Drug Coverage Policy

Effective Date.....7/15/2026
Coverage Policy Number.....IP0098
Policy Title..... Sildenafil (Viagra®, Vybrique™) for Individual and Family Plans

Phosphodiesterase Type 5 Inhibitors - Sildenafil (Viagra®, Vybrique™) for Individual and Family Plans

- Viagra® (sildenafil tablets – Pfizer, generic)
- Vybrique™ (sildenafil oral film – IBSA Pharma)

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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

OVERVIEW

Sildenafil (tablets [Viagra, generic] and oral film [Vybrique]), a phosphodiesterase type 5 (PDE5) inhibitor, is indicated for the treatment of **erectile dysfunction**.[1,17]

Sildenafil has been studied for other uses.

- **Benign Prostatic Hyperplasia.** The European Association of Urology guidelines (2024) note that phosphodiesterase type 5 inhibitors can be used in men with moderate-to-severe lower urinary tract symptoms with or without erectile dysfunction.[9] The guidelines add that based on the results from a meta-analysis[8], 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 (HAPE).** Published guidelines for the prevention and treatment of HAPE recommend nifedipine as the preferred pharmacologic treatment option.[12] Regarding PDE5 inhibitors, tadalafil is given a strong recommendation for HAPE prevention in known susceptible individuals who are not candidates for nifedipine. Dexamethasone is recommended for prevention if the patient is not a candidate for nifedipine and tadalafil. For HAPE treatment, PDE5 inhibitors may be used if nifedipine is not available.
- **Prophylaxis after Radical Prostatectomy.** Sildenafil 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.[10,11] It is better to initiate a penile rehabilitation program as soon as possible after surgery in order to limit and prevent postoperative local hypoxygenation and fibrosis.
- **Pulmonary Arterial Hypertension (PAH)**. PAH is a serious but rare condition affecting fewer than 20,000 patients in the US.[13,14] It is classified within Group 1 pulmonary hypertension among the five different groups that are recognized by the World Health Organization (WHO). In this progressive disorder, the small arteries in the lungs become narrowed, restricted, or blocked causing the heart to work harder to pump blood, leading to activity impairment. Although the mean age of diagnosis is between 36 and 50 years, patients of any age may be affected, including pediatric patients. PAH is defined as a mean pulmonary artery pressure (mPAP) > 20 mmHg (at rest) with a pulmonary arterial wedge pressure (PAWP) ≤ 15 mmHg and a pulmonary vascular resistance > 2 Wood units measured by cardiac catheterization.[15]

  The CHEST guideline and Expert Panel Report regarding therapy for PAH in adults (2019) details many medications. It was noted that PDE5 inhibitors play a vital role and have various benefits in the management of PAH.[14] The European Society of Cardiology and the European Respiratory Society guidelines regarding the treatment of pulmonary hypertension (2022) also recognize PDE5 inhibitors as having a prominent role in the management of this condition, as monotherapy or in use as combination with other agents.[16]

  Sildenafil tablets, suspension, and injection (Revatio®, generics) are approved for pulmonary arterial hypertension.[2] 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.[3,4] Doses of Viagra that were used in these reports ranged from 25 mg

twice daily to 100 mg five times daily. Patients were typically 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.[5,6] 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.[7] Phosphodiesterase type 5 inhibitors should also be considered in such clinical scenarios.

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POLICY STATEMENT

Prior Authorization is required for 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.

The use of sildenafil (Revatio®, LiQrev®) for pulmonary hypertension is addressed in a separate coverage policy.

Erectile Dysfunction therapy may be excluded under many benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

For plans that do NOT include coverage for sexual dysfunction, medical necessity review may be required for non-sexual dysfunction uses. Refer to the customer's benefit plan document for coverage details.

Documentation: Documentation is required for initiation of therapy as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes and catheterization laboratory reports. All documentation must include patient-specific identifying information. For a patient case in which the documentation requirement of the right heart catheterization upon Prior Authorization coverage review for a different medication indicated for pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1 has been previously provided, the documentation requirement in this *Phosphodiesterase Type 5 Inhibitors - Sildenafil (Viagra®, Vybrique™) for Individual and Family Plans* policy is considered to be met.

Sildenafil is considered medically necessary when ONE of the following is met:

FDA-Approved Indication

1. **Erectile Dysfunction.** Approve for 1 year.
   Note: For men with erectile dysfunction and benign prostatic hyperplasia, use criterion 2 below.

Other Uses with Supportive Evidence

2. **Benign Prostatic Hyperplasia.** Approve for 1 year if the patient meets ONE of the following (A, B or C):
   - **A.** Patient has tried an alpha-1 (α1) blocker; OR
     Note: Examples of alpha-1 (α1) blockers include doxazosin, terazosin, tamsulosin, alfuzosin

B. Patient has tried a 5-alpha-reductase inhibitor; OR
Note: Examples of a 5-alpha-reductase inhibitor include finasteride and dutasteride.
C. Patient has a diagnosis of benign prostatic hyperplasia AND erectile dysfunction.

3. **High-Altitude Pulmonary Edema (HAPE), Treatment or Prevention.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A. Patient has HAPE or 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 or prevention of HAPE are nifedipine, dexamethasone, Cialis (tadalafil tablets).

4. **Prophylaxis after Radical Prostatectomy (Early Penile Rehabilitation).** Approve for 1 year if the patient meets 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 (PAH) [World Health Organization {WHO} Group 1].** Approve for the duration noted if the patient meets ONE of the following (A or B):
   A. Initial Therapy. Approve for 1 year if the patient meets BOTH of the following (i and ii):
      i. Patient meets BOTH of the following (a and b):
         a. Patient has had a right heart catheterization **[documentation required]**; AND
         b. Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND
      ii. The medication is prescribed by or in consultation with a cardiologist or a pulmonologist; OR
   B. Patient is Currently Receiving Sildenafil for PAH. Approve for 1 year if the patient meets BOTH of the following (i and ii):
      i. Patient meets BOTH of the following (a and b):
         a. Patient has had a right heart catheterization; AND
         Note: This refers to prior to starting therapy with a medication for WHO Group 1 PAH.
         b. Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND
      ii. The medication is prescribed by or in consultation with a cardiologist or a pulmonologist.

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

Sildenafil for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Viagra® tablets [prescribing information]. New York, NY: Pfizer; December 2017.
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13. Ruopp NF, Cockrill BA. Diagnosis and treatment of pulmonary arterial hypertension. A review. JAMA. 2022;327(14):1379-1391.
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16. Humbert M, Kovacs G, Hoeper MM, et al, for the ESC/ERS Scientific Document Group. 2022 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J*. 2022;43(38):3618-3731.
17. Vybrique™ oral film [prescribing information]. Parsippany, NJ: IBSA Pharma; December 2025.

Revision Details

Summary of Changes	Review Date	Effective Date
No criteria changes	11/21/2024	2/1/2025

Policy Title: **Updated from** "Sildenafil (Viagra®)" **to** "Phosphodiesterase Type 5 Inhibitors – Sildenafil (Viagra®) for Individual and Family Plans" **Added** documentation policy statement. **Erectile Dysfunction:** **Added** Note: For men with erectile dysfunction and benign prostatic hyperplasia, use criterion 2 below. **Removed** drug quantity limits throughout policy. **Removed** reauthorization criteria. **Benign Prostatic Hyperplasia:** **Updated from** "Treatment of Benign Prostatic Hyperplasia (BPH)" **to "**Benign Prostatic Hyperplasia" **Updated from** "Documentation of failure, contraindication, or intolerance to ONE of the following: Alpha1-blocker, 5 alpha-reductase inhibitor, or 5 alpha-reductase inhibitor/alpha1-blocker combination product" **to** "Patient has tried an alpha-1 (α1) blocker; OR Patient has tried a 5-alpha-reductase inhibitor" **Added:** Note: Examples of alpha-1 (α1) blockers include doxazosin, terazosin, tamsulosin, alfuzosin **Added:** Note: Examples of a 5-alpha-reductase inhibitor include finasteride and dutasteride. **Added** "Patient has a diagnosis of benign prostatic hyperplasia AND erectile dysfunction" **Removed** reauthorization criteria. **High-Altitude Pulmonary Edema (HAPE):** **Removed** "documented" from diagnosis of HAPE or history of HAPE. **Updated from** "Documentation of failure, contraindication, or intolerance to ONE other pharmacologic therapy for the treatment or prevention of HAPE" **to** "Patient has tried one other pharmacologic therapy for the treatment or prevention of HAPE." **Added:** Note: Examples of other pharmacologic therapy for the treatment or prevention of HAPE are nifedipine, dexamethasone, Cialis (tadalafil tablets). **Removed** reauthorization criteria. **Prophylaxis after Radical Prostatectomy (Early Penile Rehabilitation):** **Updated from** "Documentation of radical prostatectomy within the previous 12 months" **to**	4/16/2026	6/15/2026

"Patient had radical prostatectomy within the previous 12 months" **Removed** reauthorization criteria. **Pulmonary Arterial Hypertension:** Use and criteria added to policy. **Raynaud's Phenomenon:** **Updated from** "Treatment of Raynaud's Phenomenon" **to** "Raynaud's Phenomenon" **Updated from** "Documentation of failure, contraindication, or intolerance to ONE calcium channel blocker" **to** "Patient has tried one calcium channel blocker" **Added:** Note: Examples of calcium channel blockers include amlodipine, felodipine, nifedipine. **Added:** According to the prescriber, use of a calcium channel blocker is contraindicated. **Added:** Note: Examples of reasons a patient cannot take calcium channel blocker therapy include right heart failure or decreased cardiac output. **Removed** reauthorization criteria.		
Policy Title: **Updated from** "Phosphodiesterase Type 5 Inhibitors - Sildenafil (Viagra®) for Individual and Family Plans" **to** "Phosphodiesterase Type 5 Inhibitors - Sildenafil (Viagra®, Vybrique™) for Individual and Family Plans" Vybrique (sildenafil oral film) was added to the policy with the same authorization criteria and exclusions as other sildenafil products.	5/7/2026	7/15/2026

The policy effective date is in force until updated or retired.

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