

## SPECIALTY GUIDELINE MANAGEMENT

### ADCIRCA (tadalafil) ALYQ (tadalafil) TADLIQ (tadalafil) tadalafil

## POLICY

### I. 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.

#### 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 New York Heart Association (NYHA) Functional Class II – III symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

#### B. Compendial Use

Secondary Raynaud's phenomenon

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

### II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist for the diagnosis of pulmonary arterial hypertension (PAH).

### III. 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:
    - a. Mean pulmonary arterial pressure (mPAP) > 20 mmHg
    - b. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
    - c. Pulmonary vascular resistance (PVR) ≥ 3 Wood units in adult members or pulmonary vascular resistance index (PVRI) ≥ 3 Wood units x m<sup>2</sup> in pediatric members
  - 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

**IV. CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for members with an indication listed in Section III 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.

**V. APPENDIX****WHO Classification of Pulmonary Hypertension****1 Pulmonary arterial hypertension (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 disease
  - 1.4.2 Human immunodeficiency virus (HIV) infection
  - 1.4.3 Portal hypertension
  - 1.4.4 Congenital heart disease
  - 1.4.5 Schistosomiasis
- 1.5 PAH long-term responders to calcium channel blockers
- 1.6 PAH with overt features of venous/capillaries (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [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 left ventricular ejection fraction (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 obstructions**

- 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 tumors of the testis
- Other tumors
- 4.2.3 Non-malignant tumors
  - 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

#### IV. REFERENCES

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