

Case Number:	CM14-0131358		
Date Assigned:	08/27/2014	Date of Injury:	12/03/2003
Decision Date:	09/29/2014	UR Denial Date:	08/14/2014
Priority:	Standard	Application Received:	08/18/2014

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 Anesthesia, 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:

This patient is a 48 year old male injured worker with date of injury 12/3/03 with related low back pain. Per progress report dated 8/12/14, the injured worker complained of low back pain and lower extremity pain. Spasms and lumbar tenderness were noted per physical exam. Imaging studies were not available for review. The documentation submitted for review did not state whether physical therapy was utilized. Treatment to date has included medication management. The date of Utilization Review (UR) decision was 8/14/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Duragesic 100mcg #15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, for chronic pain Page(s): 80-81.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 44,76,78.

Decision rationale: Per MTUS CPMTG, fentanyl transdermal is indicated for management of persistent chronic pain, which is moderate to severe requiring continuous, around-the-clock opioid therapy. It is not recommended as a first-line therapy. The FDA-approved product labeling states that Duragesic (fentanyl transdermal) is indicated in the management of chronic

pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means. 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 Duragesic 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. As MTUS recommends to discontinue opioids if there is no overall improvement in function, the request is not medically necessary and appropriate.

Nucynta 100mg #180: 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).

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. The request is not medically necessary and appropriate.

Parafon Forte 500mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 53-66.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antispasmodics Page(s): 65.

Decision rationale: Per MTUS with regard to Parafon Forte: "This drug works primarily in the spinal cord and the subcortical areas of the brain. The mechanism of action is unknown but the effect is thought to be due to general depression of the central nervous system. Advantages over other muscle relaxants include reduced sedation and less evidence for abuse." With regard to muscle relaxants, the MTUS Chronic Pain Medical Treatment Guidelines page 63 states: "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic Low Back Pain (LBP). The medical records submitted for review do not document an acute exacerbation of LBP. The request is not medically necessary and appropriate.