UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2026 P 1076-19 |
| Program | Prior Authorization/Notification – PAH Agents |
| Medication | Adcirca®* (tadalafil), Adempas® (riociguat), Alyq™ (tadalafil), Letairis®* (ambrisentan), Liqrev® (sildenafil) oral suspension*, Opsumit® (macitentan), Opsynvi®* (macitentan/tadalafil), Orenitram™ (treprostinil), Revatio® (sildenafil citrate) oral powder for suspension*, Tadliq® (tadalafil) oral suspension, Tracleer® (bosentan), Tyvaso® (treprostinil), Tyvaso DPI™ (treprostinil), Uptravi® (selexipag), Ventavis® (iloprost), Yutrepia™ (treprostinil)<br><br>**Note:** These criteria only apply to the oral suspension formulations of sildenafil citrate. The intravenous (IV) formulation is not self-administered and is therefore not covered under the pharmacy benefit. |
| P&T Approval Date | 9/2006, 4/2008, 4/2009, 8/2009, 10/2009, 7/2010, 5/2011, 5/2012, 5/2013, 10/2013, 2/2014, 5/2015, 3/2016, 3/2017, 11/2017, 11/2018, 6/2019, 6/2020, 6/2021, 6/2022, 10/2022, 12/2022, 3/2023, 2/2024, 8/2024, 8/2025, 11/2025, 6/2026 |
| Effective Date | 8/1/2026 |

## 1. Background:

Pulmonary arterial hypertension (PAH) is often a progressive disease characterized by elevated pressure in the vessels that carry blood between the heart and the lungs. This results in ventricular dysfunction, reduced exercise capacity, the potential for right sided heart failure, and even death.

Several mechanisms have been identified in the pathogenesis of PAH, leading to the development of five classes of medications to treat the disorder; endothelin receptor antagonists (ERAs), phosphodiesterase-5 (PDE-5) inhibitors, prostacyclin analogs, soluble guanylate cyclase (sGC) stimulators, and an activin signaling ligand.

Letairis* (ambrisentan), Tracleer (bosentan), and Opsumit (macitentan) are oral endothelin receptor antagonists (ERAs). Letairis is indicated for the treatment of PAH (WHO Group 1) to improve exercise ability and delay clinical worsening. It is also indicated in combination with tadalafil to reduce the risk of disease progression and hospitalization for worsening PAH, and to improve exercise ability. [2] Tracleer is indicated for the treatment of PAH (WHO Group 1) to improve exercise ability and to decrease clinical worsening in adult patients, and improve pulmonary vascular resistance, which is expected to result in an improvement in exercise ability in pediatric patients aged 3 years and older.[3] Opsumit is indicated for the treatment of PAH (WHO Group 1) to reduce the risks of disease progression and hospitalization for PAH.[8]

Revatio* (sildenafil), Liqrev* (sildenafil), Alyq (tadalafil), Adcirca* (tadalafil), and Tadliq (tadalafil) are oral PDE-5 inhibitors. Revatio* is indicated in pediatric patients 1 to 17 years old for the treatment of PAH (WHO Group 1) to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise.[4] Revatio* and Liqrev* are indicated in adult patients for the treatment of PAH (WHO

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Group 1) to improve exercise ability and delay clinical worsening.[4,15] Adcirca*, Alyq, and Tadliq are indicated for the treatment of PAH (WHO Group 1) to improve exercise ability.[5, 13-14]

Ventavis (iloprost), Tyvaso (treprostinil), Tyvaso DPI (treprostinil), and Yutrepia (treprostinil) are prostacyclin analogs. Ventavis is administered as an inhalation solution, Tyvaso is administered as an inhalation solution, and Tyvaso DPI is administered as a dry powder inhaler. Ventavis is indicated for the treatment of PAH (WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration.[6] Tyvaso, Tyvaso DPI, and Yutrepia are indicated for the treatment of PAH (WHO Group 1) to improve exercise ability. Tyvaso, Tyvaso DPI, and Yutrepia are also indicated for the treatment of pulmonary hypertension associated with interstitial lung disease (WHO Group 3) to improve exercise ability.[7,12]

Orenitram (treprostinil) is an orally administered prostacyclin analog indicated for the treatment of PAH (WHO Group 1) to delay disease progression and improve exercise capacity.[9]

Uptravi (selexipag) is a prostacyclin receptor agonist indicated for the treatment of PAH (WHO Group 1) to delay disease progression and reduce the risk of hospitalization for PAH.[11]

Adempas (riociguat) is a soluble guanylate cyclase (sGC) stimulator indicated for the treatment of adults with PAH (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening. Adempas is also indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class.[10]

Opsynvi***** (macitentan/tadalafil) is a combination of macitentan, an endothelin receptor antagonist (ERA), and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, indicated for chronic treatment of pulmonary arterial hypertension (PAH, WHO Group I) in adult patients of WHO functional class (FC) II-III.[16]

**2. Coverage Criteria[a]:**

**A. Pulmonary Arterial Hypertension**

1. **Initial Authorization**

   a. **Adcirca*, Adempas, Alyq, Letairis*, Liqrev oral suspension*, Opsumit, Opsynvi*, Orenitram, Revatio oral powder for suspension*, Tadliq oral suspension, Tracleer, Tyvaso, Tyvaso DPI, Uptravi, Ventavis,** or **Yutrepia** will be approved based on the following criterion:

      (1) Diagnosis of pulmonary arterial hypertension which is symptomatic

   **Authorization will be issued for 12 months.**

2. **Reauthorization**

   a. **Adcirca*, Adempas, Alyq, Letairis*, Liqrev oral suspension*, Opsumit, Opsynvi*, Orenitram, Revatio oral powder for suspension*, Tadliq oral suspension, Tracleer, Tyvaso, Tyvaso DPI, Uptravi, Ventavis,** or **Yutrepia** will be approved based on the following criterion:

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(1) Documentation of positive clinical response to therapy

**Authorization will be issued for 12 months.**

**B. Chronic Thromboembolic Pulmonary Hypertension (CTEPH)**

1. **Initial Authorization**

a. **Adempas** will be approved based on the following criterion:

(1) Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) which is symptomatic

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Adempas** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Adempas therapy

**Authorization will be issued for 12 months.**

**C. Pulmonary Hypertension Associated with Interstitial Lung Disease**

1. **Initial Authorization**

a. **Tyvaso, Tyvaso DPI,** or **Yutrepia** will be approved based on the following criterion:

(1) Diagnosis of pulmonary hypertension associated with interstitial lung disease which is symptomatic

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Tyvaso, Tyvaso DPI,** or **Yutrepia** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Tyvaso, Tyvaso DPI, or Yutrepia therapy

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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*Brand Adcirca, Letairis, Liqrev oral suspension, Opsynvi, and Revatio oral powder for suspension are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

**Additional Information regarding the endothelin receptor antagonists (Letairis*, Opsumit, Opsynvi*, and Tracleer):** These agents should be used with caution in patients with liver disease. Use is not recommended in moderate to severe hepatic impairment. Tracleer product labeling includes a black box warning regarding the risk of liver injury. Prescribers are cautioned to consider whether benefits of use offset the risk of liver injury in WHO Class II patients. Early liver injury may preclude future use as disease progresses. [3]

**Additional Information regarding the oral PDE-5 inhibitors (Adcirca*, Alyq, Liqrev*, Opsynvi*, Revatio*, and Tadliq):** Administration of the oral PDE-5 inhibitors to patients taking any form of organic nitrate, either regularly or intermittently, is contraindicated.[4,5, 13, 14] In addition, the concomitant administration of oral PDE-5 inhibitors with Adempas is contraindicated.

**3. Additional Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place.

**4. References:**


1. Pugh ME, Hemnes AR, Robbins IM. Combination therapy in pulmonary arterial hypertension. Clin Chest Med. 2013 Dec ;34(4) :841-55.
2. Letairis [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2025.
3. Tracleer [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; February 2024.
4. Revatio [package insert]. New York, NY: Pfizer Labs; January 2023.
5. Adcirca [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2020.
6. Ventavis [package insert]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; March 2022.
7. Tyvaso [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; May 2022.
8. Opsumit [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; April 2025.
9. Orenitram [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; August 2023.
10. Adempas [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2021.
11. Uptravi [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc; July 2022.
12. Tyvaso DPI [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; October 2024.
13. Alyq [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc..; September 2021.
14. Tadliq [package insert]. Farmville, NC: CMP Pharma, Inc.; October 2023.
15. Liqrev [package insert]. Farmville, NC: CMP Pharma, Inc.; April 2023.
16. Opsynvi [package insert]. Titusville, NJ: Actelion Pharmaceuticals US Inc.; April 2025.
17. Yutrepia [package insert]. Morrisville, NC: Liquidia Technologies, Inc.; June 2025.


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| **Change Control** | |
| 10/2013 | Added note that Revatio tablets are typically excluded from coverage effective 1/1/2014. |
| 2/2014 | Added Adempas, Orenitram, and Opsumit. Updated Background, Additional Information and References. Extended reauthorization period to 24 months. |
| 5/2015 | Annual review. Updated references. |
| 3/2016 | Updated to include Uptravi. |
| 3/2017 | Annual review. Updated background and references. |
| 11/2017 | Removed authorization criteria for generic Revatio tablets as this formulation will no longer require prior authorization. Updated references. |
| 11/2018 | Annual review. Added Adcirca brand tablets to exclusion. Updated background and references. |
| 6/2019 | Removed "Standard" from title. Removed reference statement regarding Revatio tablet switch to generic. |
| 6/2020 | Annual review. Updated background and references. Updated duration of authorization for continuation of therapy. |
| 6/2021 | Annual review. Added criteria for PH-ILD for Tyvaso. Updated background and references. |
| 6/2022 | Annual review. Changed Revatio solution to suspension. Added Letairis brand tablets to exclusion. Updated references. |
| 10/2022 | Added coverage criteria for Tyvaso DPI formulation and Alyq per prescribing information. Added stated mandate footnote. Updated background and references. |
| 12/2022 | Added Tadliq oral suspension for PAH. Updated background and references. |
| 3/2023 | Updated background with Revatio's expanded indication in pediatric patients with no change in coverage criteria. Updated references. |
| 2/2024 | Annual review. Added Liqrev oral suspension for PAH and updated exclusion footnote. Updated background and references. |
| 8/2024 | Added Opsynvi tablets to criteria for PAH. Added Opsynvi to additional information section. Updated background and references. |
| 8/2025 | Annual review. No changes to coverage criteria. Updated references. |
| 1/2026 | Added Yutrepia to coverage criteria as a new product. Added Yutrepia to the list of products that are typically excluded from coverage. Updated background and references. |
| 6/2026 | Removed Yutrepia from the list of products that are typically excluded from coverage. |

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