

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM14-0008222 | | |
| Date Assigned: | 02/12/2014 | Date of Injury: | 03/28/2007 |
| Decision Date: | 10/07/2014 | UR Denial Date: | 12/27/2013 |
| Priority: | Standard | Application Received: | 01/22/2014 |

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 General Preventive Medicine and is licensed to practice in Indiana. 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 employee is a 49 year old male with date of injury of 3/28/2007. A review of the medical records indicate that the patient is undergoing treatment for cervical sprain, multilevel disc protrusions, prostate cancer, erectile dysfunction (after radical prostatectomy), hypogonadism, urinary incontinence, urinary frequency, and urgency. Subjective complaints include decreased libido and difficulty with erections. Objective findings include decreased range of motion of cervical and lumbar spine, and total serum testosterone of 537 ng/dl. Treatment has included IM testosterone, Kegel exercises, Trimix injections and Viagra. The utilization review dated 12/27/2013 partially-certified Trimix injection compound (3 times a week for indefinite period of time).

IMR ISSUES, DECISIONS AND RATIONALES

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

TRIMIX (INTRACORPORAL) INJECTION COMPOUND (3 TIMES A WEEK FOR INDEFINITE PERIOD OF TIME): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation PENILE REHABILITATION FOLLOWING RADICAL PROSTATECTOMY: ROLE OF EARLY INTERVENTION AND CHRONIC THERAPY, UROLOGIC CLINICS OF NORTH AMERICA, VOLUME 34, ISSUE 4 (NOVEMBER 2007).

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: (PubMed): A review of outcomes of an intracavernosal injection therapy programme. BJU Int. 2012 Dec;110(11):1787-91.

Decision rationale: The MTUS and ACOEM guidelines are silent on Trimix. According to the latest medical research, intracorporal injection (ICI) has shown a lot of success with some caveats in those who have failed PDE therapy: "In all, 1412 patients had complete data and constituted the study population. Most patients were using Trimix and 89% of Trimix users were capable of having sexual intercourse. - Response rates were lower in pelvic radiation and diabetic patients. - However, the discontinuation rate was significant; it was lower in men who had not undergone radical prostatectomy (RP). Of note, many RP patients discontinued ICI because of recovery of natural or phosphodiesterase type 5 inhibitor-assisted erections. ICI therapy is associated with very high success rates even in men with high comorbidity profiles; however, the discontinuation rates, even in men who had not undergone RP, by the end of the third year are significant. - Of note, the recorded priapism rate was extremely low (0.5%)."Due to the high potential for discontinuance, this therapy needs to be periodically monitored and potentially modified, especially if PDE inhibitors become effective again (since currently he is failing Viagra therapy). Therefore, the request for Trimix for an indefinite period of time is not medically necessary.