

Case Number:	CM14-0033295		
Date Assigned:	03/21/2014	Date of Injury:	02/07/2008
Decision Date:	06/30/2014	UR Denial Date:	02/24/2014
Priority:	Standard	Application Received:	03/17/2014

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:

The patient is a 58 year old male who was injured on 02/07/2008 when he was involved in a confrontation with someone at work. He was thrown on his desk and landed on his knees. Prior treatment history has included the following medications: Hydrocodone 10-325 mg, Nabumetone 500 mg, Pantoprazole 20 mg, Tizanidine 4 mg, Trazadone 50 mg, Fortesta 10 mg Gel Pump and Wellbutrin SR 150 mg. A progress note dated 02/18/2014 documented the patient presents with chronic neck, shoulder and bilateral knee pain. He continues to have pain level that is 8/10 with use of medications or without medications. His pain level is 10/10 on VAS. With use of his medication he is able to work better with less pain. The patient reports that he is tolerating his medications generally well. A review of systems shows no indication of erectile dysfunction. The diagnoses are neck pain, pain in lower joint leg and right knee and pain in joint of left shoulder. Per the documentations the provider states, "The patient did have testosterone level checked in 2012, which did show a low testosterone. We will request a recheck of his testosterone level to see if it is still low. Patient may have opioid-induced hypogonadism." There is a UR appeal from treating doctor that states the patient had an AME on 06/11/2012 but the actual report was not received. The patient did report an erectile dysfunction post his injury. ■■■ recommended obtaining a testosterone level to see if he needs testosterone replacement. "We did review the results of his testosterone level dated 07/06/2012, which did fall below the referenced range of 46-224.0 pg/ml at 41.9. Patient was found to be hypogonadal presumably due to chronic opioid usage." The UR report dated 02/24/2014 denied the request for Fortesta 10 mg Gel Pump with 3 refills as the patient is not documented to have any objective findings on examination consistent with hypogonadism. There are no documented subjective complaints. The patient is noted to be on opioids at the present time. There is no demonstrated objective evidence that the prescribed opioids have induced hypogonadism. Recent medical literature

indicates that the use of topical testosterone has led to an increase of coronary artery disease, heart disease and stroke. If the patient has opioid induced hypogonadism should be titrated down and off chronic opioids consistent with evidence based guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETRO: FORTESTA 10MG GEL PUMP 10MG/0.5 ACTUATION WITH 3 REFILLS (12/11/13): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 80-82.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Testosterone Replacement for Hypogonadism (related to opioids) Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2010; 95(6):2536-59 (ISSN: 1945-7197)

Decision rationale: California MTUS guidelines do not address the issue in dispute and hence ODG have been consulted. According to ODG guidelines, testosterone replacement for hypogonadism (related to opioids) is 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. Routine testing of testosterone levels in men taking opioids is not recommended. However, an endocrine evaluation and/or testosterone levels should be considered in men who are taking long term, high dose oral opioids or intrathecal opioids and who exhibit symptoms or signs of hypogonadism, such as gynecomastia. If needed, testosterone replacement should be done by a physician with special knowledge in this field given the potential side effects such as hepatomas. The patient is a 58 year old male with chronic pain injured on 2/7/08. This is a request for Fortesta (testosterone) 10 mg gel pump for treatment of hypogonadism, as evidenced by complaints of erectile dysfunction and low free serum testosterone level tested in 2012, presumed to be partially caused by chronic opioid use. Medical necessity and appropriateness have not been established in this case. It does not appear that testosterone replacement is being performed by a physician with special knowledge in this field. The patient is being prescribed testosterone gel by his pain management physician and is apparently getting annual digital rectal exams and PSA checks by a separate primary care physician, but no such records are provided for review. Only one testosterone value is discussed, and lab results are not provided for review. There is no confirmatory or serial testosterone levels provided, the latter of which should be done on at least a yearly basis along with other blood work to include hematocrit level. Further, medical records suggest the patient has obstructive sleep apnea, possibly severe given multiple high risk factors. Work-up and treatment of sleep apnea are not provided. Testosterone replacement is not recommended in patients with untreated severe obstructive sleep apnea. In sum, the patient appears to have hypogonadism, but records fail to establish that testosterone replacement is appropriate in this case or that it is being provided with appropriate ongoing evaluation.