Reference number(s)
1640-A

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^2 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

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