

**Adcirca (tadalafil tablet)  
 Alyq (tadalafil tablet)  
 tadalafil tablets (generic)**  
**Effective 04/01/2023**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical Benefit</b> <b>Pharmacy Benefit</b>	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<b>Exceptions</b>	Tadalafil (Cialis) for BPH is listed under its own policy.		

### Overview

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 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%).

#### Compendial Use

Secondary Raynaud's phenomenon

#### **Coverage Guidelines**

Authorization may be granted for members who are new to the plan and receiving treatment excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

#### **Pulmonary Arterial Hypertension (PAH)**

Authorization 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 ONE of the following:
  - a. Pretreatment right heart catheterization with ALL of the following results:
    - i. mPAP > 20 mmHg
    - ii. PCWP ≤ 15 mmHg
    - iii. PVR ≥ 3 Wood units
  - b. 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**

Authorization 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

### **Continuation of Therapy**

Reauthorization requires physician documentation of benefit from therapy as evidenced by disease stability or disease improvement.

### **Limitations**

1. Initial approvals and reauthorizations will be approved for up to 12 months.
2. A quantity limit of 60 tablets per month applies.

### **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
- 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

### References

1. Adcirca [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2020.
2. Tadalafil [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; August 2019.
3. Alyq [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; January 2019.
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16. 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.

#### **Review History**

01/11/2023 – Switched to custom from SGM. Split out MH/ComExch. Tadliq moved to NF. Effective 04/01/2023

