

## Sildenafil (PAH, Viagra)

- Sildenafil Citrate Powder for oral suspension [Pulmonary Hypertension]
- Sildenafil Citrate Oral tablet [Pulmonary Hypertension]
- Sildenafil Citrate Oral tablet (Viagra)
- Sildenafil Oral film (Vybriq) [Erectile Dysfunction]

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

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## Summary

Sildenafil (Viagra, Revatio) is a selective phosphodiesterase type 5 (PDE5) inhibitor. It is administered orally for the treatment of pulmonary arterial hypertension (PAH) and male erectile dysfunction (ED). It can be administered intravenously for the treatment of PAH when the member is temporarily unable to tolerate the oral medication. There is also evidence to support the use of sildenafil (Viagra, Revatio) in certain patients with a condition called Raynaud phenomenon (also referred to as idiopathic Raynaud phenomenon, primary Raynaud syndrome, or Raynaud disease) and for the prevention and treatment of high-altitude pulmonary edema.

Sildenafil (Viagra, Revatio) comes in the following drug strengths and formulations: 20 mg tablets, 25 mg tablets, 50 mg tablets, 100 mg tablets, 10 mg/ml powder for suspension, and 10 mg/12.5 ml solution for injection.

- Sildenafil (Viagra, Revatio) 25 mg tablets, 50 mg tablets, and 100 mg tablets are FDA indicated in the treatment of ED.
- Sildenafil 20 mg tablets, 10 mg/ml powder for suspension, and 10mg/12.5 ml solutions for injection are FDA indicated in the treatment of PAH.
- Sildenafil 20 mg tablets are also used off-label for Raynaud phenomenon.

**NOTE:** Erectile dysfunction is an excluded benefit for certain Plans. Coverage for medications to treat sexual dysfunction, including erectile dysfunction, varies depending on a member's benefits policy. Please review the member's coverage benefits to determine if erectile dysfunction is a covered benefit.

## Definitions

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Erectile Dysfunction" refers to the consistent or recurrent inability to achieve or sustain an erection of sufficient rigidity and duration for sexual intercourse.

"High-altitude pulmonary edema (HAPE)" is a life-threatening condition that can occur in some people who rapidly ascend to high altitudes, usually higher than 2500 m [8202 ft] above sea level.

"Ischemia" refers to a compromise/reduction of blood to an affected area.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"Pulmonary arterial hypertension (PAH)" is a subset of pulmonary hypertension (PH), categorized into five groups based on etiology. Patients in the first group are considered to have PAH, whereas patients in the remaining four groups are considered to have PH.

"Raynaud phenomenon (RP)" is a condition characterized by temporary narrowing of the blood vessels that supply blood to the extremities, including the fingers and toes (and sometimes the ears, lips, nipples, or tip of the nose). This leads to skin discoloration, numbness, tingling, and potentially other complications.

"Right heart catheterization (RHC)" refers to the gold standard diagnostic test used to definitively diagnose PAH and differentiate it from other types of pulmonary hypertension. RHC directly measures pressures in the right side of the heart and pulmonary arteries. PAH is defined hemodynamically by a mean pulmonary artery pressure (mPAP)  $\geq$  25 mmHg, pulmonary capillary wedge pressure (PCWP)  $\leq$  15 mmHg, and pulmonary vascular resistance (PVR)  $>$  3 Wood units.

"[s]" indicates state mandates may apply.

"WHO functional class (FC)" is a system to categorize the severity of functional impairment in patients with PAH based on symptom burden and activity limitation. WHO FC ranges from I to IV, with higher classes reflecting more severe symptoms and limitations.

## Medical Necessity Criteria for Initial Clinical Review

### Initial Indication-Specific Criteria

#### Erectile Dysfunction (if a covered benefit for the member):

The Plan considers sildenafil 25 mg, 50 mg, and 100 mg tablets (Viagra) or Vybrique (sildenafil oral film) medically necessary when ALL of the following criteria are met:

1. The member is 18 years of age and older; *AND*
2. The member is a male with erectile dysfunction (ED, impotence); *AND*
3. The member has no evidence of ED due to reversible or treatable causes (e.g., hypogonadism with inadequate testosterone replacement, hyperprolactinemia, drug-induced dysfunction, dyslipidemias, alcoholism, other substance abuse, hypertension, thyroid disease, cardiovascular

or cerebrovascular disease, neurologic disease, adrenal dysfunction, psychologic dysfunction, marital discord, smoking); *AND*

4. The member meets ALL of the following:
  - a. No evidence of concomitant guanylate Cyclase Stimulators (such as Adempas (riociguat)); *or*
  - b. No evidence of concomitant nitrates and nitrites (e.g., nitroglycerin, isosorbide dinitrate); *AND*
5. IF the request is for Vybriq (sildenafil oral film) the member meets ONE (1) of the following<sup>[s]</sup>:
  - a. The member has dysphagia; *or*
  - b. The member has tried and failed sildenafil tablets.

If the above prior authorization criteria are met, sildenafil will be approved for up to 12 months.<sup>[s]</sup>

#### Pulmonary Arterial Hypertension (PAH)

The Plan considers sildenafil 20 mg tablets, sildenafil solution, and sildenafil oral suspension medically necessary when ALL of the following criteria are met:

1. Prescribed by or in consultation with a cardiologist or pulmonologist with expertise in treating PAH; *AND*
2. The member has a diagnosis of PAH defined as WHO Group 1 class pulmonary hypertension; *AND*
3. The diagnosis of PAH has been confirmed by ONE (1) of the following methods:
  - a. Pre-treatment right heart catheterization with ALL of the following:
    - i. Mean pulmonary artery pressure (mPAP) > 20 mmHg; *and*
    - ii. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg; *and*
    - iii. Pulmonary vascular resistance (PVR) > 2 Wood units *or* pulmonary vascular resistance index (PVRI) > 3 Wood units x m<sup>2</sup> also acceptable for pediatric members; *or*
  - b. Doppler echocardiogram if right heart catheterization cannot be performed (e.g., for infants less than one year of age with post cardiac surgery, chronic heart disease, chronic lung disease associated with prematurity, or congenital diaphragmatic hernia); *AND*
4. IF the request is for sildenafil solution/suspension, the member must be unable to use, or has tried and failed sildenafil 20 mg tablets<sup>[s]</sup>; *AND*
5. Chart documentation and supporting lab work are provided for review to validate the above-listed requirements.

If the above prior authorization criteria are met, sildenafil will be approved for up to 12 months.<sup>[s]</sup>

#### Raynaud phenomenon:

The Plan considers sildenafil 20 mg tablets medically necessary when ALL of the following criteria are met:

1. Prescribed by or in consultation with a rheumatologist or a provider with expertise in treating Raynaud phenomenon; *AND*
2. The medication is being requested for the treatment of Raynaud phenomenon (also called idiopathic Raynaud phenomenon, primary Raynaud syndrome, or Raynaud disease); *AND*
3. The member has documented history of ONE (1) of the following:
  - a. Signs of critical ischemia at the affected areas (e.g., fingers, toes, ears, lips, nipples, or the tip of the nose); *or*
  - b. The quality of life of the member is affected to the degree that activities of normal living are no longer possible; *AND*
4. The member is unable to use, or has tried and failed BOTH of the following<sup>[s]</sup>:
  - a. Non-pharmacologic therapies (e.g., relaxation techniques, avoiding stressful situations, avoiding cold exposure, avoiding drugs that may precipitate RP); *and*
  - b. Calcium channel blocker (e.g., amlodipine, nifedipine); *AND*
5. Chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, sildenafil will be approved for up to 12 months.<sup>[s]</sup>

#### Prevention and Treatment of High-Altitude Pulmonary Edema

The Plan considers sildenafil 50 mg tablets (Viagra) medically necessary when ALL of the following criteria are met:

1. Sildenafil is being requested for prevention or treatment of high-altitude pulmonary edema AND BOTH of the following:
  - a. The member will be or has been exposed to high altitudes, defined as higher than 2500 m [8202 ft] above sea level; *and*
  - b. The member has a history of high-altitude pulmonary edema OR known risk factors that increase susceptibility (e.g. intracardiac shunts, pulmonary hypertension); *AND*
2. The member has tried and failed or has contraindications to first-line therapies such as gradual descent, oxygen therapy/supplementation, and/or portable hyperbaric therapy<sup>[s]</sup>; *AND*
3. The member is unable to use, or has tried and failed nifedipine<sup>[s]</sup>; *AND*
4. Sildenafil is being prescribed at a dose and frequency that is supported by compendia or evidence-based published dosing guidelines for the requested indication; *AND*
5. Chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, sildenafil 50 mg tablets (Viagra) will be approved for the member's duration of high altitude exposure or persistence of signs/symptoms.<sup>[s]</sup>

*Continued Care*

## Medical Necessity Criteria for Subsequent Clinical Review

### Subsequent Indication-Specific Criteria

#### Erectile Dysfunction

The Plan considers sildenafil 25 mg, 50 mg, and 100 mg tablets (Viagra) medically necessary when ALL of the following criteria are met:

1. The member still meets the applicable initial criteria; *AND*
2. Chart documentation shows the member has experienced a clinical improvement in symptoms since starting the requested medication.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12 months.<sup>[s]</sup>

#### Pulmonary Arterial Hypertension

The Plan considers sildenafil 20 mg tablets, sildenafil solution, and sildenafil oral suspension medically necessary when ALL of the following criteria are met:

1. The member still meets the applicable initial criteria; *AND*
2. Chart documentation shows the member experiencing therapeutic response to the requested medication as evidenced by ONE (1) of the following:
  - a. Clinical improvement in symptoms since starting the requested medication; *or*
  - b. Disease stability since starting the requested medication.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12 months.<sup>[s]</sup>

#### Raynaud Phenomenon

The Plan considers sildenafil 20 mg tablets medically necessary when ALL of the following criteria are met:

1. The member still meets the applicable initial criteria; *AND*
2. Chart documentation shows the member has experienced a clinical improvement in symptoms, quality of life, or experienced disease stability since starting the requested medication.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12 months.<sup>[s]</sup>

#### Experimental or Investigational / Not Medically Necessary<sup>[s]</sup>

sildenafil (Viagra), sildenafil 20 mg tablets, sildenafil solution, and sildenafil oral suspension for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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## Appendix A

Table 1: Clinical Classification of Pulmonary Hypertension

<p>Group 1: PAH</p> <ul style="list-style-type: none"> <li>1.1 Idiopathic               <ul style="list-style-type: none"> <li>1.1.1 Long-term responders to calcium channel blockers</li> </ul> </li> <li>1.2 Heritable#</li> <li>1.3 Associated with drugs and toxins#</li> <li>1.4 Associated with:               <ul style="list-style-type: none"> <li>1.4.1 connective tissue disease</li> <li>1.4.2 HIV infection</li> <li>1.4.3 portal hypertension</li> <li>1.4.4 congenital heart disease</li> <li>1.4.5 schistosomiasis</li> </ul> </li> <li>1.5 PAH with features of venous/capillary (PVOD/PCH) involvement</li> <li>1.6 Persistent PH of the newborn</li> </ul>
<p>Group 2: PH associated with left heart disease</p> <ul style="list-style-type: none"> <li>2.1 Heart failure:               <ul style="list-style-type: none"> <li>2.1.1 with preserved ejection fraction</li> <li>2.1.2 with reduced or mildly reduced ejection fraction</li> <li>2.1.3 cardiomyopathies with specific aetiologies¶</li> </ul> </li> <li>2.2 Valvular heart disease:               <ul style="list-style-type: none"> <li>2.2.1 aortic valve disease</li> </ul> </li> </ul>

<p>2.2.2 mitral valve disease</p> <p>2.2.3 mixed valvular disease</p> <p>2.3 Congenital/acquired cardiovascular conditions leading to post-capillary PH</p>
<p>Group 3: PH associated with lung diseases and/or hypoxia</p> <p>3.1 COPD and/or emphysema</p> <p>3.2 Interstitial lung disease</p> <p>3.3 Combined pulmonary fibrosis and emphysema</p> <p>3.4 Other parenchymal lung diseases+</p> <p>3.5 Nonparenchymal restrictive diseases:</p> <p>    3.5.1 hypoventilation syndromes</p> <p>    3.5.2 pneumonectomy</p> <p>3.6 Hypoxia without lung disease (e.g. high altitude)</p> <p>3.7 Developmental lung diseases</p>
<p>Group 4: PH associated with pulmonary artery obstructions</p> <p>4.1 Chronic thromboembolic PH</p> <p>4.2 Other pulmonary artery obstructions§</p>
<p>Group 5: PH with unclear and/or multifactorial mechanisms</p> <p>5.1 Haematological disorders<sup>f</sup></p> <p>5.2 Systemic disorders: sarcoidosis, pulmonary Langerhans cell histiocytosis and neurofibromatosis type 1</p> <p>5.3 Metabolic disorders<sup>##</sup></p> <p>5.4 Chronic renal failure with or without haemodialysis</p> <p>5.5 Pulmonary tumour thrombotic microangiopathy</p> <p>5.6 Fibrosing mediastinitis</p> <p>5.7 Complex congenital heart disease</p>

*COPD: chronic obstructive pulmonary disease; PAH: pulmonary arterial hypertension; PVOD: pulmonary veno-occlusive disease; PCH: pulmonary capillary haemangiomas. #: patients with heritable PAH or PAH associated with drugs and toxins might be long-term responders to calcium channel blockers; ¶: hypertrophic, amyloid, Fabry disease and Chagas disease; +: parenchymal lung diseases not included in group 5; §: other causes of pulmonary artery obstructions include sarcomas (high- or intermediate-grade or angiosarcoma), other malignant tumours (e.g. renal carcinoma, uterine carcinoma, germ-cell tumours of the testis), nonmalignant tumours (e.g. uterine leiomyoma), arteritis without connective tissue disease, congenital pulmonary arterial stenoses and hydatidosis; <sup>f</sup>: including inherited and acquired chronic haemolytic anaemia and chronic myeloproliferative disorders; <sup>##</sup>: including glycogen storage diseases and Gaucher disease.*

#### Clinical Guideline Revision / History Information

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