Clinical Policy Title:	Pulmonary Arterial Hypertension (PAH) Agents
Policy Number:	RxA.258
Drug(s) Applied:	Adempas, Orenitram®, Tyvaso®, Ventavis
Original Policy Date:	02/07/2020
Last Review Date:	8/27/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Pulmonary Arterial Hypertension (PAH) (must meet all):

1. Diagnosis of symptomatic Pulmonary Arterial Hypertension (PAH) (WHO Group 1).

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Pulmonary Hypertension Associated with Interstitial Lung Disease (must meet all):

1. Diagnosis of pulmonary hypertension associated with interstitial lung disease (WHO Group 3);
2. Request is for Tyvaso®;
3. If pulmonary hypertension is due to connective tissue disease, member's baseline forced vital capacity (FVC) is < 70%;
4. The member's diagnosis of interstitial lung disease is confirmed by diffuse parenchymal lung disease on computed tomography of the chest.

Approval Duration

All Lines of Business (except Medicare): 12 months.

C. Persistent or Recurrent Chronic-Thromboembolic Pulmonary Hypertension (CTEPH);

1. Diagnosis of persistent or recurrent Chronic-Thromboembolic Pulmonary Hypertension (CTEPH);
2. The request is for Adempas.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.
2. Continued therapy for the requested medication is for the appropriate indication listed above.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Kim NH, Delcroix M, Jenkins DP, et al. Chronic thromboembolic pulmonary hypertension. J Am Coll Cardiol 2013; 62(25): Suppl D92-99. Available at: https://pubmed.ncbi.nlm.nih.gov/24355646/. Accessed January 2, 2023.
2. Waxman A, Restrepo-Jaramillo R, Thenappan T, et al. Inhaled treprostinil in pulmonary hypertension due to interstitial lung disease. NEJM. 2021;384:325. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2008470. Accessed August 27th, 2024.
3. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457. doi: 10.1016/j.chest.2020.11.021]. *Chest*. 2019;155(3):565-586. Accessed August 27th, 2024.
4. Nathan SD, Deng C, King CS, et al. Inhaled Treprostinil Dosage in Pulmonary Hypertension Associated With Interstitial Lung Disease and Its Effects on Clinical Outcomes. *Chest*. 2023;163(2):398-406. Accessed August 27th, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy updated. 1. Formatting updated. 2. Criteria for approval and continued approval updated. 3. Approval duration updated. 4. Reference Updated	07/21/2020	9/14/2020
Policy updated. 1. Policy title was updated. 2. Clinical policy verbiage has been updated as 'The provision of prescriber samples…. 3. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance.." 4. References were reviewed and updated.	04/06/2021	06/10/2021
Policy updated. 1. Initial Approval Criteria, I.B: Updated to include approval criteria for indication Pulmonary Hypertension Associated with Interstitial Lung Disease. 2. Initial Approval Criteria I.A.5 and Continued Approval Criteria: Updated dose from 9 breaths to 12 breaths. 3. Initial Approval Criteria, 1.A.4 Updated to include new age criteria Age ≥ 18 years. 4. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. Continued Therapy Approval Crtierial Criteria, II.B: Updated to include approval criteria for indication Pulmonary Hypertension Associated with Interstitial Lung Disease. 6. References were reviewed and updated.	01/10/2022	04/18/2022

Policy updated. 1. References were reviewed and updated.	1/2/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed. 1. Combined polices for Adempas, Orenitram, Tyvaso, and Ventavis. 2. Removed Remodulin which is non-formulary, 3. Removed prescriber specialty, age and dosing. 4. Removed trial and failure of a calcium channel blocker. 5. Removed confirmation of pulmonary hypertension by right heart catheterization. 6. Revised continued therapy approval for lookback period of 120 days and medication is for the appropriate indication.	8/27/2024	09/12/2024