

## PRIOR AUTHORIZATION POLICY

**POLICY:** Erectile Dysfunction – Sildenafil Prior Authorization Policy

- Viagra® (sildenafil tablets – Pfizer, generic)

**REVIEW DATE:** 11/06/2024

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### OVERVIEW

Sildenafil (Viagra, generic), a phosphodiesterase type 5 (PDE5) inhibitor, is indicated for the treatment of **erectile dysfunction**.<sup>1</sup>

Sildenafil has been studied for other indications.

- **Benign Prostatic Hyperplasia.** The European Association of Urology guidelines (2022) note that phosphodiesterase type 5 inhibitors can be used in men with moderate-to-severe lower urinary tract symptoms with or without erectile dysfunction.<sup>9</sup> The guidelines add that based on the results from a meta-analysis<sup>8</sup>, younger men with lower body mass index and more severe lower urinary tract symptoms benefit the most from phosphodiesterase type 5 inhibitors.
- **High-Altitude Pulmonary Edema.** Published guidelines for the prevention of high-altitude pulmonary edema recommend nifedipine as the preferred pharmacologic treatment option.<sup>12</sup> Other pharmacologic therapies include salmeterol, tadalafil, sildenafil, dexamethasone, or acetazolamide.
- **Prophylaxis after Radical Prostatectomy.** Viagra given on a daily basis has been used to improve the return of normal spontaneous erectile function, improve tissue oxygenation, and prevent penile fibrosis after nerve-sparing radical prostatectomy.<sup>10,11</sup> It is better to initiate a penile rehabilitation program as soon as possible after surgery in order to limit and prevent postoperative local hypoxigenation and fibrosis.
- **Pulmonary Arterial Hypertension.** Sildenafil tablets (Revatio®) are approved for pulmonary arterial hypertension.<sup>2</sup> Sildenafil (Viagra, generics) are available in 25 mg, 50 mg, and 100 mg tablets, and Revatio is available as 20 mg tablets. Viagra has been used for this diagnosis.<sup>3,4</sup> Doses of Viagra that were used in these reports ranged from 25 mg twice daily to 100 mg five times daily. Patients will have usually been started on Revatio 20 mg three times daily.
- **Raynaud's Phenomenon.** There are studies which show sildenafil has been beneficial in patients with Raynauds's phenomenon.<sup>5,6</sup> Guidelines from the European League against Rheumatism (EULAR) on the treatment of systemic sclerosis (2023) recommend considering dihydropyridine calcium channel blockers (CCBs), usually oral nifedipine, for first-line therapy of Raynaud's phenomenon in patients with systemic sclerosis.<sup>7</sup> Phosphodiesterase type 5 inhibitors should also be considered in such clinical scenarios.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of sildenafil. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with sildenafil as well as the monitoring required for adverse events and long-term efficacy, some approvals require sildenafil to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** When available, the ICD-10 codes for male erectile dysfunction (ICD-10: N52.\*) will be used for automation to allow approval of the requested medication. This automation is gender-selective

and is not applicable for women; approval for use in women is always determined by prior authorization criteria.

### **RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of sildenafil is recommended in those who meet one of the following criteria:

#### **FDA-Approved Indications**

- 1. Erectile Dysfunction.** Approve for 1 year.

#### **Other Uses with Supportive Evidence**

- 2. Benign Prostatic Hyperplasia.** Approve for 1 year if the patient meets ONE of the following (A or B):

Note: For men with erectile dysfunction and benign prostatic hyperplasia, use criterion 1 above.

- A)** Patient has tried an alpha-1 ( $\alpha$ 1) blocker; OR

Note: Examples of alpha-1 ( $\alpha$ 1) blockers include doxazosin, terazosin, tamsulosin, alfuzosin.

- B)** Patient has tried a 5 $\alpha$ -reductase inhibitor.

Note: Examples of a 5 $\alpha$ -reductase inhibitor includes finasteride, dutasteride.

- 3. High-Altitude Pulmonary Edema (HAPE), Treatment or Prevention.** Approve for 1 year in patients who meet BOTH of the following (A and B):

- A)** Patient has HAPE or a of HAPE; AND

- B)** Patient has tried one other pharmacologic therapy for the treatment or prevention of HAPE.

Note: Examples of other pharmacologic therapy for the treatment of HAPE are nifedipine, Serevent (salmeterol inhalation powder), dexamethasone, acetazolamide, Cialis (tadalafil tablets).

- 4. Prophylaxis After Radical Prostatectomy (Early Penile Rehabilitation).** Approve for 1 year in patients who meet BOTH of the following (A and B):

- A)** Patient had radical prostatectomy within the previous 12 months; AND

- B)** The medication is prescribed by or in consultation with a urologist.

- 5. Pulmonary Arterial Hypertension.** Approve for 1 year.

- 6. Raynaud's Phenomenon.** Approve for 1 year if the patient meets ONE of the following (A or B):

- A)** Patient has tried one calcium channel blocker; OR

Note: Examples of calcium channel blockers include amlodipine, felodipine, nifedipine.

- B)** According to the prescriber, use of a calcium channel blocker is contraindicated.

Note: Examples of reasons a patient cannot take calcium channel blocker therapy include right heart failure or decreased cardiac output.

### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of sildenafil is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

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2. Revatio® tablets [prescribing information]. New York, NY: Pfizer; January 2023.
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