

Policy Name:	Tadalafil PAH Agents	Policy #:	2444P
---------------------	-----------------------------	------------------	--------------

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Adcirca, Alyq, or tadalafil.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Adcirca, Alyq, or tadalafil under the specialty pharmacy benefit when the following criteria have been met. Tadalafil suspension is non-formulary and requires documentation of trial with all formulary alternatives.

Criteria

1. Coverage Criteria for Pulmonary Arterial Hypertension (PAH)

- 1.1 Prescribed by a Pulmonologist (lung doctor) or Cardiologist (heart doctor)
- 1.2 Diagnosis of PAH with a resting (25 mmHg) or active (30 mmHg) mean pulmonary artery pressure confirmed by right heart catheterization or echocardiography
- 1.3 World Health Organization (WHO) Group 1, New York Heart Association (NYHA) Functional Class II or III symptoms
- 1.4 Member is at least 18 years of age
- 1.5 Documented previous failure of or contraindication to a calcium channel blocker (CCB) such as amlodipine if testing reveals vasoreactivity
- 1.6 Documented previous failure of or contraindication to sildenafil (generic Revatio)
- 1.7 Coverage of Adcirca requires a documented allergic reaction to generic tadalafil

2. Exclusion Criteria

- 2.1 Concurrent use with organic nitrates

3. Approval Period

- 3.1 12 months

CPT Codes

--	--

HCPCS Codes

--	--

References

1. Adcirca [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2020.
2. Alyq (tadalafil) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA; September 2021.
3. Chin KM, Rubin LJ. Pulmonary arterial hypertension. *J Am Coll Cardiol*. 2008;51(16):1527-1538.
4. Galie N, Corris P, Frost A, et al. Updated treatment algorithm of pulmonary arterial hypertension. *J Am Coll Cardiol*. 2013;62:D60-72.
5. Humbert M, Kovacs G, Hoeper MM, et al; ESC/ERS Scientific Document Group. 2022 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J*. 2022;43(38):3618-3731.
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. 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.
8. Chin KM, Sitbon O, Doelberg M, et al. Three- Versus Two-Drug Therapy for Patients With Newly Diagnosed Pulmonary Arterial Hypertension. *J Am Coll Cardiol*. 2021 Oct 5;78(14):1393-1403.
9. Simonneau G, Robbins IM, Beghetti M, et al. Updated clinical classification of pulmonary hypertension. *J Am Coll Cardiol*. 2009;54:S43-S54.

Created Date: 02/03/16

Effective Date: 02/03/16

Posted to Website: 01/01/2022

Revision Date: 06/07/2023

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies.

Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.