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| <b>Case Number:</b>   | CM14-0205550 |                              |            |
| <b>Date Assigned:</b> | 12/17/2014   | <b>Date of Injury:</b>       | 10/30/2002 |
| <b>Decision Date:</b> | 02/17/2015   | <b>UR Denial Date:</b>       | 11/12/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 12/09/2014 |

### 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 Anesthesiology, has a subspecialty in Acupuncture & Pain Medicine 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:

65y/o female injured worker with date of injury 10/30/02 with related neck and low back pain. Per progress report dated 10/27/14, the injured worker complained of neck pain that radiated down the bilateral upper extremities. She also complained of low back pain that radiated down the bilateral lower extremities. Her pain was accompanied by numbness frequently in the bilateral lower extremities to the level of the feet and muscle weakness constantly in the bilateral lower extremities. She rated her pain 8/10 in intensity with medications, and 10/10 without. Per cervical examination, there was spasm noted bilaterally in the trapezius muscles and bilaterally in the paraspinous muscles. Spinal vertebral tenderness was noted in the cervical spine C4-C7. There was tenderness to palpation at C4-C7. Myofascial trigger points with twitch response were noted in the trapezius muscles bilaterally. Range of motion was moderately limited due to pain. Per lumbar examination, there was spasm noted in the bilateral paraspinous musculature. Tenderness was noted upon palpation in the bilateral paravertebral area L4-S1 levels. There was decreased strength of the extensor muscles along the L4-S1 dermatome and flexor muscles along the L4-S1 dermatome in the bilateral lower extremities. Straight leg raise was positive bilaterally in the seated position. Treatment to date has included physical therapy and medication management. The date of UR decision was 11/12/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Nucynta ER 50mg Tablet, SIG take 1 po BID Qty 60:** 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) (Tapentadol (Nucynta))

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78.

**Decision rationale:** Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug related behaviors. These domains have been summarized as the '4 As' (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." The MTUS is silent on the use of Nucynta specifically. With regard to tapentadol (Nucynta), the ODG states: "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." Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug related behaviors. These domains have been summarized as the '4 As' (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Review of the available medical records reveals no documentation to support the medical necessity of Nucynta nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for my review. The MTUS recommends to discontinue opioids if there is no overall improvement in function. Furthermore, the documentation submitted for review did not contain evidence of failure of first line opioids. Medical necessity cannot be affirmed. Therefore this request is not medically necessary.