

<b>Case Number:</b>	CM15-0132359		
<b>Date Assigned:</b>	07/20/2015	<b>Date of Injury:</b>	05/08/2007
<b>Decision Date:</b>	10/09/2015	<b>UR Denial Date:</b>	06/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/08/2015

### 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, Arizona, Maryland  
 Certification(s)/Specialty: Psychiatry

### 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 51 year old male with an industrial injury dated 05/08/2007. The injured worker's diagnoses includes status post left knee pain with history of sprain/strain injury and status post left knee arthroscopic surgery in December 2007 and 01/19/2012. Treatment consisted of diagnostic studies, prescribed medications, psychiatric consultations and periodic follow up visits. In a psychiatric follow up visit report dated 03/30/2015, the treating physician reported that the injured worker was being treated for anxiety and depression associated with work related injury. Documentation noted that the injured worker also suffers from chronic pains and has medical issues. The treating physician reported that he was on a complex medication regimen for his psychiatric wellbeing and his symptoms remain controlled. In a primary physician progress note dated 04/27/2015, the injured worker reported sharp pain in the left knee. The injured worker rated pain a 4-5/10 with his medications and severe pain without the medications. Objective findings revealed left knee brace in place, ambulation without any restrictions and no usage of mobility aid. The treating physician reported that the injured worker submitted a specimen for urine drug screen on 03/30/2015 and it was positive for illicit substance. The treating physician prescribed Savella 50mg #60, Klonopin 0.5mg #60, Latuda 80mg #30, Lunesta 3mg #30, Prazosin 1mg #30, and Nudexta 20/10 #60 now under review.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Savella 50mg #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Milnacipran (Ixel). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental & Stress- Antidepressants for treatment of MDD (major depressive disorder).

**Decision rationale:** MTUS states "Milnacipran (Ixel(R)) - Not Recommended as it is not FDA approved and not available in the US at this time. 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 ( [REDACTED] ) has been approved for the treatment of depression outside of the U.S. and is in a new class of antidepressants known as Norepinephrine Serotonin Reuptake Inhibitors (or NSRIs). What makes Milnacipran different from the Selective Serotonin Reuptake Inhibitors (SSRIs) - drugs like Prozac(R) - and Selective Norepinephrine Reuptake Inhibitors (SNRIs) - drugs like Effexor(R) - is that Milnacipran affects two neurotransmitters, norepinephrine and serotonin. (Rooks, 2007) ODG states "Milnacipran, one of the pioneer SNRIs, was designed from theoretic considerations to be more effective than SSRIs and better tolerated than TCAs, and with a simple pharmacokinetic profile. Milnacipran has the most balanced potency ratio for reuptake inhibition of the two neurotransmitters compared with other SNRIs (1:1.6 for milnacipran, 1:10 for duloxetine, and 1:30 for venlafaxine), and in some studies milnacipran has been shown to inhibit norepinephrine uptake with greater potency than serotonin (2.2:1). Clinical studies have shown that milnacipran has efficacy comparable with the TCAs and is superior to SSRIs in severe depression. In addition, milnacipran is well tolerated, with a low potential for pharmacokinetic drug-drug interactions. Milnacipran is a first-line therapy suitable for most depressed patients. It is frequently successful when other treatments fail for reasons of efficacy or tolerability. (Kasper, 2010) Note: In the US the FDA has approved milnacipran (Savella) for fibromyalgia, but not for depression. (FDA, 2009)" According to the guidelines quoted above, Savella is not FDA approved in U.S for treatment of depression. The only FDA approval it has at this time is for Fibromyalgia. The injured worker has been prescribed Savella for treatment of depression and chronic pain. He has not been diagnosed with fibromyalgia. The request for Savella 50mg #60 is not medically necessary at this time.

**Klonopin 0.5mg #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): Biofeedback, Weaning of Medications.

**Decision rationale:** MTUS states "Benzodiazepines are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Upon review of the Primary Treating Physicians' Progress Reports, the injured worker has been Klonopin 0.5 mg twice daily on an ongoing basis with no documented plan of taper. The MTUS guidelines state that the use of benzodiazepines should be limited to 4 weeks. The request for Klonopin 0.5mg #60 is not medically necessary.

**Latuda 80mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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 Atypical Antipsychotics.

**Decision rationale:** ODG states: Atypical anti-psychotics not recommended as a first-line treatment. There is insufficient evidence to recommend atypical antipsychotics (eg, quetiapine, risperidone) for conditions covered in ODG. Antipsychotic drugs are commonly prescribed off-label for a number of disorders outside of their FDA-approved indications, schizophrenia and bipolar disorder. In a new study funded by the National Institute of Mental Health, four of the antipsychotics most commonly prescribed off label for use in patients over 40 were found to lack both safety and effectiveness. The four atypical antipsychotics were aripiprazole (Abilify), olanzapine (Zyprexa), quetiapine (Seroquel), and risperidone (Risperdal). The authors concluded that off-label use of these drugs in people over 40 should be short-term, and undertaken with caution. Upon review of the submitted documentation, there is no evidence of conditions for which Latuda is indicated (Depressive Episodes Associated with Bipolar I Disorder or Schizophrenia). The request for Latuda 80mg #30 is excessive and not medically necessary as there is insufficient evidence to recommend atypical antipsychotics (eg, quetiapine, risperidone) for conditions covered in ODG.

**Lunesta 3mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Stress and Mental Illness Insomnia treatment; Eszopiclone/Lunesta.

**Decision rationale:** ODG states "Lunesta" not recommended for long-term use, but recommended for short-term use. Recommend limiting use of hypnotics to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. In this study, eszopiclone (Lunesta) had a Hazard ratio for death of 30.62 (C.I., 12.90 to 72.72), compared to zolpidem at 4.82 (4.06 to 5.74). In general, receiving hypnotic

prescriptions was associated with greater than a threefold increased hazard of death even when prescribed less than 18 pills/year. (Kripke, 2012) The FDA has lowered the recommended starting dose of eszopiclone (Lunesta) from 2 mg to 1 mg for both men and women. Previously recommended doses can cause impairment to driving skills, memory, and coordination as long as 11 hours after the drug is taken. Despite these long-lasting effects, patients were often unaware they were impaired." The request for Lunesta 3mg #30 is excessive and not medically necessary as sleep medications are not indicated for long term use per guidelines.

**Prazosin 1mg #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) FDA.gov- Prazosin/ MINIPRESS.

**Decision rationale:** MINIPRESS/ Prazosin is indicated in the treatment of hypertension. It can be used alone or in combination with other antihypertensive drugs such as diuretics or beta-adrenergic blocking agents. The use of Prazosin this case seems to be off label for sleep related problems. FDA does not indicate use of prazosin for the same. Thus, the request for Prazosin 1mg #30 is not medically necessary.

**Nuedexta 20/10 #60: 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), Mental Illness & Stress.

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

**Decision rationale:** Nuedexta is indicated for the treatment of pseudobulbar affect (PBA). PBA occurs secondary to a variety of otherwise unrelated neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the underlying emotional state. PBA is a specific condition, distinct from other types of emotional liability that may occur in patients with neurological disease or injury. The use of Nuedexta this case is off label. Thus, the request for Nuedexta 20/10 #60 is not medically necessary.

