

Case Number:	CM14-0003665		
Date Assigned:	01/31/2014	Date of Injury:	05/25/2009
Decision Date:	08/04/2014	UR Denial Date:	12/05/2013
Priority:	Standard	Application Received:	01/09/2014

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 Pain Management 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 has submitted a claim for cervical sprain/strain, cervical radiculitis right upper extremity, right shoulder sprain/strain, bilateral median and ulnar neuropathies per EMG, history of elevated liver enzymes, anxiety, sleep disturbance, sexual dysfunction associated with an industrial injury date of May 25, 2009. Medical records from 2012- 2013 were reviewed which revealed persistent cervical spine pain. He reported presence of erectile dysfunction and lack of libido. He remained symptomatic with anxiety and insomnia. Pain was 5/10. He was able to do his ADLs with his medications. No side effects were noted except low testosterone level. Physical examination of the cervical spine showed moderate bilateral cervical paraspinous tenderness with muscle spasm. There was decreased cervical range of motion. Right shoulder exam revealed tenderness over the anterior aspect. Neer and Hawkin tests were positive. Spurling maneuver was positive. Phalen's sign was positive. Laboratory study done on February 12, 2013 showed testosterone level of 736 ng/dL (normal range 241-827 ng/dL). Bioavailable testosterone was 61.7 ng/dL (normal range 110-575ng/dL), free testosterone was 35.2 (normal range 46-224 pg/mL) and total testosterone was 884 (normal range 250-1100). Treatment to date has included, cervical epidural injections and medications such as, Norco 10/325 mg, Prilosec, Xanax, Ambien, Lunesta and Fortesta. Utilization review from December 5, 2013 denied the request for Fortesta 2% #60 because patient's laboratory study indicated that his testosterone level is near the high range of normal and does not support medical necessity of testosterone therapy.

IMR ISSUES, DECISIONS AND RATIONALES

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

FORTESTA 2 % # 60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/fortesta.html>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: A Novel Testosterone 2% Gel for the Treatment of Hypogonadal Males, Journal of Andrology, Vol 33, No.4, page 601 (<http://www.ncbi.nlm.nih.gov/pubmed/21979302>).

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy, Journal of Andrology, Vol.33, No. 4 was used instead. It stated that testosterone replacement therapy (TRT) could improve the symptoms, signs, and well being of hypogonadal men by restoring serum testosterone concentration to physiologic levels. In this case, patient has been taking Fortesta, a testosterone replacement therapy since at least 12/13/12. No significant improvement was mentioned in the medical records with the use of Fortesta. He still has erectile dysfunction and lack of libido. In addition, progress report, dated February 12, 2013, revealed that patient's testosterone level was already 736ng/dL, which is within physiologic level (normal range 241-827 ng/dL). Medical necessity of the requested drug was not established. Therefore, the request for FORTESTA 2 % # 60 is not medically necessary.