

<b>Case Number:</b>	CM14-0173445		
<b>Date Assigned:</b>	10/24/2014	<b>Date of Injury:</b>	09/18/2004
<b>Decision Date:</b>	12/03/2014	<b>UR Denial Date:</b>	10/16/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/21/2014

### 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 Preventive Medicine, has a subspecialty in Occupational Medicine, and is licensed to practice in Iowa. 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:

This patient is a 31 year old male employee with date of injury of 9/18/2014. A review of the medical records indicates that the patient is undergoing treatment for joint and ankle pain. Subjective complaints include leg pain, back pain, joint pain, difficulty exercising, and difficulty getting out of chair; swelling in feet and ankles. Physical exam reveals normal gait; unremarkable bones, joints, and muscles; 5/5 strength for feet, hamstrings, hip flexors, dorsiflexors, gluteal muscles. Exam also revealed tenderness to the plantar aspect of the left foot extending from the proximal first toe to the mid arch; no swelling or bruising; sensory is intact. There is decreased light touch sensation on the left (L4 dermatome and L5 dermatome). Medication has included Cymbalta, Inderal, Lunesta (started Jan 2012), Lyrica capsule (started Nov 2011), Naprosyn, Norco (started Jan 2012), Prilosec, Wellbutrin. Additional medications include Butrans and Savella. The utilization review dated 10/16/2014 partially certified the request for Lyrica 50mg #120 w 3 refills modified to 1 refill of Lyrica 50mg #120, partially certified the request for Lunesta 3mg #30 w 3 refills, non-certified the requests for Savella 50mg and Flexeril 10mg #60.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Lyrica 50 mg, #120 with 3 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lyrica (Pregabalin).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pregabalin (Lyrica) Page(s): 99. Decision based on Non-MTUS Citation Guidelines (ODG) Pain, Anti-epilepsy drugs (AEDs) for pain

**Decision rationale:** MTUS and ODG state, "Pregabalin (Lyrica) has been documented to be effective in treatment of diabetic neuropathy and post herpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Pregabalin listing for more information and references. While the treating physician documents a burning sensation in the L4 and L5 dermatome of the left foot and 30 percent reduction in symptoms, Lyrica requires frequent monitoring. Follow up visits need to document if the patient has decreased pain and improved functionality and functionality. The utilization review modified the request to a one-month supply to allow for frequent monitoring. As such, the request for Lyrica 50 mg, #120 with 3 refills is not medically necessary.

**Lunesta 3 mg, #30, with 3 refills:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Chronic Pain, insomnia, Mental Illness, Eszopicolone (Lunesta)

**Decision rationale:** ODG states regarding Eszopicolone, "Not recommended for long-term use, but recommended for short-term use. See Insomnia treatment. See also the Pain Chapter. Recommend limiting use of hypnotics to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase." For insomnia ODG recommends that "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." Medical records do not indicate patient's sleep hygiene or the need for variance from the guidelines, such as "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." Medical documents indicate that the patient has been on Eszopicolone since at least Jan 2012, far exceeding guidelines. Medical records do not indicate what components of insomnia have been addressed, treated with conservative measures, and the results of those conservative treatments. Additionally, there is no evidence of sleep quality while on Lunesta. As such, the request for Lunesta 3 mg, #30, with 3 refills is not medically necessary.

**Retrospective request for Savella 50 mg, dispensed on 9/26/2014: 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 (Chronic), Fibromyalgia Syndrome (FMS), Milnacipran (Savella)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Milnacipran, Ixel Page(s): 62-63. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Savella (Milnacipran, Ixel)

**Decision rationale:** ODG States "Under study as a treatment for fibromyalgia syndrome. An FDA Phase III study demonstrated "significant therapeutic effects" of Milnacipran for treatment of fibromyalgia syndrome. Milnacipran has been approved for the treatment of depression outside of the U.S. and is a dual serotonin- and norepinephrine-reuptake inhibitor (SNRI). (Rooks, 2007) Milnacipran, one of the pioneer serotonin and norepinephrine reuptake inhibitors (SNRIs), was designed from theoretic considerations to be more effective than selective serotonin reuptake inhibitors (SSRIs) and better tolerated than tricyclic antidepressants (TCAs). (Kasper, 2010) See also the Mental Chapter. FDA has now approved Milnacipran (Savella) for the management of fibromyalgia. Milnacipran should be prescribed with caution in patients with a history of seizure disorder, mania, or controlled narrow-angle glaucoma and should ordinarily not be prescribed in patients with substantial alcohol use or evidence of chronic liver disease. (FDA, 2009) As there is little to no evidence that the cause of fibromyalgia is related to industrial injuries, the use of Savella should be restricted to documented cases of fibromyalgia as part of an appropriate treatment plan"Savella (Milnacipran, Ixel) is not recommended. It is under study as a treatment for fibromyalgia syndrome. The treating physician did not document that the patient met the criteria for fibromyalgia. Additionally, the treating physician did not detail a trial and failure not first line treatments. As such, the retrospective request for Savella 50 mg, dispensed on 9/26/2014, is not medically necessary.

**Retrospective request for Flexeril 10 mg, #60, dispensed on 9/26/2014: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Medications for chronic pain, Antispasmodics Page(s): 41-42,60-61,64-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Cyclobenzaprine (Flexeril)

**Decision rationale:** MTUS Chronic Pain Medical Treatment states for Cyclobenzaprine, "Recommended as an option, using a short course of therapy. . . The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief." The medical documents indicate that patient began taking Flexeril in Jan 2012, which is far in excess of the initial treatment window and period. Additionally, MTUS outlines that "Relief of pain with the use of medications is generally temporary, and measures of the

lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain, the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)" Up-to-date "Flexeril" also recommends "Do not use longer than 2-3 weeks". Medical documents do not fully detail the components outlined in the guidelines above and do not establish the need for long term/chronic usage of Cyclobenzaprine. ODG states regarding cyclobenzaprine. "Recommended as an option, using a short course of therapy. The addition of cyclobenzaprine to other agents is not recommended." Several other pain medications are being requested, along with cyclobenzaprine, which ODG recommends against. As such, the request for Retrospective request for Flexeril 10 mg, #60, dispensed on 9/26/2014 is not medically necessary.