

<b>Case Number:</b>	CM13-0063788		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	06/16/2003
<b>Decision Date:</b>	10/31/2014	<b>UR Denial Date:</b>	11/21/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/09/2013

### 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 Physical Medicine and Rehabilitation and is licensed to practice in California. 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:

The injured worker is a 32 year old male with a date of injury on 6/16/2003. As per the report of 05/31/13, he complained of continued low back pain/leg pain, persistent left leg weakness and anxiety. Back exam revealed tightness and tenderness to palpation of bilateral lumbosacral paraspinal muscles. Magnetic resonance imaging scan of the lumbar-sacral spine dated 08/11/03 revealed left disc protrusion and spondylolisthesis at L5-S1 with left foraminal narrowing. Urine drug screens done on 08/08/13 and 10/03/13 were normal. Qualitative drug screen dated 09/27/13 revealed positive Meprobamate. He underwent a total disc replacement at L5-S1 on 01/15/08. His current medications include Nucynta, Soma, Daypro, Valium, Ketoprofen ointment, Cymbalta, Atarax, Abilify, BuSpar, and Senokot-S. He had inadequate pain relief, constipation and sedation with Lortab. He has been taking Nucynta since at least 05/22/13. Valium helped with anxiety and panic attacks. Transcutaneous electrical nerve stimulation unit helped with pain. His diagnoses include lumbosacral disc injury, lumbosacral radiculopathy and chronic pain syndrome with depression. The request for Nucynta 100MG #240 eight tablets per day plus one refill was modified to #210 seven tablets per day plus one refill on 11/22/13 in accordance with medical guidelines.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Nucynta 100mg #210 Seven Tablets per Day plus One Refill: 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), TWC, Pain, Tapentadol (Nucynta) and <http://www.drugs.com/tapentadol.html>.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Tapentadol (Nucynta)

**Decision rationale:** Chronic Pain Medical Treatment Guidelines do not address the issue. Per the Official Disability Guidelines, Nucynta is recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids. These recent large randomized clinical trials concluded that 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. Guidelines indicate "four domains have been proposed as most relevant for ongoing monitoring of chronic pain workers on opioids; pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. There is no documentation of any significant improvement in pain level (i.e. visual analog scale) or function with prior use to demonstrate the efficacy of this medication. The medical documents do not show failure of first line therapy. Furthermore, conversion to long acting opioids should be considered when large doses of short-acting opioids are desired for continuous around the clock pain management. Therefore, the medical necessity for Nucynta has not been established based on guidelines and lack of documentation.