

<b>Case Number:</b>	CM15-0133131		
<b>Date Assigned:</b>	07/21/2015	<b>Date of Injury:</b>	07/22/2002
<b>Decision Date:</b>	09/23/2015	<b>UR Denial Date:</b>	06/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/09/2015

### 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 64 year old male patient, who sustained an industrial injury on 07/22/2012. He is currently retired. The diagnoses include lumbar radiculopathy and cervical radiculopathy. Per the progress note dated 06/04/2015, his pain was fairly well controlled on current medications which allow him to exercise by walking. He had back pain, bilateral hand swelling, joint pain and muscle ache. The physical examination revealed cervical spine-abnormal head held in forward position. The medications list includes ibuprofen, docuprene, omeprazole, nucynta, lyrica, metformin and hydrocortisone. He has undergone cervical spine fusion surgery at C5-6 and hernia repair in 2008. He has had cervical MRI which revealed protrusion at C5-6 and annular tear at C6-7; lumbar MRI dated 11/10/2011 which revealed multilevel degenerative changes. He has had physical therapy, home exercise program and epidural injections for this injury. He has had urine drug screen on 4/8/15 with consistent results. The treating physician reported requesting authorization for Lyrica and 2 prescriptions of Nucynta.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Nucynta ER 100mg, #60 (Between 06/04/2015-08/10/2015):** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**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 09/08/15) 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 had chronic back pain. He had history of cervical spine fusion surgery. His pain was fairly well controlled on current medications which allow him to exercise by walking. Patient had urine drug screen on 4/08/15 with consistent findings. He has had diagnostic studies with significant abnormal findings. The patient has chronic pain with abnormal objective findings. The chronic pain is prone to intermittent exacerbations. A request for Nucynta ER 100mg, #60 (Between 06/04/2015-08/10/2015) is medically appropriate and necessary for this patient at this juncture for chronic pain as well as for use during acute exacerbations.

**Lyrica 150mg, #60, 1 refill (Between 06/04/2015-09/09/2015):** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Anti-epilepsy Drugs, for pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs), page 16 Pregabalin (Lyrica, no generic available), page 19 Page(s): 99.

**Decision rationale:** Lyrica 150mg, #60, 1 refill (Between 06/04/2015-09/09/2015). Lyrica is an anti-epilepsy medication. According to MTUS chronic pain guidelines, anti-epilepsy drugs are "recommended for neuropathic pain (pain due to nerve damage). 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." According to the records provided patient had chronic back pain. His diagnoses included cervical and lumbar radiculopathy. He had history of cervical spine fusion surgery. His pain was fairly well controlled on current medications which allow him to exercise by walking. Patient has history of cervical spine fusion surgery. Lyrica is medically appropriate and necessary in such a clinical situation. The request of Lyrica 150mg, #60, 1 refill (Between 06/04/2015-09/09/2015) is medically necessary and appropriate for this patient.

**Nucynta ER 100mg, #60 (Between 06/04/2015-07/03/2015):** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chapter: Pain (updated 09/08/15) Tapentadol (Nucynta) Page(s): 74-96.

**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 had chronic back pain. He had history of cervical spine fusion surgery. His pain was fairly well controlled on current medications that allow him to exercise by walking. Patient had urine drug screen on 4/08/15 with consistent findings. He has had diagnostic studies with significant abnormal findings. The patient has chronic pain with abnormal objective findings. The chronic pain is prone to intermittent exacerbations. A request for Nucynta ER 100mg, #60 (Between 06/04/2015-07/03/2015) is medically appropriate and necessary for this patient at this juncture for chronic pain as well as for use during acute exacerbations.