

<b>Case Number:</b>	CM15-0205091		
<b>Date Assigned:</b>	10/22/2015	<b>Date of Injury:</b>	05/18/2004
<b>Decision Date:</b>	12/09/2015	<b>UR Denial Date:</b>	10/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/19/2015

### 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: Texas, California

Certification(s)/Specialty: Family Practice

### 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 is a 48 year old male patient who sustained an industrial injury on May 18, 2004. The diagnoses include low back pain; lumbar radiculopathy and post-laminectomy syndrome. Per the doctor's note dated October 02, 2015, he had complaints of low back pain described as constant burning pressure worsened by bending, lifting and prolonged sitting, relieved with medications, ice and heat application and exercise. In addition he reported over the past month or two, that he developed swelling of lips and hands itching with a note of having taken Allegra. He is concerned for allergy to Tramadol. The physical examination revealed thorax and lumbar spine with tenderness and significantly limited flexion and extension in lumbar range of motion and a positive SLR bilaterally with thigh pain to the knee on the right. Per the notes dated April 29, 2015, physical examination revealed diffuse wheel like hives throughout his back. The medications list includes on April 29, 2015- Tramadol ER 200mg, and Naproxen; on May 22, 2015: decreasing Tramadol ER and prescribed Naproxen; on September 07, 2015 and October 02, 2015: Tramadol IR (noted with denial) and ER with noted lowered dose secondary to injection. A trial of the following medications was noted: OxyContin, Norco, Vicodin, Percocet, Oxycodone, Duragesic patches, Tylenol, Ibuprofen, Aleve, and Gabapentin (rash). The current medication regimen: Tramadol HCL, Lidoderm 5% patch, Naproxen, Tramadol ER. A trial of Nucynta was prescribed. He had undergone a lumbar laminectomy. He had a FRP ( functional restoration program), lumbar interlaminar injection in May 2014, bilateral lumbar epidural injection in 11/2014 and on May 07, 2015 and home exercise programs. He had a urine drug

screen on 10/2/15 with consistent results. On October 05, 2015 a request was made for Nucynta ER 50mg #84 that was noncertified by Utilization Review on October 12, 2015.

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

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

**Nucynta ER 50mg #84:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 10/09/15) Tapentadol (Nucynta).

**Decision rationale:** CA MTUS does not specifically address Nucynta. Nucynta (Tapentadol) is a centrally acting opioid agonist similar to tramadol. Per the ODG cited above "Tapentadol 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. (Afilalo, 2010) (Buynak, 2010) (Lange, 2010)" On November 21, 2008, the FDA approved Tapentadol immediate-release tablets for relief of moderate to severe acute pain. "Nucynta has the same pain-relieving benefits of OxyIR, as well as the same risks that come with any opioid, but shows a significant improvement in gastrointestinal tolerability compared with Oxycodone. Nucynta was already approved for acute pain. (FDA, 2011)." According to the records provided patient has chronic low back pain with history of lumbar spine surgery. Patient has objective findings on the physical examination- thorax and lumbar spine with tenderness and significantly limited flexion and extension in lumbar range of motion and a positive SLR bilaterally with thigh pain to the knee on the right. The patient has chronic pain with abnormal objective findings. The chronic pain is prone to intermittent exacerbations. A request for Nucynta ER 50mg #84 is medically appropriate and necessary for this patient at this juncture.