VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

EDEX®(Alprostadil)

Effective Date: 10/27/05
Date Developed: 8/15/05 by C. Wilhelmy MD
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Alprostadil is a prostaglandin. It causes vasodilation by means of direct effect on vascular and ductus arteriosus smooth muscle. It relaxes trabecular smooth muscle by dilation of cavernosal arteries when injected along the penile shaft, allowing blood flow to and entrapment in the lacunar spaces of the penis (ie, corporeal veno-occlusive mechanism.)
Alprostadil is used for the treatment of erectile dysfunction of vasculogenic, psychogenic, or neurogenic etiology.

Pre-Auhorization Criteria treatment of erectile dysfunction due to neurogenic, vasculogenic, psychogenic, or mixed etiology:

A. Erectile Dysfunction (ED) secondary to:
- organic ED secondary to diabetes mellitus with neuropathy;
- peripheral vascular disease affecting the ileofemoral system;
- spinal cord injuries;
- prior surgery of the prostate or lower urinary tract;
- radical pelvic surgery or significant injuries of the genitals, lower urinary tract, pelvic nerves or rectum;
- multiple sclerosis;
- hypogonadism-related ED despite androgen replacement therapy.
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B. patients taking medications* which cause ED but alternative medications are either not available or the patient has failed or is intolerant of the alternatives.
C.
*These medications include estrogen, Elexin, Lupron, Zoladex for prostate cancer treatment; amiodarone, mexilitine; hydrochlorothiazide, spironolactone, indapamide; propranolol, atenolol, metoprolol, labetolol; clonidine, methyldopa, hydralazine, verapamil; Tegretol, Dilantin, Zarontin; antidepressants; antipsychotics.

General Information:
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Quantity Limit:
VCHCP will authorize 6 injections per 30 days.

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DOSING: ADULTS

2. Recommended Dosing Regimen and Authorization Limit:

Drug	Dosing Regimen	Authorization Limit
Caverject	Initial dosage titration should be done in the physician's office. <u>Dosage range:</u> 1.25 mcg - 60 mcg intracavernosally prior to sexual activity. The recommended frequency of injection is no more than 3 times weekly, with at least 24 hours between each dose.	6 months Quantity limits are plan specific
Edex	Initial dosage titration should be done in the physician's office. <u>Dosage range</u>: 1- 40 mcg intracavernosally prior to sexual activity. The recommended frequency of injection is no more than 3 times weekly, with at least 24 hours between each dose.	6 months Quantity limits may be plan specific
Caverject/Edex	Studies used doses of 6 to 10 nanograms/kg/min intravenously for 12 to 72 hours.	Length of benefit

1. Product Availability:

   Caverject vials lyophilized powder: 20 mcg, 40 mcg

   Caverject Impulse: 10 mcg, 20 mcg

   Edex kits (w/ diluent): 10 mcg, 20 mcg

WARNINGS / PRECAUTIONS - When used in erectile dysfunction: priapism may occur; patient must be instructed to report to physician or seek immediate medical assistance if an erection persists greater than 4 hours. Treat immediately to avoid penile tissue damage and permanent loss of potency; discontinue therapy if signs of penile fibrosis develop (penile angulation, cavernosal fibrosis, or Peyronie's disease). When used in erectile dysfunction, syncope occurring within 1 hour of administration, has been reported; the potential for drug-drug interactions may occur when alprostadil is prescribed concomitantly with antihypertensives; some lowering of blood pressure may occur without symptoms, and swelling of leg veins, leg pain, perineal pain, and rapid pulse have been reported in <2% of patients during in-clinic titration and home treatment.
DRUG INTERACTIONS - Risk of hypotension and syncope may be increased with antihypertensives.

PATIENT EDUCATION - Store in refrigerator; if self-injecting for the treatment of impotence, dilute with the supplied diluent and use immediately after diluting; see prescriber at least every 3 months to ensure proper technique and for dosage adjustment. Alternate sides of the penis with each injection; do not inject more than 3 times/week, allowing at least 24 hours between each dose; dispose of the syringe, needle, and vial properly; discard single-use vials after each use; report moderate to severe penile pain or erections lasting >4 hours to a prescriber immediately; inform a prescriber as soon as possible if any new penile pain, nodules, hard tissue or signs of infection develop; the risk of transmission of blood-borne diseases is increased with use of alprostadil injections since a small amount of bleeding at the injection site is possible. Do not share this medication or needles/syringes; do not drive or operate heavy machinery within 1 hour of administration.
REFERENCES

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3. Williams, G, Abbou, CC, Amar, ET, et al. The Effect of Transurethral Alprostadil on the Quality of Life of Men With Erectile Dysfunction, and Their Partners. MUSE Study Group. Br J Urol 1998; 82:847.

5. Health Net National Medical Policy. Alprostadil Intravenous for Raynaud_s Syndrome. February 2010.

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