Reference number(s)
1640-A

Specialty Guideline Management
Tadalafil Products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Adcirca	tadalafil
Alyq	tadalafil
Tadliq	tadalafil

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.

FDA-approved Indications

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.

Compendial Uses

Secondary Raynaud's phenomenon

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

Reference number(s)
1640-A

Prescriber Specialties

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

Coverage Criteria

Pulmonary arterial hypertension (PAH)

Authorization of 12 months may be granted for treatment of PAH when ALL of the following criteria are met:

- Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
- PAH was confirmed by either criterion (i) or criterion (ii) below:
    - Pretreatment right heart catheterization with all of the following results:
        - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
        - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
        - 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
    - 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 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:

- Calcium channel blockers
- Angiotensin II receptor blockers
- Selective serotonin reuptake inhibitors
- Alpha blockers
- Angiotensin-converting enzyme inhibitors
- Topical nitrates

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section 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

- Pulmonary arterial hypertension (PAH)
    - Idiopathic PAH
    - Heritable PAH
    - Drug- and toxin-induced PAH
    - PAH associated with:
        - Connective tissue disease
        - Human immunodeficiency virus (HIV) infection
        - Portal hypertension
        - Congenital heart disease
        - Schistosomiasis
    - PAH long-term responders to calcium channel blockers
    - PAH with overt features of venous/capillaries (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
    - Persistent PH of the newborn syndrome
- PH due to left heart disease
    - PH due to heart failure with preserved left ventricular ejection fraction (LVEF)
    - PH due to heart failure with reduced LVEF
    - Valvular heart disease
    - Congenital/acquired cardiovascular conditions leading to post-capillary PH
- PH due to lung diseases and/or hypoxia
    - Obstructive lung disease
    - Restrictive lung disease
    - Other lung disease with mixed restrictive/obstructive pattern
    - Hypoxia without lung disease
    - Developmental lung disorders

- PH due to pulmonary artery obstructions
    - Chronic thromboembolic PH
    - Other pulmonary artery obstructions
        - Sarcoma (high or intermediate grade) or angiosarcoma
        - Other malignant tumors
            - Renal carcinoma
            - Uterine carcinoma
            - Germ cell tumors of the testis
            - Other tumors
        - Non-malignant tumors
            - Uterine leiomyoma
        - Arteritis without connective tissue disease
        - Congenital pulmonary artery stenosis
        - Parasites
            - Hydatidosis
- PH with unclear and/or multifactorial mechanisms
    - Hematologic disorders: Chronic hemolytic anemia, myeloproliferative disorders
    - Systemic and metabolic disorders: Pulmonary Langerhans cell histiocytosis, Gaucher disease, glycogen storage disease, neurofibromatosis, sarcoidosis
    - Others: Chronic renal failure with or without hemodialysis, fibrosing mediastinitis
    - Complex congenital heart disease

References

1. Adcirca [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2020.
2. Alyq [package insert]. Parsippany, NJ: Teva Pharmaceuticals; April 2023.
3. Tadliq [package insert]. Farmville, NC: CMP Pharma, Inc.; June 2022.
4. Tadalafil [package insert]. Bridgewater, NJ: Ajanta Pharma USA Inc.; July 2022.
5. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed April 8, 2024.
6. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association developed in collaboration with the American College of Chest Physicians, American Thoracic Society, Inc., and the Pulmonary Hypertension Association. J Am Coll Cardiol. 2009;53(17):1573-1619.
7. Badesch DB, Champion HC, Gomez-Sanchez MA, et al. Diagnosis and assessment of pulmonary arterial hypertension. J Am Coll Cardiol. 2009;54:S55-S66.
8. Taichman DB, Ornelas J, Chung L, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults: CHEST guideline and expert panel report. Chest. 2014;146(2):449-475.
9. Abman SH, Hansmann G, Archer SL, et al. Pediatric pulmonary hypertension: guidelines from the American Heart Association and American Thoracic Society. Circulation. 2015;132(21):2037-99.

10. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for pulmonary arterial hypertension in adults: update of the CHEST guideline and expert panel report. Chest. 2019;155(3):565-586.
11. Galie N, McLaughlin VV, Rubin LJ, Simonneau G. An overview of the 6th World Symposium on Pulmonary Hypertension. Eur Respir J. 2019;53(1):1802148. doi: 10.1183/13993003.02148-2018.
12. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. Eur Respir J. 2019;53(1):1801913. doi:10.1183/13993003.01913-2018.
13. Hughes M, Ong VH, Anderson ME, et al. Consensus best practice pathway of the UK Scleroderma Study Group: digital vasculopathy in systemic sclerosis. Rheumatology. 2015;54:2015-2024.
14. 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.
15. Walker KM, Pope J, et al. Treatment of systemic sclerosis complications: what to use when first-line treatment fails – a consensus of systemic sclerosis experts. Semin Arthritis Rheum. 2012;42(1):42-55.
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.