

Case Number:	CM15-0223248		
Date Assigned:	11/19/2015	Date of Injury:	11/15/2003
Decision Date:	12/31/2015	UR Denial Date:	10/09/2015
Priority:	Standard	Application Received:	11/13/2015

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: California, District of Columbia,
Maryland Certification(s)/Specialty: Anesthesiology, Pain
Management

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 48 year old male, who sustained an industrial injury on 11-15-2003. The injured worker is currently off work. Medical records indicated that the injured worker is undergoing treatment for lumbar radiculopathy, hypogonadism, and depression. Treatment and diagnostics to date has included lumbar spine MRI and medications. Recent medications have included Duragesic patch, Vicodin, Pristiq, and Testosterone. Subjective data (08-17-2015 and 09-28-2015), included radiating low back pain down to lower extremities. Objective findings (09-28-2015) included positive straight leg raise test and tenderness to L4, L5, and S1. The request for authorization dated 10-01-2015 requested Fentanyl patch 100mg every 72 hours #15, Hydrocodone, Pristiq, and AndroGel 1% pump, 8 pumps daily #150. The Utilization Review with a decision date of 10-08-2015 non-certified the request for Fentanyl patches 100mg #15 and Testosterone 200mg.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fentanyl patch 100mg, #15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Duragesic (fentanyl transdermal system), Opioids for chronic pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Duragesic (fentanyl transdermal system), Opioids, criteria for use.

Decision rationale: Per MTUS CPMTG with regard to Duragesic: "Not recommended as a first-line therapy. Duragesic is the trade name of a fentanyl transdermal therapeutic system, which releases fentanyl, a potent opioid, slowly through the skin. [REDACTED]"

[REDACTED] The FDA-approved product labeling states that Duragesic 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 non-adherent) drug related behaviors. These domains have been summarized as the '4 A's' (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 fentanyl patch 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, medical necessity cannot be affirmed.

Testosterone 200mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Testosterone replacement for hypogonadism (related to opioids).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Testosterone replacement for hypogonadism (related to opioids).

Decision rationale: With regard to testosterone replacement, the MTUS CPMTG states: "Recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. Hypogonadism has been noted in patients receiving intrathecal opioids and long-term high dose opioids." The documentation submitted for review reveals no documented subjective complaints or objective findings that indicate signs or symptoms of hypogonadism. Without documentation of testosterone levels or symptoms of hypogonadism, medical necessity cannot be affirmed. Furthermore, the injured worker is not currently being treated with opiates. The request is not medically necessary.