

<b>Case Number:</b>	CM15-0134657		
<b>Date Assigned:</b>	07/30/2015	<b>Date of Injury:</b>	01/19/2000
<b>Decision Date:</b>	09/25/2015	<b>UR Denial Date:</b>	06/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/13/2015

### 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: California

Certification(s)/Specialty: Preventive Medicine, Occupational 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 64-year-old female, who sustained an industrial injury on January 19, 2000. The injured worker was diagnosed as having major depressive disorder, pain disorder and psychological factors affecting medical condition. Treatment to date has included psychotherapy and medication. A progress note dated June 11, 2015 provides the injured worker complains of depression, pain and sleep disturbance. The plan includes Trazodone, Escitalpram, propranolol, Belsomra and Lamectal.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Belsomra 15mg at night for sleep:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress Chapter/Suvorexant (Belsomra) Section.

**Decision rationale:** The MTUS guidelines do not address the use of Belsomra for insomnia; therefore, the ODG was consulted. Per the ODG Belsomra is not recommended as a first-line treatment due to adverse effects. FDA approved a first-in-class insomnia drug suvorexant (Belsomra, Merck) after the manufacturer lowered the dosages to satisfy the agency's safety concerns. Originally, the FDA had declined to approve suvorexant until the starting dose for most patients was 10 mg. The agency also said that proposed upper-limit doses of 30 mg for elderly patients and 40 mg for nonelderly patients were unsafe. Suvorexant, an orexin receptor antagonist, is the first drug of its kind to be approved for patients with insomnia. It alters the signaling of orexins, neurotransmitters responsible for regulating the sleep-wake cycle. Drowsiness was the most commonly reported adverse event for clinical trial participants taking suvorexant, which is classified as a Schedule IV controlled substance. In next-day driving tests, both male and female participants who took the 20-mg dose proved to be impaired drivers. The FDA advises physicians to caution patients against next-day driving or other activities requiring full alertness. In this case, the injured worker is using the sedative medication Trazodone for insomnia. It is unclear why this second sedative is being requested. Additionally, there is no quantity information included with this request. The request for Belsomra 15mg at night for sleep is determined to not be medically necessary.

**Lamictal 25mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy Drugs (AEDs) Section Page(s): 16-21. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Anti-Epilepsy Drugs (AEDs) for Pain Section.

**Decision rationale:** The MTUS guidelines do not address the use of Lamotrigine (Lamictal) specifically but it does address the use of anti-epilepsy drug in general. The MTUS Guidelines recommend the use of anti-epilepsy drugs for neuropathic pain. Most randomized controlled trials for the use of anti-epilepsy drugs for neuropathic pain have been directed at post herpetic neuralgia and painful polyneuropathy, with polyneuropathy being the most common example. There are few RCTs directed at central pain, and none for painful radiculopathy. A good response to the use of anti-epilepsy drugs has been defined as a 50% reduction in pain and a moderate response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response to this magnitude may be the trigger for switching to a different first line agent, or combination therapy if treatment with a single drug fails. After initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of anti-epilepsy drugs depends on improved outcomes versus tolerability of adverse effects. Per the ODG, Lamictal (lamotrigine) has been proven to be moderately effective for treatment of trigeminal neuralgia, HIV, and central post-stroke pain. It has not been shown to be effective for diabetic neuropathy. Due to side effects and slow titration period, lamotrigine is not generally recommended as a first-line treatment for neuropathic pain. This medication is also used in depression associated with bipolar disorder. There is no indication that the injured worker suffers from neuropathic pain or depression associated with bipolar disorder. Additionally, there

is no quantity information included with this request. The request for Lamictal 25mg is determined to not be medically necessary.