

Case Number:	CM15-0125189		
Date Assigned:	07/13/2015	Date of Injury:	11/18/2011
Decision Date:	08/06/2015	UR Denial Date:	06/19/2015
Priority:	Standard	Application Received:	06/29/2015

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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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(n) 45 year old male, who sustained an industrial injury on 11/18/11. He reported pain in his back and legs after a 24 foot fall off a ladder. The injured worker was diagnosed as having right L5 and S1 radiculopathy, right lateral disc protrusion at L4-L5, lumbar degenerative disc disease and lumbar facet joint arthropathy. Treatment to date has included a lumbar epidural injection on 4/19/12, physical therapy, a selective nerve root block with 50% relief, a lumbar MRI showing L5-S1 4mm disc protrusion and NSAIDs. Current medications include Atenolol, medical THC, Norco and Nucynta since at least 12/27/12. On 4/9/15, the injured worker reported 8/10 pain without medications and 6/10 with medications. The pain medication provides relief after 30-60 minutes. As of the PR2 dated 6/4/15, the injured worker reports low back pain that radiates to the right lower extremity. Objective findings include restricted lumbar range of motion in all directions due to pain, a positive straight leg raise test on the right and tenderness to palpation of the lumbar paraspinal muscles. The treating physician requested to continue Nucynta ER 100mg #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nucynta ER 100mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: MTUS states regarding the use of opioids that ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. ODG states "Recommended only as second line therapy for patients who develop intolerable adverse effects with first line opioids. Three large RCTs 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. (Afilalo, 2010) (Buynak, 2010) (Lange, 2010) Tapentadol is a centrally acting oral analgesic. It has two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition. (Johnson, 2008) Nucynta (tapentadol) was made a Schedule II controlled substance. Nucynta may be abused by crushing, chewing, snorting or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death. (FDA, 2009) 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; if patients on OxyIR complain of constipation, nausea, and/or vomiting, Nucynta might be considered as a second-line choice. (Daniels, 2009) (Daniels2, 2009) (Hale, 2009) (Hartrick, 2009) (Stegmann, 2008) In one study, gastrointestinal adverse events led to discontinuation in 9% of the tapentadol group versus 22% of the oxycodone group. (Wild, 2010) This review questioned the opioid potency of tapentadol, and suggested that it affects pain modulation through inhibition of norepinephrine. (Prommer, 2010) But the manufacturer disagrees. (Nelson, 2011) In August 2011 FDA approved tapentadol extended release (Nucynta ER) for moderate to severe chronic pain. Nucynta was already approved for acute pain. (FDA, 2011)" Guidelines recommend Nucynta as a second line medication when patient has adverse effects from first line opioids. Medical documentation provided indicates this patient is currently taking Norco without adverse effects. As such, the request for Nucynta ER 100mg #60 is not medically indicated.