

<b>Case Number:</b>	CM15-0192525		
<b>Date Assigned:</b>	10/06/2015	<b>Date of Injury:</b>	05/07/2007
<b>Decision Date:</b>	12/14/2015	<b>UR Denial Date:</b>	09/03/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/30/2015

### 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  
Certification(s)/Specialty: Internal 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 52 year old female who sustained an industrial injury on 5-7-07. Diagnoses are noted as low back pain, lumbar spine strain-sprain, lumbar spine status post (ALDF) anterior lumbar discectomy and fusion L4 through S1 (8-4-09), lumbar surgery complicated by postoperative infection, lumbar spine radiculopathy, and diabetes mellitus (insulin dependent with 30 units at night). In a progress report dated 7-30-15, the physician notes pain is rated at its worst as 10 out of 10 without medications, at its least at 5 out of 10, and on average at 7 out of 10. With medications current pain is reported to be 5 out of 10. Low back pain is noted to be unchanged and with shooting pain into the right leg and is associated with spasm and notes that she has more spasm in the upper back and it is affecting the shoulders. The injured worker reports her regular pain pattern as constant, across the low back with paresthesia in both legs especially numbness and weakness. She continues to have insomnia and depression and notes that Lunesta has been helpful for insomnia. A urine drug screen was done 7-15-15. Objective exam notes tenderness to palpation of the lower back and decreased range of motion of the lumbar spine. It is noted, that since she is diabetic with a high dose of insulin, she is not a good candidate for oral steroid for pain relief at this point. It is noted there are no aberrant drug taking behaviors and that she has been on Ultram ER for persistent pain and Nucynta to help with breakthrough pain control. Previous treatment includes psychiatric treatment, medication Ultram ER, Nucynta, Lunesta and Celebrex (since at least 6-4-15), and physical therapy. A request for authorization is dated 7-30-15. On 9-3-15, the requested treatment of caudal epidural

steroid injection, Toradol 60mg intramuscular injection, Celebrex 200mg #30 with 2 refills, Nucynta 100mg #90, Lunesta 3mg #30 with 2 refills was non-certified.

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

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

#### **Caudal Epidural Steroid Injection: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Epidural steroid injections (ESIs).

**Decision rationale:** This requested treatment for Epidural steroid injections (ESIs) is evaluated in light of the CA MTUS and the Official Disability Guidelines (ODG) recommendations. The California MTUS Chronic Pain Medical Treatment Guidelines recommend epidural steroid injections as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy). Most current guidelines recommend no more than 2 epidural steroid injections. Current recommendations suggest a second epidural injection if partial success is produced with the first injection. Epidural steroid injections can offer short term pain relief and use should be in conjunction with other rehab efforts, including continuing with home exercise. Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. Academy of Neurology recently concluded that “epidural steroid injections may lead to an improvement of radicular lumbosacral pain, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendations for use of epidural steroid injections to treat radicular cervical pain.” ODG criteria do not recommend additional epidural steroid injections, if significant improvement is not achieved with an initial treatment. The injured worker has chronic back pain. Review of medical documentation does not specify neurological deficits within a dermatomal pattern. The notes from treating provider do not indicate abnormal neurological exam. There is no evidence of nerve entrapment or radiculopathy documented by physical exam and corroborated by imaging studies and/or electrodiagnostic testing. Based on the cited guidelines and the submitted documentation, the request for Caudal Epidural Steroid injection is not medically necessary.

#### **Toradol 60mg IM Injection: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, NSAIDs (non-steroidal anti-inflammatory drugs), Ketorolac (Toradol).

**Decision rationale:** The CA MTUS indicates Ketorolac (Toradol) is a non-steroidal anti-inflammatory drug (NSAID) with a boxed warning that it is not indicated for minor or chronic painful conditions. The ODG guidelines, that oral Toradol should not be given as an initial dose, but only as continuation following IV or injection dosing. The injection is recommended as an option to corticosteroid injections in the shoulder, with up to 3 injections. Ketorolac, when administered intramuscularly, may be used as an alternative to opioid therapy. The oral form is only recommended for short term (up to 5 days) in management of moderately severe acute pain that requires analgesia at the opioid level. In this case, there is no discussion of an acute exacerbation or re-injury of his chronic low back pain. Therefore, the request for IM Injection of Toradol 60mg is not medically necessary.

**Celebrex 200mg #30 with 2 refills:** Upheld

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

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

**Decision rationale:** Celebrex (Celecoxib) is a selective nonsteroidal anti-inflammatory drug (NSAID) that is a COX-2 selective inhibitor, a drug that directly targets COX-2, an enzyme responsible for inflammation and pain. Unlike other NSAIDs, Celebrex does not appear to interfere with the antiplatelet activity of aspirin and is bleeding neutral when patients are being considered for surgical intervention or interventional pain procedures. Celebrex may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months. Review of Medical Records did not indicate that in this injured worker, previous use of this medication has been effective in maintaining effective functional improvement. The medical necessity of the requested medication has not been established. The requested medication: Celebrex 200mg #30 with 2 refills is not medically necessary.

**Nucynta 100mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification), Opioids, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC], Opioids, criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter: Opioids.

**Decision rationale:** The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that central acting analgesics such as Nucynta may be used to treat chronic pain. Central analgesics drugs are reported to be effective in managing

neuropathic pain. The MTUS guidelines discourage long-term usage unless there is evidence of ongoing review and documentation of pain relief, functional status and appropriate medication use and side effects. Pain assessment should include: current pain, the least reported pain over the period since last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief and how long the pain relief lasts. A satisfactory response to treatment may be indicated by the injured worker's decreased pain level, increased level of function or improved quality of life. The MTUS guideline indicate functional improvement is "evidenced by 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 and a reduction in the dependency on continued medical treatment." The Official Disability Guidelines recommend Nucynta only as a second-line therapy for patients who develop intolerable adverse effects with first-line opioids. "Three large randomized controlled trials concluded that Nucynta was efficacious and provided efficacy that was similar to oxycodone for the management of chronic osteoarthritis knee and low back pain, with a superior gastrointestinal tolerability profile and fewer treatment discontinuations." In this case, the injured worker was noted to have chronic low back pain with paresthesia in both legs especially numbness and weakness. The Official Disability Guidelines recommend Nucynta ER as a second-line therapy for patients who develop adverse effects with first-line opioids. Documentation does not indicate, that there were no tried or failed first line medications. Medical Records do not indicate that in this injured worker, previous use of this medication has been effective in maintaining any measurable objective evidence of functional improvement. Medical necessity of the requested item has not been established. Of note, discontinuation of an opioid analgesic should include a taper, to avoid withdrawal symptoms. The requested medication is not medically necessary.

**Lunesta 3mg #30 with 2 refills:** 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 Chapter, 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 Chapter--Eszopiclone (Lunesta).

**Decision rationale:** Eszopiclone (Lunesta) is a prescription short-acting non-benzodiazepine sedative-hypnotic, which is recommended for short-term treatment of insomnia (two to six weeks). Benzodiazepine-receptor agonists work by selectively binding to type-1 benzodiazepine receptors in the CNS. Lunesta is indicated for the treatment of insomnia with difficulty of sleep onset and/or sleep maintenance. According to the ODG guidelines, non-Benzodiazepine sedative-hypnotics are considered first-line medications for insomnia. All of the benzodiazepine-receptor agonists are schedule IV controlled substances, which have potential for abuse and dependency. It appears that the non-benzodiazepines have similar efficacy to the benzodiazepines with fewer side effects and short duration of action. Eszopiclone has demonstrated reduced sleep latency and sleep maintenance and is recommended for short-term use. In this case, there is no documentation of the use of sleep hygiene techniques being used to correct sleep deficits.

According to the guidelines, "The FDA has lowered the recommended starting dose of Eszopiclone (Lunesta) from 2 mg to 1 mg for both men and women." The treating physician prescribed 3 mg of Lunesta for the injured worker, which exceeds the guideline recommendations. Medical necessity of the requested item has not been established. The requested medication: Lunesta 3mg #30 with 2 refills is not medically necessary and appropriate.