



## PRIOR AUTHORIZATION POLICY

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

- Viagra® (sildenafil tablets – Pfizer, generic)

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

### INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

## CIGNA NATIONAL FORMULARY COVERAGE:

### 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 hypoxxygenation 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 Raynaud'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.

- **Viagra® (sildenafil tablets (Pfizer, generic))**

**is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):**

## 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 history 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 COVERED

- **Viagra® (sildenafil tablets (Pfizer, generic))**

**is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

- 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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## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/01/2023
Annual Revision	No criteria changes.	11/06/2024

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