

<b>Case Number:</b>	CM14-0098518		
<b>Date Assigned:</b>	09/16/2014	<b>Date of Injury:</b>	04/25/1988
<b>Decision Date:</b>	10/15/2014	<b>UR Denial Date:</b>	05/29/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/26/2014

### 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 Family 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 is a 52-year-old male who reported an industrial injury to the back on 4/25/1988, over 26 years ago, attributed to the performance of his usual and customary job tasks. The patient has been treated for the diagnoses of lumbar disc injury; lumbar facet arthralgia; bilateral sciatica; and L5-S1 fusion. The patient is reported to complain of continued lower back pain radiating to the bilateral lower extremities. The patient is being treated with radiofrequency ablation. The patient is being prescribed Percocet 10 mg; soma 350 mg; and fentanyl patches 25 mcg/hr. Clinical documentation to support the medical necessity of the requested Andro Gel pump 1.62% was not provided. The patient was documented to have a Testosterone level tested 10 months ago; however, there were no findings on examination provided to support medical necessity. The treatment plan included a refill of Soma and a refill of AndroGel 1.62% pump.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **Three Refills of AndroGel Pump 1.62%: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation <http://www.endo-society.org/guidelines/final/upload/FINAL-Androgens-in Men-Standalone.pdf>

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 74-97. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

pain chapter-opioids Other Medical Treatment Guideline or Medical Evidence: Endocrine Society clinical practice guideline-testosterone therapy in adult men with androgen deficiency syndromes

**Decision rationale:** The medical literature has reported that the use of topical testosterone has led to a significant increase in heart disease; coronary artery disease; and CVAs. Attorneys have initiated class action suits against the manufacturers based on the manufacture of topical agents that lead to increased heart disease and strokes. There is no demonstrated medical necessity for the provision of topical testosterone for ED as topical testosterone may act to improve desire, it has no demonstrated effect for ED. There is no demonstrated medical necessity for the prescribed AndroGel pump topical testosterone for the effects of the industrial injury and there is no objective evidence provided for the medical necessity of supplemental testosterone. It is not clear that the prior use of topical testosterone has resulted in any functional improvement. It is not clear that the patient is not being treated only for a lower number somewhat consistent with age with the laboratory findings of testosterone levels. The lower testosterone level is speculated to be due to the prolonged opioid therapy; however, there is no evidence that the current testosterone levels are not consistent with the patient's age. There is no objective evidence documented of a prostate examination or a PSA to evaluate side effects of the previously prescribed topical testosterone. The patient is demonstrated to have been placed on chronic opioid therapy and is reportedly at risk of hypogonadism attributed to low testosterone levels induced by opioid therapy; however, 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. There was no quantitative serum value provided to support the medical necessity of prescribing topical testosterone. There were no objective findings on examination and no subjective complaints related to possible hypogonadism. The patient was speculated to have possible low testosterone levels without documentation of a current serum level for objective findings on examination consistent with hypogonadism. Recent medical literature indicates that the use of topical testosterone has led to an increase in coronary artery disease; heart disease; and strokes. The newer precautions directed to the use of topical steroid applications suggest that there is no medical necessity for the provision of topical testosterone for the treatment of ongoing opioid therapy. If the patient has opioid induced hypogonadism should be titrated down and off chronic opioids consistent with evidence based guidelines. The treating physician has provided no objective evidence to support the medical necessity of the requested AndroGel pump 1.62% with 3 refills to treat a suspected hypogonadism based on the prolonged use of opioids with no current quantitative serum testosterone level to support the medical necessity of topical therapy with testosterone. The request for Three Refills of AndroGel Pump 1.62% is not medically necessary.