

<b>Case Number:</b>	CM15-0160202		
<b>Date Assigned:</b>	08/26/2015	<b>Date of Injury:</b>	08/19/2009
<b>Decision Date:</b>	10/09/2015	<b>UR Denial Date:</b>	07/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/17/2015

### 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: New York, California  
 Certification(s)/Specialty: Emergency 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 47-year-old female, who sustained an industrial injury on 8-19-2009. She reported left shoulder and upper arm pain. The mechanism of injury is not indicated. The injured worker was diagnosed as having chronic left shoulder and upper arm pain. Treatment to date has included medications, and x-rays. The request is for Belsomra, Meloxicam, Flexeril, and TN1 cream. On 1-22-2015, she reported having a flare of fibromyalgia pain and shoulder pain, along with fatigue, and poor sleep quality. She indicated having 4-5 hours of disturbed sleep, and her activity level has decreased. She indicated she spends most of her time on her sofa. Nucynta ER and Norco were reported as helping but not as much as previously. She has been using more Norco, because she ran out of Nucynta, Flexeril and Meloxicam "due to scheduling issues". She averages about 6 Norco per day. Her average pain level is 7 out of 10. She is on disability. The provider noted that the 4 A's were discussed and documented; however the discussion and documentation is not available for this review. The treatment plan included Nucynta, Norco, increase Cymbalta, continue Flexeril, Meloxicam, TN1 cream, and consider Savella, Lyrica and baclofen, trial Lyrica. On 5-21-2015, she was started on trial of Belsomra. She had indicated her sleep quality to be poor due to pain. On 7-21-2015, she reported increased left upper extremity and torso pain. She also reported increased fatigue and difficulty with daily activities. She reported that her medications were working fair, and that Lyrica and Belsomra were not working much. Norco is noted to be used on an as needed basis. Physical findings revealed her pain to be tolerable when she has full regimen of her pain meds, and minimal radiating pain to her left upper extremity otherwise, there is no new deficit and she looks otherwise stable. The treatment

plan included: Nucynta, Norco, Cymbalta, Flexeril, Meloxicam, TN1 cream, Abilify, discontinued Lyrica.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Flexeril 10mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril).

**Decision rationale:** Per the CA MTUS, Cyclobenzaprine (Flexeril) is an antispasmodic muscle relaxant. Non-sedating muscle relaxants are recommended with caution as a second line option for short-term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. Antispasmodics are used to decrease muscle spasm in conditions such as low back pain although it appears that these medications are often used for the treatment of musculoskeletal conditions whether spasm is present or not. The mechanism of action for most of these agents is not known. Cyclobenzaprine is recommended for a short course therapy. There is limited, mixed evidence that does not allow for recommendation for chronic use. The CA MTUS states, Cyclobenzaprine (Flexeril) is recommended as an option, using a short course of therapy. Cyclobenzaprine (Flexeril) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. There is also a post-op use. The addition of Cyclobenzaprine to other agents is not recommended. Cyclobenzaprine-treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant. According to the CA MTUS, all therapies must be focused on the goal of functional restoration rather than just the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement, with functional improvement being documented in reduction of pain, increased pain control, and improved quality of life. Functional improvement means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit; and a reduction in the dependency on continued medical treatment. In this case, Flexeril has been utilized on a long-term basis without noted benefit. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. Therefore, the request for Flexeril 10mg #60 is not medically necessary.

## **Meloxicam 15mg #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, specific drug list & adverse effects.

**Decision rationale:** Per the CA MTUS, Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) for the relief of the signs and symptoms of osteoarthritis. Per the CA MTUS, non-steroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. The CA MTUS does not recommend chronic NSAIDs for low back pain; NSAIDs should be used for the short term only. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. Package inserts for NSAIDs recommend periodic monitoring of a complete blood count (CBC) and chemistry profile (including liver and renal function tests). According to the CA MTUS, all therapies must be focused on the goal of functional restoration rather than just the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement, with functional improvement being documented in reduction of pain, increased pain control, and improved quality of life. Functional improvement means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit; and a reduction in the dependency on continued medical treatment. In this case, she has been prescribed Meloxicam on a long-term basis. There is no discussion of periodic monitoring of blood work. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. Therefore, the request for Meloxicam 15mg #30 is not medically necessary.

## **TN1 Cream #1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The CA MTUS guidelines do not recommend any compounded product that contains at least one drug (or drug class) that is not recommended. Medical necessity cannot be determined for unspecified compounds, and unpublished ingredients cannot be assumed to be safe or effective. The MTUS recommends topical analgesics for neuropathic pain when anticonvulsants and antidepressants have been trialed and failed. There is notation of failure of Celebrex. The ingredients of the requested TN1 cream have not been specified. In addition, there is no indication of the body part for application or the frequency of use. Therefore, the request for TN1 Cream #1 is not medically necessary.

## **Belsomra 20mg #30: 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 (updated 07/15/15) - Online Version, Insomnia treatment.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Chronic pain programs (functional restoration programs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, insomnia, insomnia treatment and Other Medical Treatment Guidelines [www.Belsomra.com](http://www.Belsomra.com).

**Decision rationale:** The CA MTUS and ODG guidelines do not directly address Belsomra. Per [Belsomra.com](http://Belsomra.com), Suvorexant (Belsomra) is a prescription medication for those with trouble falling or staying asleep (insomnia). The ODG guidelines recommend correcting insomnia deficits, as non-restorative sleep is one of the strongest predictors for pain. Definition: Difficulty in sleep initiation or maintenance, and/or early awakening. Also characterized by impairment in daily function due to sleep insufficiency. These impairments include fatigue, irritability, decreased memory, decreased concentration, and malaise. Classifications: (1) Based on symptoms: Categories of symptoms include sleep onset, sleep maintenance, non-restorative sleep. These symptoms have been found to change over time. (2) Based on duration: (a) Acute insomnia (transient insomnia): Usually the result of specific environmental or social events. Generally treated by addressing the episode directly (death of a family member, working on a different shift, travel), or prophylactically. (b) Chronic insomnia: Generally defined as lasting more than one month. This condition may be correlated with other intrinsic sleep disorders, primary insomnia, or chronic medical conditions. Chronic insomnia is more likely to occur in the elderly, depressed patients, and medically ill populations. (3) Based on etiology: (a) Primary insomnia: No known physical or mental condition is noted as an etiology. This condition is generally consistent and responsive to treatment. (b) Secondary insomnia (comorbid insomnia): insomnia that is secondary to other medical and psychiatric illnesses, medications, or sleep disorders. Examples include chronic pain, gastroesophageal reflux disease (GERD), heart failure, end-stage renal disease, diabetes, neurologic problems, psychiatric disorders, and certain medications. Diabetic patients appear to suffer insomnia due to alterations of circadian rhythm. They may also suffer from sleep disorders related to obesity. Psychiatric disorders associated with insomnia include depression, anxiety and alcoholism. The ODG guidelines state there are four main categories for pharmacologic treatment of insomnia: 1) Benzodiazepines, 2) non-benzodiazepines 3) Melatonin & melatonin receptor agonists and 4) over the counter medications. The majority of studies have only evaluated short-term treatment of no more than 4 weeks. Non-pharmacologic treatment includes: Empirically supported treatment includes stimulus control, progressive muscle relaxation, and paradoxical intention. Treatments that are

thought to probably be efficacious include sleep restriction, biofeedback, and multifaceted cognitive behavioral therapy. Suggestions for improved sleep hygiene: (a) Wake at the same time every day; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping. In a head-to-head comparison of treatment approaches to determine separate and combined effects on insomnia, adding a prescription sleeping pill to cognitive behavioral therapy (CBT) appeared to be the optimal initial treatment approach in patients with persistent insomnia, but after 6 weeks, tapering the medication and continuing with CBT alone produced the best long-term outcome. These results suggest that there is a modest short-term benefit to starting therapy with CBT plus a medication, especially with respect to total sleep gained, but that this benefit does not persist. In terms of first-line therapy, for acute insomnia lasting less than 6 months, medication is probably the best treatment approach, but for chronic insomnia, a combined approach might give the best of both worlds; however, after a few weeks, the recommendation is to discontinue the medication and continue with CBT. Prescribing medication indefinitely will not work. The authors said that the conclusion that patients do better in the long term if medication is stopped after 6 weeks and only CBT is continued during an additional 6-month period is an important new finding. According to the CA MTUS, all therapies must be focused on the goal of functional restoration rather than just the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement, with functional improvement being documented in reduction of pain, increased pain control, and improved quality of life. Functional improvement means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit; and a reduction in the dependency on continued medical treatment. In this case, there is no discussion of a sleep assessment, cognitive behavioral therapy, or attempts at non-pharmacologic treatment. She reported feeling like Belsomra was not working much for her. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. Therefore, the request for Belsomra 20mg #30 is not medically necessary.