

<b>Case Number:</b>	CM14-0084516		
<b>Date Assigned:</b>	07/21/2014	<b>Date of Injury:</b>	08/05/1995
<b>Decision Date:</b>	10/03/2014	<b>UR Denial Date:</b>	05/08/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/06/2014

### 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 Occupational 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:

According to the provided documents, this is a 50-year-old gentleman with a date of injury of 8/5/95. There is a 4/14/14 report indicating that patient is followed for chronic low back pain and right more than left leg pain. The report indicates patient had a comprehensive metabolic profile 10/24/13 that was normal except for one liver function test which was elevated but has decreased with every lab draw. Patient's testosterone was low but was increasing with every lab draw indicating that the testosterone therapy was effective. He said he is feeling somewhat better from testosterone therapy. Medications include Flector patch, Clonidine and soma for muscle spasms, Gabapentin for nerve pain, Cymbalta for neuropathy depression and anxiety, Aciphex for gastroesophageal reflux disease. Opiates listed in the current medications are Hydromorphone 4 mg 1-2 tablets every 4 hours and Testosterone Cypionate 200 mg/ml intramuscular oil use .5 ml every 2 weeks. The report requests laboratory test for testosterone prostate specific antigen (PSA) values to monitor testosterone therapy related to hypogonadism from chronic opioid use. There is no mention of what the baseline PSA value was or when the PSA was last measured. There is no mention of any digital rectal examination of the prostate and there is no documentation of any objective findings of physical changes consistent with hypogonadism. There is no mention of when the patient last had a testosterone level drawn, or what the levels were. There is no mention how long the patient's been on testosterone replacement therapy. 2/11/14 and progress report included Testosterone Cypionate as one of the medications, mention the previous 10/24/13 laboratory reports. A 1/16/14 progress report indicated 9/9/13 the patient was concerned about having allergic reaction to the androgen patches. It states that the patient had been on the testosterone IM for 4 months now. 11/14/13 progress report mentioned use of the intramuscular testosterone preparation.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**PSA LAB value:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pmc/articles/pmc1472884> Rev Urol. 2004; 6 )Suppl 6): S3-S8, PMID: PMC1472884 Diagnosis of Hypogonadism: Clinical Assessment and Laboratory Tests, Christina Carnegie, MB, BS, FFPM

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Endocrine Society Guidelines, <http://www.endo-society.org/guidelines/final/upload/FINAL-Androgens-in-Men-Standalone.pdf>: and on the Non-MTUS Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes. First published in Journal of Clinical Endocrinology & Metabolism, June 2010, Vol. 95(6):2536-2559 and on the Non-MTUS website, <http://www.cancer.gov/cancertopics/factsheet/detection/PSA>

**Decision rationale:** Although both MTUS chronic pain guidelines and ODG guidelines address testosterone replacement they do not address appropriate laboratory monitoring for that. The prostate specific antigen test is a protein that is produced by the prostate gland and the higher the level the more likely it is that he has prostate cancer. A person with prostate cancer should not use testosterone supplementation as this can enhance the growth and spread of the cancer. The Endocrine Society guidelines indicates that men over age 40, as this injured worker is, should have a baseline PSA and if that is greater than >0.6 ng/mL should have a digital examination the prostate. There should be PSA measurements after initiating treatment 3-6 months then in accordance with evidence-based guidelines for prostate cancer screening. The submitted documents do not indicate what the patient's initial PSA levels were(or if it was done). The testosterone therapy appears to originally have been instituted with the androgen patch and switched to the intramuscular oil by November 2013, possibly September 2013. Switching a patient to a completely different form of testosterone would logically require checking the PSA level after 3-6 months to make sure that it had not changed substantially. The problem is that the report does not indicate when the patient's PSA levels were last tested. However, the timeframe of this request falls within 3-6 months of starting the new testosterone formulation. In view of the significance of this potential side effect (screening for prostate cancer, which would be a red flag and contraindicates use of testosterone) this request is considered to be medically necessary based upon the evidence and the guidelines.

**Testosterone Lab Test:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pmc/articles/pmc1472884> Rev Urol. 2004; 6 )Suppl 6): S3-S8, PMID: PMC1472884 Diagnosis of Hypogonadism: Clinical Assessment and Laboratory Tests, Christina Carnegie, MB, BS, FFPM

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**Decision rationale:** As noted above, MTUS and ODG guidelines are silent on laboratory monitoring for patients taking testosterone replacement therapy. The above-mentioned guidelines recommend baseline testosterone levels in men monitoring levels 3 to 6 months after initiation of testosterone therapy. For men receiving the testosterone Cypionate, the suggestion is to aim for testosterone levels between 400-700 mg/dL one week after the injection. In this case, the requesting document states that "Patients testosterone was low but was increasing with every lab draw indicating that the testosterone therapy was effective." This implies that there have been serial testosterone levels drawn. There is no mention when the last one was or what the value was. Without that knowledge it is impossible to determine if it is time to repeat the level. Therefore, based upon the evidence and the guidelines this is not considered to be medically necessary.