

Case Number:	CM14-0119078		
Date Assigned:	08/06/2014	Date of Injury:	08/01/2006
Decision Date:	09/11/2014	UR Denial Date:	07/28/2014
Priority:	Standard	Application Received:	07/29/2014

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 Orthopedic Surgery and is licensed to practice in Pennsylvania, Connecticut and Texas. 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 claimant is a 54-year-old female injured in a work-related accident on August 1, 2006. The records provided for review state that the claimant has not performed work activities since mid-2007 due to neck, cervical and upper extremity complaints. A June 19, 2014, progress report describes complaints of headache and severe neck and upper extremity pain. Objective findings include restricted cervical and thoracic range of motion with multiple myofascial trigger points, tenderness to the neck, diminished grip strength to the upper extremities and restricted shoulder motion. The claimant was diagnosed with chronic myofascial pain syndrome, cervical sprain, radiculopathy, bilateral carpal tunnel syndrome, bilateral shoulder strain and daily headaches. This request is for continued use of Nucynta.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nucynta Tablets 50mg QTY: 240: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Treatment Guidelines; Opioids for Chronic Pain; When to Discontinue Opioids; When to Continue Opioids Page(s): ; 79, 80, 81.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Worker's Comp, 18th Edition, 2013 Updates: pain procedure Tapentadol

(Nucynta®) Recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids. These recent 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) On November 21, 2008, the FDA approved tapentadol immediate-release tablets for relief of moderate to severe acute pain. Tapentadol, manufactured by Johnson & Johnson Pharmaceutical, is a new 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. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty. 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, so if patients on OxyIR complain of constipation, nausea, and/or vomiting, Nucynta might be recommended as a second-line choice. (Daniels, 2009) (Daniels2, 2009) (Hale, 2009) (Hartrick, 2009) (Stegmann, 2008) 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).

Decision rationale: California MTUS and ACOEM Guidelines do not provide criteria relevant to this request. Under at Official Disability Guidelines, the use of Nucynta would not be indicated. According to the ODG Guidelines, this agent is recommended as a second-line therapy for claimants who develop intolerable adverse effects from first-line opioid agents. The documentation does not identify unsuccessful management with first-line opioids. Therefore, the request for Nucynta cannot be recommended as medically necessary.