	TTER HEALTH® Policy/Guideline	<b>*ae</b>	etna™	
Name:	Tadalafil Products		Page:	1 of 5
Effective Date: 11/1/2024			Last Review Date:	10/2024
Applies to:	⊠Illinois □New Jersey □Pennsylvania Kids	□Florida □Maryland □Virginia	□Florida Kids □Michigan □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. <u>Compendial Use</u> Secondary Raynaud's phenomenon

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

# **Applicable Drug List:**

<u>Preferred:</u> Tadalafil 20 mg tablet Adcirca 20 mg tablet Alyq 20 mg tablet

<u>Non-preferred:</u> Tadliq 20mg/5 mL suspension

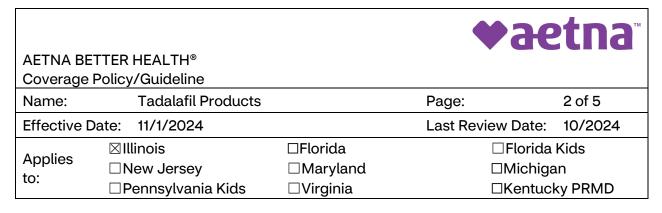
# **Policy/Guideline:**

#### **Prescriber Specialty**

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

# **Criteria for Initial Approval**

**Note: F**or Tadliq 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.



# 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:
    - a. mPAP > 20 mmHg
    - b.  $PCWP \le 15 \text{ mmHg}$
    - c. Pulmonary vascular resistance (PVR)  $\geq$  3 Wood units in adult patients or pulmonary vascular resistance index (PVRI)  $\geq$  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.

# 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. Angiotensin-converting enzyme inhibitors
- 6. 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



#### **AETNA BETTER HEALTH®**

Coverage Policy/Guideline

Name: Tadalafil Products Page:	3 of 5	
Effective Date: 11/1/2024 Last Review	Date: 10/2024	
Applies Illinois DFlorida DF	□Florida Kids	
Applies New Jersey Maryland	□Michigan	
$\Box$ Pennsylvania Kids $\Box$ Virginia $\Box$ K	□Kentucky PRMD	

- 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

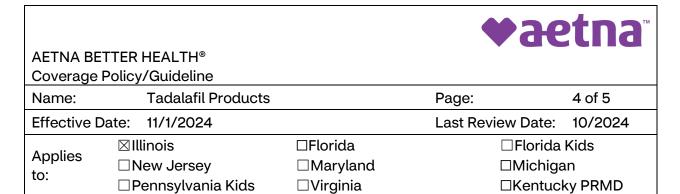
- 2.1 PH due to heart failure with preserved LVEF
- 2.2 PH due to heart failure with reduced LVEF
- 2.3 Valvular heart disease
- 2.4 Congenital/acquired cardiovascular conditions leading to post-capillary PH

# 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



### 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:**

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

#### **References:**

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- 3. Tadliq [package insert]. Farmville, NC: CMP Pharma, Inc.; June 2022.
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- 16. 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.