

Case Number:	CM15-0033836		
Date Assigned:	02/27/2015	Date of Injury:	03/29/2007
Decision Date:	04/10/2015	UR Denial Date:	01/23/2015
Priority:	Standard	Application Received:	02/23/2015

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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 a 38-year-old male, who sustained an industrial injury on March 29, 2007. The diagnoses have included paraplegia and erectile dysfunction. Currently, the injured worker reports left shoulder and neck pain, which he describes as a pulling sensation when he turns his head to the right. He reports minimal low back pain. The injured worker continues going to the gym and following a home exercise program. The documentation indicates the injured worker is trying to get his prescription for Tri-Mix filled for his sexual dysfunction. On January 23, 2015 Utilization Review non-certified a request for Tri-Mix 5 ml prostaglandin E1, 30 mg/ml Papaverine, 10 mcg Phentolamine and one injection kit with five refills, noting that the medical records do not reflect a trial of PDE51 drugs and intracavernous injections are considered second line treatment options. Failure of first-line treatment options must be documented prior to the use of second-line treatments. Non-MTUS references were cited. On February 23, 2015, the injured worker submitted an application for IMR for review of Tri-Mix 5 ml prostaglandin E1, 30 mg/ml Papaverine, 10 mcg Phentolamine and one injection kit with five refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 Prescription of Tri-Mix 5ml Prostaglandin E1, 30mg/ml Papaverine, 10mcg Phentolamine: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Guidelines on male sexual dysfunction: erectile dysfunction and premature ejaculation. Arnhem (The Netherlands): European Association of Urology (EAU); 2013 Mar. 54 p.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate, Treatment of male sexual dysfunction Tsertsvadze A et al, Oral phosphodiesterase-5 inhibitors and hormonal treatments for erectile dysfunction: a systematic review and meta-analysis. Ann Intern Med. 2009; 151(9):650. Manou BK et al, Effect of sildenafil on erectile dysfunction in spinal cord injured patients. Ghana Med J 2009 Sept; 43(3): 132-134.

Decision rationale: The MTUS and ODG are silent on the treatment of erectile dysfunction so other guidelines were used. The current recommendations state that "first-line therapy, we recommend the phosphodiesterase-5 (PDE-5) inhibitors because of their efficacy, ease of use, and favorable side effect profile." In the event of a failure of therapy, or "if PDE-5 inhibitors are ineffective, we suggest vacuum devices, penile self-injectable drugs, and intraurethral alprostadil as second-line therapy." Specific to this case, the patient is a paraplegic. Manou looked at paraplegic and quadriplegic patients and treated them with oral PDE-5 inhibitors. Their results showed "The mean age (range) of the patients was 32.75 yrs (21-53 yrs). The mean duration of their disability was 47.75 months (4 yr). Trauma was the etiology in 87.5% of the cases (44% were road accidents). 12/16 patients were paraplegics (10 above T10) and 4 were tetraplegics (1 above C4 and 3 below C5). The mean duration of sildenafil treatment was 18.75 months (17 days-7 yr). 70% of the patients were satisfied with their erection after treatment. However, 10/16 patients had concomitant treatment with alprostadil." They concluded that "Sildenafil is a vasoactive drug which can be used as a simple, discrete and effective treatment for erectile dysfunction in SCI patients. This approach is compatible with the efforts to improve the quality of life and rehabilitation of these patients." In this case, there is no documentation that the patient has failed first like oral PDE-5 inhibitors. In fact, a UR approved a request for Cialis 5mg on 09/08/14 but there is no documentation if the patient took the medication and how effective it was. As such, the request for 1 Prescription of Tri-Mix 5ml, Prostaglandin E1, 30mg/ml Papaverine, 10mcg Phentolamine is not medically necessary.

1 Injection Kit with 5 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Guidelines on male sexual dysfunction: erectile dysfunction and premature ejaculation. Arnhem (The Netherlands): European Association of Urology (EAU); 2013 Mar. 54 p.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate, Treatment of male sexual dysfunction Tsertsvadze A et al, Oral phosphodiesterase-5 inhibitors and hormonal treatments for erectile dysfunction: a systematic review and meta-analysis. Ann Intern Med.

2009; 151(9):650. Manou BK et al, Effect of sildenafil on erectile dysfunction in spinal cord injured patients. Ghana Med J 2009 Sept; 43(3): 132-134.

Decision rationale: The MTUS and ODG are silent on the treatment of erectile dysfunction so other guidelines were used. The current recommendations state that "first-line therapy, we recommend the phosphodiesterase-5 (PDE-5) inhibitors because of their efficacy, ease of use, and favorable side effect profile." In the event of a failure of therapy, or "if PDE-5 inhibitors are ineffective, we suggest vacuum devices, penile self-injectable drugs, and intraurethral alprostadil as second-line therapy." Specific to this case, the patient is a paraplegic. Manou looked at paraplegic and quadriplegic patients and treated them with oral PDE-5 inhibitors. Their results showed "The mean age (range) of the patients was 32.75 yrs (21-53 yrs). The mean duration of their disability was 47.75 months (4 yr). Trauma was the etiology in 87.5% of the cases (44% were road accidents). 12/16 patients were paraplegics (10 above T10) and 4 were tetraplegics (1 above C4 and 3 below C5). The mean duration of sildenafil treatment was 18.75 months (17 days-7 yr). 70% of the patients were satisfied with their erection after treatment. However, 10/16 patients had concomitant treatment with alprostadil." They concluded that "Sildenafil is a vasoactive drug which can be used as a simple, discrete and effective treatment for erectile dysfunction in SCI patients. This approach is compatible with the efforts to improve the quality of life and rehabilitation of these patients." In this case, there is no documentation that the patient has failed first like oral PDE-5 inhibitors. In fact, a UR approved a request for Cialis 5mg on 09/08/14 but there is no documentation if the patient took the medication and how effective it was. As such, the request for 1 Injection Kit with 5 refills is not medically necessary.