

<b>Case Number:</b>	CM13-0058667		
<b>Date Assigned:</b>	06/09/2014	<b>Date of Injury:</b>	10/08/1998
<b>Decision Date:</b>	07/24/2014	<b>UR Denial Date:</b>	10/30/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/27/2013

### 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 Practice 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:

47 yr. old male claimant sustained a work injury on involving the low back, neck and head. He had multiple fractures from a fall as well as a traumatic brain injury. He has a diagnosis of degenerative disc disease, disk herniation, spinal stenosis and chronic back pain. In the past he had used Flexeril and Oxcontin for chronic pain. A progress note in October 2013 indicated he had been on Cymbalta and Flexeril for pain. He had been on Viagra and Androgel for erectile dysfunction for several months. The treating physician prescribed Androgel on 10/22/13.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**ANDROGEL 1% 5GM:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 110.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines testosterone replacement Page(s): 110.

**Decision rationale:** According to the MTUS guidelines Testosterone replacement for hypogonadism (related to opioids). 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. There are multiple delivery mechanisms for testosterone. Hypogonadism secondary to opiates appears to be central, although the exact mechanism has not been determined. The evidence on testosterone levels in long-term opioid users is not randomized or double-blinded, but there are studies that show that there is an increased incidence of hypogonadism in people taking opioids, either intrathecal or oral. There is also a body of literature showing that improvement in strength and other function in those who are testosterone deficient who receive replacement. (Nakazawa, 2006) (Page, 2005) (Rajagopal, 2004) This appears to be more pronounced than in patients taking oral opiates than in patients receiving intrathecal opioids, and this difference seems to be related to differences in absorption. Hypogonadism secondary to opiates appears to be central, although the exact mechanism has not been determined. (Abs, 2000) (Roberts, 2002) (Roberts, 2000) Etiology of decreased sexual function, a symptom of hypogonadism, is confounded by several factors including the following: (1) The role of chronic pain itself on sexual function; (2) The natural occurrence of decreased testosterone that occurs with aging; (3) The documented side effect of decreased sexual function that is common with other medications used to treat pain (SSRIs, tricyclic antidepressants, and certain anti-epilepsy drugs); & (4) The role of comorbid conditions such as diabetes, hypertension, and vascular disease in erectile dysfunction. There is little information in peer-reviewed literature as to how to treat opioid induced androgen deficiency. Long-term safety data of testosterone replacement (overall): Not available. Cardiovascular risk: There have been no large randomized controlled trials to evaluate the cardiovascular risk associated with long-term testosterone use, although current studies weakly support that there is no association with important cardiovascular effects. (Haddad 2007); Osteoporosis: The extent to which testosterone can prevent and treat osteoporosis remains unclear. (Tracz 2006) (Isidori, 2005); Sexual function: Current trials of testosterone replacement in patients with documented low testosterone levels have shown a moderate nonsignificant and inconsistent effect of testosterone on erectile function, a large effect on libido, and no significant effect on overall sexual satisfaction. (Bolona, 2007) (Isidori, 2005); The one study (sponsored by the drug company) that has evaluated the use of testosterone replacement in patients with opioid-induced androgen deficiency, measured morning serum free testosterone levels and PSA prior to replacement. This study did not include patients taking antidepressants. (Daniell, 2006); In this case, the claimant was not recently on opioids (October 2013) to suggest long-term high dose opioid use. In addition, no testosterone levels were performed to note a low level. Furthermore, it is not clear if the testosterone replacement is necessary based on the injury or as a process of aging. In addition there is insubstantial evidence to support its long-term use. Therefore the request for Androgel is not medically necessary.