

	
AETNA BETTER HEALTH® Coverage Policy/Guideline	
Name: Tadalafil Products	Page: 1 of 5
Effective Date: 2/28/2025	Last Review Date: 1/2025
Applies to:	<div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"><input checked="" type="checkbox"/> Illinois</div> <div style="width: 50%;"><input type="checkbox"/> Florida</div> <div style="width: 50%;"><input type="checkbox"/> Florida Kids</div> <div style="width: 50%;"><input type="checkbox"/> New Jersey</div> <div style="width: 50%;"><input type="checkbox"/> Maryland</div> <div style="width: 50%;"><input type="checkbox"/> Michigan</div> <div style="width: 50%;"><input type="checkbox"/> Pennsylvania Kids</div> <div style="width: 50%;"><input type="checkbox"/> Virginia</div> <div style="width: 50%;"><input type="checkbox"/> Kentucky PRMD</div> </div>

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:

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

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 Uses⁵

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 Specialty

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



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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)^{1-4,6-9}

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 Phenomenon^{5,10-13}

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
- 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.



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Appendix

WHO Classification of Pulmonary Hypertension (PH)⁷

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



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- 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.



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2. Alyq [package insert]. Parsippany, NJ: Teva Pharmaceuticals; April 2023.
3. Tadliq [package insert]. Farmville, NC: CMP Pharma, Inc.; October 2023.
4. Tadalafil tablet [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 November 20, 2024.
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. 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.
11. 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.
12. 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.
13. 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.