

<b>Case Number:</b>	CM15-0149506		
<b>Date Assigned:</b>	08/12/2015	<b>Date of Injury:</b>	06/27/2005
<b>Decision Date:</b>	09/09/2015	<b>UR Denial Date:</b>	07/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/31/2015

### 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive Medicine

### 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 injured worker is a 54 year old male who reported an industrial injury on 6-27-2005. His diagnoses, and or impression, were noted to include: chronic pain; status-post lumbar fusion; history of lumbar epidural hematoma with cauda equina syndrome; neurogenic bladder; cauda equina spinal cord injury; and impotence of organic origin. No current imaging studies were noted. His treatments were noted to include: lumbar spine surgeries (2008, 2010 & 2013); trigger point injection therapy; medication management; and rest from work. The progress notes of 6-15-2015 reported complaints which included severe, constant pain to the low back that radiated down, was aggravated by activities, with the presence of bowel and bladder dysfunction resulting in the need for self-catheterization, and causing interference with activities of daily living and his sexual activities. Objective findings were noted to include: a slow and antalgic gait with use of crutches; tenderness over the lumbosacral vertebrae with severely limited range-of-motion secondary to pain; positive bilateral lumbar facet signs; decreased sensation in the lumbosacral dermatomes in the bilateral lower extremities; positive bilateral straight leg raise; and right foot drop. He was noted to be on Cialis. The Urology notes of 6-10-2015 reported a follow-up visit for his complaints for lack of libido, testosterone, erectile dysfunction and self-catheterizing. The objective findings included the reference of a urodynamic study; results of a urinalysis; the unsuccessful attempts at self-Prostaglandin injections; the discussion of a penile implant; and a re-teaching of proper injection techniques for increased success. The physician's

requests for treatments were noted to include injectable Alprostadil kit of 6 intracavernosal injectables, as needed for intercourse at home, with refills.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **Alprostadil 40 mcg (Caverject) 6 kits, plus 5 refills: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation American Urological Association (<http://www.auanet.org/education/guidelines/erectile-dysfunction.cfm>).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation [uptodate.com](http://uptodate.com), [Alprostadil](http://www.auanet.org/education/guidelines/erectile-dysfunction.cfm)<https://www.auanet.org/education/guidelines/erectile-dysfunction.cfm>.

**Decision rationale:** MTUS is silent regarding Alprostadil. Uptodate.com states "Dosing: Adult Erectile dysfunction." Intracavernous (Caverject, Caverject Impulse, Edex): Individualize dose by careful titration; doses >40 mcg (Edex) or >60 mcg (Caverject, Caverject Impulse) are not recommended: Initial dose must be titrated in physician's office. Patient must stay in the physician's office until complete detumescence occurs; if there is no response, then the next higher dose may be given within 1 hour; if there is still no response, a 1-day interval before giving the next dose is recommended; increasing the dose or concentration in the treatment of impotence results in increasing pain and discomfort. Initial dose titration: Vasculogenic, psychogenic, or mixed etiology: Initiate dosage titration at 2.5 mcg. If there is a partial response, increase dose by 2.5 mcg to a dose of 5 mcg and then, in increments of 5 to 10 mcg (depending on erectile response) until the dose that produces an erection suitable for intercourse and not exceeding a duration of 1 hour is reached. If there is no response to the initial 2.5 mcg dose, the second dose may be increased to 7.5 mcg and administered within 1 hour, followed by increments of 5 to 10 mcg. According to the prescribing information for Caverject Impulse, no more than 2 doses during the initial titration should be given within a 24 hour period. If there is a response, then there should be at least a 24 hour interval before the next dose is given. Neurogenic etiology (e.g., spinal cord injury): Note: Caverject powder must be used to prepare a 1.25 mcg dose: Initiate dosage titration at 1.25 mcg; may increase to a dose of 2.5 mcg within 1 hour and if necessary, to a dose of 5 mcg; may increase further in increments of 5 mcg until the dose is reached that produces an erection suitable for intercourse, not lasting >1 hour. Maintenance: Once an appropriate dose has been determined, patient may self-administer injections at a frequency of no more than 3 times/week with at least 24 hours between doses Intraurethral (Muse Pellet): Initial: 125 to 250 mcg Maintenance: Administer as needed to achieve an erection; duration of action is about 30-60 minutes; use only two systems per 24-hour period. Per the American Urological Association ([www.auanet.org](http://www.auanet.org)) "Recommendation: Patients who have failed a trial with phosphodiesterase type 5 (PDE5) inhibitor therapy should be informed of the benefits and risks of other therapies, including the use of a different PDE5 inhibitor, alprostadil intra-urethral suppositories, intracavernous drug injection, vacuum constriction devices, and penile prostheses. Standard: Physicians who prescribe intracavernous injection therapy should (1) inform patients prolonged erections and (3) inform the patient of the plan." Although the medical documentation provided indicate this patient was previously prescribed Cialis, the treating physician has not provided documentation of a lack of therapeutic response and failure of this therapy as outlined above. As such, the request for Alprostadil 40 mcg (Caverject) 6 kits, plus 5 refills is not medically necessary.



