



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Tadalafil Products Page: 1 of 5

Effective Date: 12/21/2023 Last Review Date: 11/2023

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:

A. FDA-Approved Indication

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 NYHA Functional Class II – III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).

B. Compendial Use

Secondary Raynaud's phenomenon

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

Applicable Drug List:

Tadalafil 20 mg tablet
Adcirca 20 mg tablet
Alyq 20 mg tablet
Tadliq 20mg/5 mL suspension

Policy/Guideline:

Prescriber Specialty

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

Criteria for Initial Approval

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

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).
2. PAH was confirmed by either criterion (i) or criterion (ii) below:
 - i. Pretreatment right heart catheterization with all of the following results:



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- a. mPAP > 20 mmHg
 - b. PCWP ≤ 15 mmHg
 - c. Pulmonary vascular resistance (PVR) ≥ 3 Wood units in adult patients or pulmonary vascular resistance index (PVRI) ≥ 3 Wood units x m² 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.
3. For Tadalafil suspension: Patient 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.

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 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.

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



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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

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



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5.4 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

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15. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019;53:1801913; doi:10.1183/13993003.01913-2018.



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- 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.