Pulmonary Arterial Hypertension Therapies

Bosentan (Tracleer), epoprostenal (Flolan, Veletri), ambrisentan (Letairis), Treprostinil (Remodulin, Tyvaso, Orenitram), iloprost (Ventavis), selexipag (Uptravi), macitentan (Opsumit), macitentan/tadalafil (Opsynvi), and sotatercept (Winrevair)

Coverage Criteria:
Initial Authorizations for Type I pulmonary arterial hypertension (PAH):

1. Prescribed by pulmonologist or cardiologist; and,
2. Patient has a diagnosis of pulmonary hypertension (WHO group 1) as confirmed by pretreatment right heart catheterization meeting all of the following parameters:
    a. Mean pulmonary arterial pressure (mPAP) ≥ 20 mmHg; and,
    b. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg; and,
    c. Pulmonary vascular resistance (PVR) ≥ 3 Wood units; and,
3. A negative response to acute pulmonary vasodilator testing or a trial and failure of calcium channel blocker therapy; and,
4. Patients prescribed sequential combination use therapy requires documentation of medical necessity (including documentation of inadequate response to single-drug therapy and rationale for adding an additional agent); and,
5. For Orenitram only, patient meets ALL of the following:
    a. Prescribed for current treprostinil users seeking an oral therapy option; and,
    b. Clinical documentation that shows use of Orenitram as a sole vasodilator is medically necessary, despite small effect on exercise; and,
    c. Orenitram will not be prescribed together with other vasodilator therapies (e.g., ambrisentan, sildenafil, riociguat); and,
6. For Winrevair only, patient meets ONE of the following:
    a. Patient has been on background PAH therapy for at least 3 months with at least TWO of the following medications from different drug classes:
        i. Oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, Opsumit); or,
        ii. Oral phosphodiesterase-5 inhibitor for PAH (e.g., sildenafil, tadalafil); or,
        iii. Oral cGMP stimulator (e.g., Adempas); or,
        iv. Intravenous or subcutaneous prostacyclin (e.g., epoprostenol, Treprostinil); or,
    b. Patient is on ONE medication from the following drug classes for at least 3 months, AND has a contraindication or intolerance to ALL of the other drug classes:
        i. Oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, Opsumit); or,
        ii. Oral phosphodiesterase-5 inhibitor for PAH (e.g., sildenafil, tadalafil); or,
        iii. Oral cGMP stimulator (e.g., Adempas); or,
        iv. Intravenous or subcutaneous prostacyclin (e.g., epoprostenol, treprostinil); and,

7. For brand products with available generics, patient must have a documented allergic reaction to the generic prior to approval of the brand name product; and,
8. Prescribed within FDA approved dosing.

Initial Authorizations for Type III pulmonary arterial hypertension with interstitial lung disease (PAH-ILD) [applies to Tyvaso only]:

Tyvaso (inhaled treprostinil) is reserved for patients meeting the following criteria:

1. Prescribed by a pulmonologist or cardiologist, and,
2. A diagnosis of pulmonary arterial hypertension with interstitial lung disease (WHO group 3) confirmed by right heart catheterization meeting all of the following parameters:
    a. PVR ≥ 3 Wood Units (WU)
    b. mPAP ≥ 25 mmHg
    c. PCWP ≤ 15
3. For brand products with available generics, patient must have a documented allergic reaction to the generic prior to approval of the brand name product.

Initial authorizations for Type IV pulmonary arterial hypertension (PAH) or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) [applies to Uptravi only]:

Uptravi is reserved for patients meeting the following criteria:

1. Prescribed by a pulmonologist or cardiologist, and,
2. A diagnosis of Group 4 or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) after surgical treatment or inoperable CTEPH; and,
3. For products with available generics, patient must have a documented allergic reaction to the generic prior to approval of the brand name product.

Renewal Criteria:

1. Patient has been seen by the provider in the past 12 months; and,
2. Clinical chart documentation that supports patient has experienced clinical benefit from therapy, including but not limited to:
    a. Improved hemodynamic status (mPAP, PVR, etc.); or
    b. Reductions in hospitalizations; or,
    c. Improved functional capacity; and,
3. Prescribed within FDA approved dosing regimen; and,
4. For brand products with available generics, patient must have a documented allergic reaction to the generic prior to approval of the brand name product.

Coverage Duration:

Initial approvals and reauthorizations will be provided for 12 months.