



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Sildenafil Page: 1 of 6

Effective Date: 11/1/2023 Last Review Date: 9/12/2023

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input checked="" type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for sildenafil under the patient's prescription drug benefit.

### Description:

#### A. FDA-Approved Indication

1. Sildenafil/Revatio/Liqrev is indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1) in adults to improve exercise ability and delay clinical worsening.
2. Sildenafil/Revatio is indicated in pediatric patients 1 to 17 years old for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise.

#### B. Compendial Use

1. Secondary Raynaud's phenomenon (*Tablets only*)
2. Pulmonary arterial hypertension (PAH) (WHO Group I) in pediatric members less than 1 year of age

All other indications are considered experimental/investigational and not medically necessary.

### Applicable Drug List:

#### Preferred Agent:

Sildenafil 20mg tablet  
Liqrev 10mg/mL oral suspension

#### Non-Preferred Agents:

Sildenafil 10mg/mL oral suspension  
Sildenafil 10mg/12.5 mL IV solution

### Policy/Guideline:

#### Prescriber Specialty:

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist for the diagnosis of pulmonary arterial hypertension (PAH).

#### Criteria for Initial Approval:

##### A. **Pulmonary Arterial Hypertension (PAH)**



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Sildenafil

Page: 2 of 6

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Authorization of 12 months may be granted for treatment of PAH when ALL of the following criteria are met:

1. Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix). PAH was confirmed by either criterion (i) or criterion (ii) below:
  - i. Pretreatment right heart catheterization with all of the following results:
    - a. Mean pulmonary arterial pressure (mPAP) > 20 mmHg
    - b. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
    - c. Pulmonary vascular resistance (PVR) ≥ 3 Wood units in adult patients or pulmonary vascular resistance index (PVRI) ≥ 3 Wood units x m<sup>2</sup> in pediatric patients
  - ii. For infants less than one year of age, PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed.
2. Requests for sildenafil 10 mg/mL oral suspension require the patient to have a trial and inadequate treatment response or intolerance, or a contraindication to Liqrev and sildenafil 20mg tablets
3. Requests for sildenafil 10 mg/12.5 mL IV solution require that the patient is unable to use the oral dosage forms.

#### B. Secondary Raynaud's Phenomenon

Authorization of 12 months may be granted for treatment of secondary Raynaud's phenomenon when the member has had an inadequate response to one of the following medications:

1. Calcium channel blockers
2. Angiotensin II receptor blockers
3. Selective serotonin reuptake inhibitors
4. Alpha blockers
5. Topical nitrates

#### Criteria for Continuation of Therapy:

Authorization of 12 months may be granted for members with an indication listed in criteria for initial approval who are currently receiving the requested medication through a paid pharmacy or medical benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

#### Appendix

#### WHO Classification of Pulmonary Hypertension

##### 1 PAH

##### 1.1 [Idiopathic \(PAH\)](#)



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Sildenafil

Page: 3 of 6

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## 1.2 Heritable PAH

## 1.3 Drug- and toxin-induced PAH

## 1.4. PAH associated with:

- 1.4.1 Connective tissue diseases
- 1.4.2 HIV infection
- 1.4.3 Portal hypertension
- 1.4.4 Congenital heart diseases
- 1.4.5 Schistosomiasis

## 1.5 PAH long-term responders to calcium channel blockers

## 1.6 PAH with overt features of venous/capillaries (PVOD/PCH) involvement

## 1.7 Persistent PH of the newborn syndrome

## **2 PH due to left heart disease**

- 2.1 PH due to heart failure with preserved LVEF
- 2.2 PH due to heart failure with reduced LVEF
- 2.3 Valvular heart disease
- 2.4 Congenital/acquired cardiovascular conditions leading to post-capillary PH

## **3 PH due to lung diseases and/or hypoxia**

- 3.1 Obstructive lung disease
- 3.2 Restrictive lung disease
- 3.3 Other lung disease with mixed restrictive/obstructive pattern
- 3.4 Hypoxia without lung disease
- 3.5 Developmental lung disorders

## **4 PH due to pulmonary artery obstruction**

- 4.1 Chronic thromboembolic PH
- 4.2 Other pulmonary artery obstructions
  - 4.2.1 Sarcoma (high or intermediate grade) or angiosarcoma
  - 4.2.2 Other malignant tumors
    - Renal carcinoma
    - Uterine carcinoma
    - Germ cell tumours of the testis
    - Other tumours
  - 4.2.3 Non-malignant tumours
    - Uterine leiomyoma
  - 4.2.4 Arteritis without connective tissue disease
  - 4.2.5 Congenital pulmonary artery stenosis
  - 4.2.6 Parasites
    - Hydatidosis



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Sildenafil Page: 4 of 6

Effective Date: 11/1/2023 Last Review Date: 9/12/2023

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## 5 PH with unclear and/or multifactorial mechanisms

5.1 Hematologic disorders: Chronic hemolytic anemia, myeloproliferative disorders

5.2 Systemic and metabolic disorders: Pulmonary Langerhans cell histiocytosis, Gaucher disease, glycogen storage disease, neurofibromatosis, sarcoidosis

5.3 Others: chronic renal failure with or without hemodialysis, fibrosing mediastinitis

5.4 Complex congenital heart disease

### Approval Duration and Quantity Restrictions:

**Approval:** 12 months

### Quantity Level Limit:

- Sildenafil 20mg tablets: 360 tablets per 30 days
- Sildenafil 10mg/mL suspension: 784mL per 30 days
- Liqrev 10mg/mL suspension: 720mL per 30 days

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AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name:	Sildenafil	Page:	5 of 6
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AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Sildenafil

Page: 6 of 6

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