



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Tadalafil Products Page: 1 of 5

Effective Date: 10/15/2025 Last Review Date: 9/2025

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"/> Kentucky PRMD

**Intent:**

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

**Description:**

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 Indications<sup>1-4</sup>

Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with New York Heart Association (NYHA) Functional Class II – III symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Compendial Uses<sup>5</sup>

Secondary Raynaud’s phenomenon

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

**Applicable Drug List:**

Preferred:

- Tadalafil 20 mg tablet
- Adcirca 20 mg tablet
- Alyq 20 mg tablet

Non-preferred:

- Tadliq 20mg/5 mL suspension

**Policy/Guideline:**

**Prescriber Specialties**

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



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Tadalafil Products Page: 2 of 5  
Effective Date: 10/15/2025 Last Review Date: 9/2025

Applies to:  Illinois  Florida  Florida Kids  
 New Jersey  Maryland  Michigan  
 Pennsylvania Kids  Virginia  Kentucky PRMD

### Coverage Criteria

**Note:** For Tadalafil suspension requests require that member is unable to take the required number of formulary alternatives (3) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

#### Pulmonary Arterial Hypertension (PAH)<sup>1-4,6-9</sup>

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 m<sup>2</sup> 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 Phenomenon<sup>5,10-12</sup>

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
- Alpha blockers
- Angiotensin-converting enzyme inhibitors

### 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 a tadalafil product through a paid pharmacy or medical benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Tadalafil Products

Page: 3 of 5

Effective Date: 10/15/2025

Last Review Date: 9/2025

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"/> Kentucky PRMD

## Appendix

### WHO Classification of Pulmonary Hypertension (PH)<sup>7</sup>

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
  - 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



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Tadalafil Products Page: 4 of 5

Effective Date: 10/15/2025 Last Review Date: 9/2025

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"/> Kentucky PRMD

- 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

#### Approval Duration and Quantity Restrictions:

**Approval:** 12 months

#### Quantity Level Limit:

- Adcirca, Alyq, and tadalafil 20 mg tablets: 60 per 30 days
- Tadliq 10 mg/5 mL suspension: 300 mL per 30 days

#### References:

1. Adcirca [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2020.



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Tadalafil Products Page: 5 of 5

Effective Date: 10/15/2025 Last Review Date: 9/2025

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"/> Kentucky PRMD

2. Alyq [package insert]. Parsippany, NJ: Teva Pharmaceuticals; April 2023.
3. Tadiq [package insert]. Farmville, NC: CMP Pharma, Inc.; October 2023.
4. Tadalafil [package insert]. Bridgewater, NJ: Ajanta Pharma USA Inc.; May 2023.
5. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed April 1, 2025.
6. 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
7. Kovacs G, Bartolome S, Denton CP, et al. Definition, classification and diagnosis of pulmonary hypertension. *Eur Respir J.* 2024;64(4):2401324. doi: 10.1183/13993003.01324-2024
8. Chin KM, Gaine SP, Gerges C, et al. Treatment algorithm for pulmonary arterial hypertension. *Eur Respir J.* 2024;64(4):2401325. doi: 10.1183/13993003.01325-2024
9. Ivy D, Rosenzweig EB, Abman SH, et al. Embracing the challenges of neonatal and paediatric pulmonary hypertension. *Eur Respir J.* 2024;64(4):2401345. doi: 10.1183/13993003.01345-2024
10. Curtiss P, Svigos K, Schwager Z, Lo Sicco K, Franks AG Jr. Part II: The treatment of primary and secondary Raynaud's phenomenon. *J Am Acad Dermatol.* 2024 Feb;90(2):237-248. doi: 10.1016/j.jaad.2022.05.067
11. Maltez N, Maxwell LJ, Rirash F, et al. Phosphodiesterase 5 inhibitors (PDE5i) for the treatment of Raynaud's phenomenon. *Cochrane Database Syst Rev.* 2023 Nov 6;11(11):CD014089. doi: 10.1002/14651858
12. Del Galdo F, Lescoat A, Conaghan PG, et al. EULAR recommendations for the treatment of systemic sclerosis: 2023 update. *Annals of the Rheumatic Diseases* Published Online First: 11 October 2024. doi: 10.1136/ard-2024-226430