Pharmacy Drug Policy & Procedure

Policy Name:	Pulmonary Arterial Hypertension Products	Policy#:	3246P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for medications used for treatment of pulmonary arterial hypertension (PAH).

Statement of the Policy

Health Alliance Medical Plans will approve the use of use of the below PAH treatments under the pharmacy or medical benefit as applicable if the following criteria are met.

Medications: Adcirca, Alyq, Tadliq (tadalafil), Revatio, Liqrev (sildenafil), Adempas (riociguat), Letairis (ambrisentan), Tracleer (bosentan), Opsumit (macitentan), Uptravi (selexipag), Flolan/Veletri (epoprostenol) Ventavis (iloprost), Remodulin/Tyvaso/ Orenitram (treprostinil), Winrevair (sotatercept), Opsynvi (macitentan/ tadalafil).

Criteria

1. Coverage Criteria

1.1 Diagnosis of pulmonary arterial hypertension (PAH) with a resting (≥20 mmHg) mean pulmonary artery pressure (mPAP) and pulmonary vascular resistance (PVR) ≥2 wood units confirmed by right heart catheterization or echocardiography

1.2 Prescribed by or in consultation with a Pulmonologist (lung doctor) or Cardiologist (heart doctor)

1.3 World Health Organization (WHO) Group 1 with Functional Class II or III symptoms
- Epoprostenol products, Tyvaso and Ventavis are only approved in patients with Functional Class III or IV symptoms
- Remodulin/Treprostinil and Tracleer are also approved in patients with Functional Class IV symptoms

1.4 Age 18 years or older (age 1 year or older for sildenafil, age 3 years or older for Tracleer)

1.5 Documented previous failure of or contraindication to a calcium channel blocker (CCB) if testing reveals vasoreactivity

1.6 Coverage of any brand product requires a documented allergic reaction to the equivalent generic
- Revatio – sildenafil
- Adcirca – tadalafil
- Flolan/Veletri – epoprostenol
- Remodulin – tresprostinil
- Letairis – ambrisentan
- Tracleer – bosentan

1.7 Coverage of Opsumit/Opsynvi requires a documented previous failure of or contraindication to ambrisentan (generic Letairis)

2. Exclusion Criteria

2.1 Pregnancy

2.2 Multiple medications within the same therapeutic class will not be covered simultaneously as this is a

duplication of therapy

3. Approval Period

3.1 Initial: 12 months

3.2 Reauthorization: 12 months with documented clinical benefit from therapy

CPT Codes	
HCPCS Codes	
J1325	Injection, epoprostenol, 0.5 mg
Q4074	Iloprost, inhalation solution, administered through DME, up to 20 mcg
J3285	Injection, treprostinil, 1 mg
J7686	Treprostinil, inhalation solution, administered through DME, 1.74 mg

References

1. 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 Mar;155(3):565-586.
2. 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: Developed by the task force for the diagnosis and treatment of pulmonary hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Endorsed by the International Society for Heart and Lung Transplantation (ISHLT) and the European Reference Network on rare respiratory diseases (ERN-LUNG). Eur Heart J. 2023 Apr 17;44(15):1312.
3. Kuwana M, Blair C, Takahashi T, et al. Initial combination therapy of ambrisentan and tadalafil in connective tissue disease-associated pulmonary arterial hypertension (CTD-PAH) in the modified intention-to-treat population of the AMBITION study: post hoc analysis. Ann Rheum Dis. 2020 May;79(5):626-634.
4. 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.

Created Date: 06/05/24
Effective Date: 06/05/24
Posted to Website: 06/05/24
Revision Date:

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.