signs at L5-S1 with referred pain to the right buttock and right lower extremity. Trigger points and muscle spasm were not evident. Straight leg raise was positive on the right side. Sensation and reflexes were intact. Current medications are listed as Cyclobenzaprine, Gabapentin, Ibuprofen, and Lidoderm patch, Melatonin, Omeprazole, Zorvolex and Flexeril. Treatment plan consists of continuing with pain psychology sessions, physical therapy, start acupuncture therapy, laboratory blood work and the current request for Melatonin for insomnia and Zorvolex for low back pain.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Melatonin 5mg #30 Refills: 3: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Melatonin.

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

**Decision rationale:** ODG states "Recommend that treatment be based on the etiology, with the medications recommended below. See also Insomnia. For more detail on Insomnia treatment, see the Mental Chapter. 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." Additionally, ODG states, "Recommended. See Insomnia treatment. There are also experimental and clinical data supporting an analgesic role of melatonin. In published studies melatonin shows potent analgesic effects in a dose-dependent manner, and melatonin has been shown to have analgesic benefits in patients with chronic pain. Also, the repeated administration of melatonin improves sleep and thereby may reduce anxiety, which leads to lower levels of pain. (Wilhelmsen, 2011)" Medical records do not indicate what components of insomnia have been addressed, treated with conservative measures, and the results of those conservative treatments. The treating physician has not met the above guidelines. As such, the request for Melatonin 5mg #30 Refills: 3 is not medically necessary.

**Zorvolex 18mg #90 with no refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal anti-inflammatory drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Diclofenac.

**Decision rationale:** Zorvolex is the name brand version of Diclofenac, which is a NSAID. MTUS specifies four recommendations regarding NSAID use: 1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. 2) Back Pain: Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. 3) Back Pain: Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than

placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. 4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. The medical documents do not indicate that the patient is being treated for osteoarthritis. The treating physician does not document failure of primary (Tylenol) treatment. Importantly, ODG also states that diclofenac is "Not recommended as first line due to increased risk profile... If using diclofenac then consider discontinuing as it should only be used for the shortest duration possible in the lowest effective dose due to reported serious adverse events." The treating physician has not provided documentation of objective functional improvement with the use of this medication. As such, the request for Zorvolex 18mg #90 with no refills is not medically necessary.