



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Sildenafil

Page: 1 of 7

Effective Date: 2/28/2025

Last Review Date: 1/2025

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

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:

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹⁻⁴

- Revatio/Liqrev/sildenafil is indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.
- Revatio/sildenafil 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.

Compendial Uses

Secondary Raynaud's phenomenon^{8,9}

PAH (WHO Group I) in pediatric members less than 1 year of age^A

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

Applicable Drug List:

Preferred:

Revatio 10 mg/mL suspension

Sildenafil 20 mg tablet

Non-preferred:

Revatio 20 mg tablet

Sildenafil 10 mg/mL suspension

Revatio (sildenafil) 10 mg/12.5 mL IV solution



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Sildenafil

Page: 2 of 7

Effective Date: 2/28/2025

Last Review Date: 1/2025

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

Policy/Guideline:

Prescriber Specialty:

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist.

Coverage Criteria

Notes:

- For IV Revatio (sildenafil), sildenafil suspension, or Revatio tablets: Member is unable to use formulary alternatives due to a trial and inadequate treatment response or intolerance, or a contraindication.
- Use of sildenafil suspension or Revatio tablets will require inability to use the corresponding preferred formulary alternative
- Use of IV Revatio (sildenafil) will require inability to use oral dosage forms

Pulmonary Arterial Hypertension (PAH)^{1-4,14,17-19}

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

- Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
- PAH was confirmed by either of the following criteria:
 - Pretreatment right heart catheterization with all of the following results:
 - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 2 Wood units. For pediatric members, pulmonary vascular resistance index (PVRI) > 3 Wood units x m² is also acceptable.
 - For infants less than one year of age, PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed.

Secondary Raynaud's Phenomenon⁸⁻¹³

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:

- Calcium channel blockers
- Angiotensin II receptor blockers
- Selective serotonin reuptake inhibitors



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Sildenafil

Page: 3 of 7

Effective Date: 2/28/2025

Last Review Date: 1/2025

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

- Alpha blockers
- Angiotensin-converting enzyme inhibitors
- Topical nitrates

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section 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 (PH)¹⁷

Note: Patients with heritable PAH or PAH associated with drugs and toxins might be long-term responders to calcium channel blockers.

Group 1: Pulmonary Arterial Hypertension (PAH)

- Idiopathic
 - Long-term responders to calcium channel blockers
- Heritable
- Associated with drugs and toxins
- Associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis
- PAH with features of venous/capillary (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
- Persistent PH of the newborn

Group 2: PH associated with Left Heart Disease

- Heart failure:
 - With preserved ejection fraction
 - With reduced or mildly reduced ejection fraction
 - Cardiomyopathies with specific etiologies (i.e., hypertrophic, amyloid, Fabry disease, and Chagas disease)
- Valvular heart disease:
 - Aortic valve disease



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Sildenafil

Page: 4 of 7

Effective Date: 2/28/2025

Last Review Date: 1/2025

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

- Mitral valve disease
- Mixed valvular disease
- Congenital/acquired cardiovascular conditions leading to post-capillary PH

Group 3: PH associated with Lung Diseases and/or Hypoxia

- Chronic obstructive pulmonary disease (COPD) and/or emphysema
- Interstitial lung disease
- Combined pulmonary fibrosis and emphysema
- Other parenchymal lung diseases (i.e., parenchymal lung diseases not included in Group 5)
- Nonparenchymal restrictive diseases:
 - Hypoventilation syndromes
 - Pneumonectomy
- Hypoxia without lung disease (e.g., high altitude)
- Developmental lung diseases

Group 4: PH associated with Pulmonary Artery Obstructions

- Chronic thromboembolic PH
- Other pulmonary artery obstructions:
 - Sarcomas (high- or intermediate-grade or angiosarcoma)
 - Other malignant tumors (e.g., renal carcinoma, uterine carcinoma, germ-cell tumors of the testis)
 - Non-malignant tumors (e.g., uterine leiomyoma)
 - Arteritis without connective tissue disease
 - Congenital pulmonary artery stenoses
 - Hydatidosis

Group 5: PH with Unclear and/or Multifactorial Mechanisms

- Hematological disorders, including inherited and acquired chronic hemolytic anemia and chronic myeloproliferative disorders
- Systemic disorders: Sarcoidosis, pulmonary Langerhans cell histiocytosis, and neurofibromatosis type 1
- Metabolic disorders, including glycogen storage diseases and Gaucher disease
- Chronic renal failure with or without hemodialysis
- Pulmonary tumor thrombotic microangiopathy
- Fibrosing mediastinitis
- Complex congenital heart disease



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Sildenafil

Page: 5 of 7

Effective Date: 2/28/2025

Last Review Date: 1/2025

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

Appendix

WHO Classification of Pulmonary Hypertension

1 PAH

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

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



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Sildenafil

Page: 6 of 7

Effective Date: 2/28/2025

Last Review Date: 1/2025

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

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

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:

- Revatio (sildenafil) 20 mg tablets: 360 tablets per 30 days
- Revatio (sildenafil) 10 mg/mL suspension: 784 mL per 30 days

References:

1. Revatio [package insert]. Morgantown, WV; Viatris Specialty LLC; January 2023.
2. Liqrev [package insert]. Farmville, NC: CMP Pharma, Inc.; April 2023.
3. Sildenafil [package insert]. Piscataway, NJ: Camber Pharmaceuticals, Inc.; February 2024.
4. Sildenafil for oral suspension [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; January 2024.
5. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association developed in collaboration with the American College of Chest Physicians; American Thoracic Society, Inc.; and the Pulmonary Hypertension Association. *J Am Coll Cardiol*. 2009;53(17):1573-1619.
6. Badesch DB, Champion HC, Gomez-Sanchez MA, et al. Diagnosis and assessment of pulmonary arterial hypertension. *J Am Coll Cardiol*. 2009;54:S55-S66.
7. Taichman DB, Ornelas J, Chung L, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults: CHEST guideline and expert panel report. *Chest*. 2014;146(2):449-475.
8. Barst RJ, Ivy DD, Gaitan G, et al. A randomized, double-blind, placebo-controlled, dose-ranging study of oral sildenafil citrate in treatment-naïve children with pulmonary arterial hypertension. *Circulation*. 2012;125:324-334.
9. Abman, SH, Hansmann G, Archer SL, et al. Pediatric pulmonary hypertension: guidelines from the American Heart Association and American Thoracic Society. *Circulation*. 2015;132(21):2037-99.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Sildenafil

Page: 7 of 7

Effective Date: 2/28/2025

Last Review Date: 1/2025

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

10. Galiè N, Ghofrani HA, Torbicki A, et al. Sildenafil citrate therapy for pulmonary arterial hypertension. *N Engl J Med*. 2005;353:2148-2157.
11. Rubin LJ, Badesch DB, Fleming RT, et al. Long-term treatment with sildenafil citrate in pulmonary arterial hypertension. *Chest*. 2011;140(5):1274-1283.
12. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed April 12, 2024.
13. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed April 12, 2024.
14. Hughes M, Ong VH, Anderson ME, et al. Consensus best practice pathway of the UK Scleroderma Study Group: digital vasculopathy in systemic sclerosis. *Rheumatology*. 2015;54:2015-2024.
15. Roustit M, Blaise S, Allanore Y, et al. Phosphodiesterase-5 inhibitors for the treatment of secondary Raynaud's phenomenon: systematic review and meta-analysis of randomized trials. *Ann Rheum Dis*. 2013;72(10):1696-1699.
16. Walker KM, Pope J, et al. Treatment of systemic sclerosis complications: what to use when first-line treatment fails – a consensus of systemic sclerosis experts. *Semin Arthritis Rheum*. 2012;42(1):42-55.
17. Kowal-Bielecka O, Fransen J, Avouac J, et al. Update of EULAR recommendations for the treatment of systemic sclerosis. *Ann Rheum Dis*. 2017;76(8):1327-1339.
18. Klinger, JR., Elliott, CG, Levine, DJ, et al. Therapy for pulmonary arterial hypertension in adults: update of the CHEST guideline and expert panel report. *Chest*. 2019;155(3):565-586.
19. Galie, N., McLaughlin, VV, Rubin, LJ, Simonneau, G. An overview of the 6th World Symposium on Pulmonary Hypertension. *Eur Respir J* 2019;53(1):1802148. doi: 10.1183/13993003.02148-2018
20. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019;53(1):1801913. doi: 10.1183/13993003.01913-2018.
21. Barst RJ, Beghetti M, Pulido T, et al. STARTS-2: long-term survival with oral sildenafil monotherapy in treatment-naïve pediatric pulmonary arterial hypertension. *Circulation*. 2014;129(19):1914-23.
22. Kwan WC, Shavelle DM, Laughrun DR. Pulmonary vascular resistance index: getting the units right and why it matters. *Clin Cardiol*. 2019;42(3):334-338.