

<b>Case Number:</b>	CM15-0080308		
<b>Date Assigned:</b>	05/01/2015	<b>Date of Injury:</b>	05/09/1995
<b>Decision Date:</b>	06/01/2015	<b>UR Denial Date:</b>	04/07/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/27/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: New Jersey

Certification(s)/Specialty: Family Practice

### 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 injured worker is 65 year old male, who sustained an industrial injury on May 9, 1995. The injured worker has been treated for low back, shoulder and knee complaints. The diagnoses have included cervical disc disease, lumbar disc disease, bilateral chronic knee pain, status post bilateral knee replacements, left shoulder pain, status post left shoulder dislocation, right shoulder sprain/strain, bilateral ankle sprain/strain, erectile dysfunction, status post penile implant and hypogonadism, which is industrially caused. Treatment to date has included medications, radiological studies, electrodiagnostic studies, urology consultation and Testopel pellet implantation. Current documentation dated March 10, 2015 notes that the injured worker reported fatigue and less libido. The injured workers hypogonadism was noted to be contributed to the use of his chronic pain medication. The injured worker had prior testosterone pellet implantation performed, which was effective with improved energy, drive, and lack of fatigue for three months. The documentation notes that the effects of the pellets were now gone and the treating physician recommended a follow-up visit for a testosterone draw and to repeat the implantation of the Testopel pellets. The treating physician's plan of care included a request for a follow-up visit, Testopel implantation and Testopel pellets # 10.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Follow-up visit:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 5 Cornerstones of Disability Prevention and Management.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Low Back section, Office visits.

**Decision rationale:** The MTUS Guidelines are silent on office visits with a physician. The ODG, however, states that they are recommended as determined to be medically necessary, and clearly should be encouraged. The need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs, and symptoms, clinical stability, and reasonable physician judgment. A set number of visits cannot be reasonable established, however, the clinician should be mindful of the fact that the best patient outcomes are achieved with eventual patient independence from the health care system through self care as soon as clinically feasible. In the case of this worker, the purpose of the follow-up visit requested was to perform a repeat implantation of Testopel testosterone pellets to help treat what was diagnosed as hypogonadism, reportedly related to his opioid use. He reported his symptoms of fatigue, reduced libido was returning months after a previous implantation of Testopel pellets. However, the request for repeat implantation must be preceded with recent objective supportive evidence of a testosterone deficiency beforehand, which was not seen in the documentation provided for review. Therefore, the follow-up and procedure will be considered not medically necessary until a current testosterone level is provided for review.

**Testopel pellets x 10:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Institutes of Health.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids) Page(s): 110-111.

**Decision rationale:** The MTUS Chronic Pain Guidelines state that testosterone supplementation is recommended in limited circumstances for documented cases of low testosterone levels associated with symptoms of low testosterone (gynocomastia, decreased libido, etc.) and only when clearly associated with chronic high-dose opioid use. Decreased sexual function can also be related to normal aging, diabetes, side effects of other medication besides opioids (antidepressants, certain anti-epileptics), cardiovascular disease, and hypertension, any of which may confound any determination of causation from opioid use alone. There is little information in peer-reviewed literature that discusses how to treat opioid-induced androgen deficiency. Prescribing testosterone, if considered, should be done by an experienced physician with a special knowledge in this field, given the potential side effects such as hepatomas. In the case of this worker it was requested to perform a repeat implantation of Testopel testosterone pellets (x10) to help treat what was diagnosed as hypogonadism, reportedly related to his opioid use. He reported his symptoms of fatigue and reduced libido was returning months after a previous implantation of Testopel pellets. However, the request for repeat implantation must be preceded

with recent objective supportive evidence of a testosterone deficiency beforehand, which was not seen in the documentation provided for review. Also it is recommended to use up to 6 Testopel pellets per implantation and the request was for 10. Therefore, Testopel pellets will be considered not medically necessary until a current testosterone level is provided for review and the dose reduced.

**Testopel implantation x 1:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Institute of Health.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids) Page(s): 110-111.

**Decision rationale:** The MTUS Chronic Pain Guidelines state that testosterone supplementation is recommended in limited circumstances for documented cases of low testosterone levels associated with symptoms of low testosterone (gynecomastia, decreased libido, etc.) and only when clearly associated with chronic high-dose opioid use. Decreased sexual function can also be related to normal aging, diabetes, side effects of other medication besides opioids (antidepressants, certain anti-epileptics), cardiovascular disease, and hypertension, any of which may confound any determination of causation from opioid use alone. There is little information in peer-reviewed literature that discusses how to treat opioid-induced androgen deficiency. Prescribing testosterone, if considered, should be done by an experienced physician with a special knowledge in this field, given the potential side effects such as hepatomas. In the case of this worker it was requested to perform a repeat implantation of Testopel testosterone pellets (x10) to help treat what was diagnosed as hypogonadism, reportedly related to his opioid use. He reported his symptoms of fatigue and reduced libido was returning months after a previous implantation of Testopel pellets. However, the request for repeat implantation must be preceded with recent objective supportive evidence of a testosterone deficiency beforehand, which was not seen in the documentation provided for review. Therefore, Testopel implantation will be considered not medically necessary until a current testosterone level is provided for review and the dose reduced.