

Prior Authorization DRUG Guidelines

VIAGRA® (sildenafil)/CIALIS (tadalafil)

Effective Date: 10/27/05

Date Developed: 8/15/05 by C. Wilhelmy MD

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Sildenafil is a phosphodiesterase-5 enzyme inhibitor. It does not directly cause penile erections, but affects the response to sexual stimulation. The physiologic mechanism of erection of the penis involves release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation. NO then activates the enzyme guanylate cyclase, which results in increased levels of cyclic guanosine monophosphate (cGMP), producing smooth muscle relaxation and inflow of blood to the corpus cavernosum. Sildenafil enhances the effect of NO by inhibiting phosphodiesterase type 5 (PDE-5), which is responsible for degradation of cGMP in the corpus cavernosum; when sexual stimulation causes local release of NO, inhibition of PDE-5 by sildenafil causes increased levels of cGMP in the corpus cavernosum, resulting in smooth muscle relaxation and inflow of blood to the corpus cavernosum. At recommended dosing, it has no effect in the absence of sexual stimulation. Sildenafil (Viagra) is approved by the Food and Drug Administration (FDA) for the treatment of erectile dysfunction (ED). Organic causes of erectile dysfunction are vascular, neurologic, hormonal, medical, or drug-related, and some men may have multiple etiologic factors.

Pre-Authorization Criteria:

A. VCHCP authorizes Viagra for patients with organic ED secondary to:

- diabetes mellitus with neuropathy;
- peripheral vascular disease affecting the iliofemoral 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;
- and hypogonadism-related ED despite androgen replacement therapy.

B. VCHCP will also authorize Viagra for patients who are taking medications* which cause ED but alternative medications are either not available or the patient has failed or is intolerant of the alternatives.

C. **Raynaud disease (men or women).**

Approve if the patient has tried

at least 2 of the following therapies for Raynaud disease: calcium channel blockers (e.g., amlodipine, felodipine, isradipine, nifedipine), α -adrenergic blockers (e.g., prazosin), nitroglycerin, losartan (Cozaar[®]), fluoxetine, or angiotensin converting enzyme (ACE) inhibitors)

OR

one vasodilator (e.g., intravenous epoprostenol, intravenous alprostadil, bosentan [Tracleer[®]]).

D. **Lower urinary tract symptoms (LUTS) secondary to benign prostatic hypertrophy (BPH).** Approve in men who meet all of the following criteria:

- Patient has LUTS secondary to BPH, and
- Patient has tried both an α_1 -blocker (doxazosin [Cardura[®] XL], terazosin, tamsulosin [Flomax[^]], alfuzosin extended-release [UroXatral[^]]), and a 5 α -reductase inhibitor (finasteride, dutasteride [Avodart[®]]), and [Note: Patients with a contraindication to an α_1 -blocker and/or a 5 α -reductase inhibitor are not required to try these medications.]
- Sildenafil (Viagra) is prescribed by a urologist or in consultation with a urologist.

E. **Prophylaxis after nerve-sparing radical prostatectomy (early penile rehabilitation).**

Approve in men who meet all of the following criteria:

- Patient has had a nerve-sparing radical prostatectomy within the previous 12 months.
- Sildenafil is prescribed by a urologist.

In the professional opinion of specialist physicians reviewing the data, we have adopted these criteria.

F. **Women with antidepressant-associated sexual dysfunction.** Approve in women who are currently taking a selective serotonin reuptake inhibitor (SSRI) (e.g., citalopram, escitalopram [Lexapro[^]], fluoxetine, fluvoxamine, paroxetine, sertraline), a serotonin and norepinephrine reuptake inhibitor (SNRI) (e.g., venlafaxine [Effexor[®] XR], duloxetine [Cymbalta[®]], desvenlafaxine [Pristiq[™]]), or clomipramine.

G. **High-altitude pulmonary edema (HAPE), treatment or prevention.** Approve in patients who have HAPE or a history of HAPE AND if one other pharmacologic therapy (i.e., nifedipine, salmeterol, dexamethasone, acetazolamide, tadalafil) has been tried for treatment or prevention of HAPE

*These medications include estrogen, Elexin, Lupron, Zoladex for prostate cancer treatment; amiodarone, mexilitine; hydrochlorothiazide, spironolactone, indapamide; propranolol, atenolol, metoprolol, labetalol; clonidine, methyl dopa, hydralazine, verapamil; Tegretol, Dilantin, Zarontin; antidepressants; antipsychotics.

Quantity Limit:

VCHCP will authorize 8 tablets per 30 days.

DOSING: ADULTS

Erectile dysfunction: Oral: 50 mg tablet, approximately 1 hour before sexual activity (30 minutes - 4 hours). An initial and maximum dose of 25 mg is recommended in patients with factors which may increase sildenafil levels (age >65, hepatic impairment, severe renal impairment, and concomitant use of inhibitors of CYP3A4 such as erythromycin, ketoconazole, and itraconazole). Adjust dose in other patients based on effectiveness or tolerance, decrease to 25 mg or increase to the maximum daily dose of 100 mg. Do not take more than once daily.

Primary pulmonary hypertension (unlabeled use): Oral: 25 mg twice daily, titrated based on response. Dosages up to 100 mg 5 times/day have been used (limited data).

DOSING: ELDERLY — Initial: 25 mg, 1 hour before sexual activity. Age >65 years was associated with increased serum sildenafil concentrations which may increase side effects and efficacy.

DOSING: RENAL IMPAIRMENT — $Cl_{cr} < 30$ mL/minute: Initial: 25 mg, 1 hour before sexual activity.

DOSING: HEPATIC IMPAIRMENT — Hepatic impairment; cirrhosis: Initial: 25 mg, 1 hour before sexual activity.

ADMINISTRATION — Administer orally ~1 hour before sexual activity (may be used anytime from 4 hours to 30 minutes before).

CONTRAINDICATIONS — Hypersensitivity to sildenafil or any component of the formulation; concurrent use of organic nitrates (nitroglycerin) in any form (potentiates the hypotensive effects).

WARNINGS / PRECAUTIONS — There is a degree of cardiac risk associated with sexual activity; therefore, physicians may wish to consider the cardiovascular status of their patients prior to initiating any treatment for erectile dysfunction. Agents for the treatment of erectile dysfunction should be used with caution in patients with anatomical deformation of the penis (angulation, cavernosal fibrosis, or Peyronie's disease), or in patients who have conditions which may predispose them to priapism (sickle cell anemia, multiple myeloma, leukemia).

PATIENT EDUCATION — Discuss with your prescriber the contraindication of sildenafil citrate with concurrent organic nitrates. The use of sildenafil offers no protection against sexually-transmitted diseases. Counseling of patients about the protective measures necessary to guard against transmitted diseases, including the human immunodeficiency virus (HIV), may be considered.

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