

<b>Case Number:</b>	CM14-0091140		
<b>Date Assigned:</b>	09/10/2014	<b>Date of Injury:</b>	03/03/2004
<b>Decision Date:</b>	10/08/2014	<b>UR Denial Date:</b>	06/09/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/11/2014

### 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 Pain Management and Rehabilitation, has a subspecialty in Interventional Spine 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 patient is a 53 year old male with an injury date of 03/03/04. The 05/19/14 report by ■■■. ■■■ states that the patient presents with lower back pain that radiates down the bilateral lower extremities accompanied by frequent muscle spasms in the lower back bilaterally. Pain is aggravated by activity and walking. The patient also presents with ongoing headaches, insomnia associated with ongoing pain, nausea and constipation. Pain is rated 7/10 with medications and 8/10 without. The patient is currently not working. Lumbar examination notes spasm and tenderness upon palpation in the spinal vertebral area L2-S1. The range of motion of the lumbar spine was moderately limited secondary to pain. Motor examination shows decreased strength. Tenderness is noted in the bilateral knees, and the range of motion was decreased due to pain. Motor exam shows decreased strength of the extensor muscles along the L4-S1 dermatome in bilateral lower extremities. The treater discusses the Insomnia Severity Index. The patient's score of 21 the treater determines moderate severity clinical insomnia. The patient's diagnoses include: 1. Lumbar Disc Degeneration 2. Chronic pain other 3. Failed back surgery syndrome, lumbar 4. Lumbar radiculopathy 5. Bilateral knee pain 6. Iatrogenic opioid dependency. The following medications are noted as renewed, Cymbalta (duloxetine), Gabapentin, OxyContin, Percocet (oxycodone), Restone, Norflex, Senna/docusate, and Orphenadrine Citrate. The utilization review being challenged is dated 06/09/14. The rationale is that the clinical information submitted lack documentation of functional improvement, pain relief and improved sleep by the requested medications. Treatment reports were provided from 12/02/13 to 07/07/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**30 capsules of Cymbalta 60 mg: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cymbalta SNRIs (Serotonin Noradrenaline Reuptake Inhibitors) Page(.).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Duloxetine (Cymbalta) Page(s): 43-44.

**Decision rationale:** The patient presents with lower back pain radiating down the lower extremities, spasm, headaches, and insomnia. The treater presents for Cymbalta (Duloxetine) 60 mg 30 capsules. Reports provided show the patient has been taking this medication since at least 12/02/13. MTUS pp 43, 44 state that Duloxetine (Cymbalta) Recommended as an option in first-line treatment option in neuropathic pain. It has FDA approval for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy. The treater notes this medication is beneficial with intended effect at prescribed dose and that this patient has had limited response to other classes of antidepressant medications for treatment of chronic pain. The patient does not have hepatic insufficiency. In this case, the treater has prescribed a medication that is a first line option of neuropathic pain and documented efficacy. The medical necessity for 30 Capsules of Cymbalta 60 mg has been established.

**30 tablets of Restone 3-100 mg: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Treatment Index 11th Edition (web) 2013, Pain/Melatonin, Insomnia Treatment

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

**Decision rationale:** You can authorize restone.Rationale: Restone (melatonin and I-tryptophan) 100 mg 30 tablets. The patient presents with lower back pain radiating down the lower extremities, headaches, spasm, and insomnia. The treater presents for Restone (melatonin and I-tryptophan) 100 mg 30 tablets. . Reports provided show the patient has been taking this medications since at least 12/02/13. MTUS is silent on Restone/melatonin/tryptophan. ODG guidelines Mental Illness and Stress regarding melatonin state under insomnia treatment " 3) Melatonin-receptor agonist: Ramelteon (Rozerem) is a selective melatonin agonist (MT1 and MT2) indicated for difficulty with sleep onset; is nonscheduled (has been shown to have no abuse potential). One systematic review concluded that there is evidence to support the short-term and long-term use of ramelteon to decrease sleep latency; however, total sleep time has not been improved." The treater notes that Restone is for severe insomnia associated with chronic pain and that the patient has failed more conservative sleep aid modalities. The treater also notes that sleep hygiene education and cognitive behavioral therapy strategies have been emphasized with the patient with the goal of discontinuing medicinal sleep agents as early as possible. Finally, it is noted that the medication is beneficial with intended effect at prescribed

dose. In this case, there appears to be some support for melatonin in the guidelines. The medical necessity for 30 Tablets of Restone has been established.