I. **POLICY**

It is the policy of UPMC Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The agents used in the treatment of Pulmonary Arterial Hypertension (PAH) are subject to the prior authorization process.

II. **PURPOSE**

The purpose of this policy is to define the Prior Authorization Process for the agents used in the treatment of Pulmonary Arterial Hypertension (PAH).

III. **DEFINITIONS**

N/A

IV. **SCOPE**

This policy applies to the Pharmacy Services Department.
V. **PROCEDURE**

PAH is defined as a mean pulmonary artery pressure $\geq 25$ mmHg with a pulmonary capillary wedge pressure $\leq 15$ mm Hg measured by cardiac catheterization. PAH is classified accordingly by the World Health Organization PAH classification system (WHO I-IV):

Class I: Members with no symptoms and for whom ordinary physical activity does not cause dyspnea or fatigue, chest pain or near syncope
Class II: Members who are comfortable at rest but who have symptoms** with ordinary physical activity
Class III: Members who are comfortable at rest but have symptoms** with less-than-ordinary effort
Class IV: Members who have symptoms** at rest

**Key symptoms of PAH include dyspnea or fatigue, chest pain, or near syncope (fainting)

**Criteria for PAH Agents**

PAH agents will be approved for members who meet the following criteria based on FDA approved indications and American College of Chest Physicians guideline recommendations with a definitive diagnosis of *pulmonary arterial hypertension*:

- Written by a cardiologist or pulmonologist AND
- Confirmed diagnosis by right heart catheterization

**Revatio™ (sildenafil)**

a. Member has a confirmed diagnosis of PAH with WHO functional class I-IV symptoms; AND
b. Member is NOT currently taking a nitrate product

**Letairis™ (ambrisentan)**

a. Member has a confirmed diagnosis of PAH with WHO functional class II or III symptoms; AND
b. Member has had baseline liver function tests (ALT, AST) prior to initiation of therapy; AND
   If a member is a woman of childbearing potential, she has had a baseline negative pregnancy test prior to initiation of therapy.

**Tracleer® (bosentan)**

a. Member has a confirmed diagnosis of PAH with WHO functional class III or IV symptoms; AND
b. Member is NOT currently taking glyburide or cyclosporine AND  
c. Member has had baseline liver function tests (ALT, AST) prior to initiation of therapy; AND  
d. If a member is a woman of childbearing potential, she has had a baseline negative pregnancy test prior to initiation of therapy.

**Flolan® (epoprostenol)**

a. Member has a confirmed diagnosis of PAH with WHO class III or IV symptoms or pulmonary hypertension associated with scleroderma

**Remodulin® (treprostinil)**

a. Member has a confirmed diagnosis of PAH with WHO functional class II-IV symptoms

**Ventavis® (iloprost)**

a. Member has a confirmed diagnosis of PAH with WHO functional class III or IV symptoms

If the above criteria are met, authorization will be granted for a 3-month period for each agent as initial therapy.

**Reauthorization Criteria**

Additional yearly authorizations may be granted upon review of chart documentation from the prescriber indicating that the member’s condition has improved as a result of therapy.

**Limitations**

If a member does not meet the above approval criteria, the request will be referred to a UPMC Health Plan Medical Director for review.

**VII. BIBLIOGRAPHY**


Proprietary and Confidential Information of UPMC Health Plan


46. Iloprost. Drugdex Summary in Micromedx.


