Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Pulmonary Hypertension Agents***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2008 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for the agents used in the treatment of Pulmonary Hypertension (PH).

DEFINITIONS

Chronic thromboembolic pulmonary hypertension (CTEPH) – a mean pulmonary artery pressure greater than 25 mm Hg that persists 6 months after pulmonary embolism is diagnosed.

Pulmonary arterial hypertension (PAH) – PAH is a syndrome resulting from restricted flow through the pulmonary arterial circulation resulting in increased pulmonary vascular resistance and subsequent right heart failure. The diagnosis of PAH requires confirmation with a complete right heart catheterization. The hemodynamic definition of PAH includes a mean pulmonary artery pressure (mPAP) greater than 25 mm Hg in the setting of a normal pulmonary capillary wedge pressure (PCWP) of 15 mm Hg or less with a pulmonary vascular resistance (PVR) greater than 3 Wood units.

Pulmonary endarterectomy (PEA) – surgical procedure to remove obstructive hardened, thromboembolic materials from the pulmonary arteries to improve hemodynamics in patients CTEPH.

Pulmonary Hypertension Specialist – a cardiologist or pulmonologist who is a member of the Pulmonary Hypertension Association

Pulmonary Vascular Resistance (PVR) – PVR (wood units) = (mPAP – PCWP)/ Cardiac Output. PVR (wood units) = PVR (dynes-sec-cm-5)/80

WHO Etiologic Classification of Pulmonary Hypertension

Group 1	Pulmonary arterial hypertension
Group 2	Pulmonary hypertension with left heart disease
Group 3	Pulmonary hypertension associated with lung disease and/or hypoxemia
Group 4	Pulmonary hypertension due to chronic thrombotic and/or embolic disease
Group 5	Miscellaneous

WHO Functional Classification of PH

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 PH include dyspnea or fatigue, chest pain, or near syncope (fainting)

POLICY
It is the policy of the 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 Hypertension (PH) are subject to the prior authorization process.

PROCEDURE
Initial Authorization Criteria:

The following drugs are FDA approved for the treatment of PAH.

Phosphodiesterase-5 Inhibitors	**Endothelin Receptor Antagonists**	**Soluble Guanylate Cyclase Stimulator**	**Prostacyclins**
Adcirca® (tadalafil)	Letairis® (ambrisentan)	Apempas® (riociguat)	Flolan® (epoprostenol)
Revatio® (sildenafil)	Tracleer® (bosentan)		Remodulin® (treprostinil)
	Opsumit® (macitentan)		Tyvaso™ (treprostinil)
			Veletri® (epoprostenol)
			Ventavis® (iloprost)
			Orenitram™ (treprostinil)

A consensus document by the American College of Cardiology Foundation and the American Heart Association encompasses pathogenesis, classification, diagnosis, and treatment of pulmonary hypertension. Therapy within the document is recommended based on prognosis/risk.

The recommended first-line therapy for lower risk/good prognosis patients is oral therapy with an endothelin receptor antagonist or a phosphodiesterase-5 (PDE5) inhibitor. If an oral regimen is not appropriate, the other treatments would be considered.

The recommended first-line therapy for higher risk/poor prognosis patients is continuous treatment with IV prostacyclin (epoprostenol or treprostinil). If the patient is not a candidate for IV treatment, the other therapies would be considered.
Combination therapy would be considered when patients are not responding adequately to initial monotherapy and patient has been referred to a pulmonary hypertension specialist.

PAH agents are approved for members who meet the following criteria based on FDA approved indications and consensus recommendations with a definitive diagnosis of pulmonary arterial hypertension.

Initial Authorization Criteria:

1. **For Pulmonary Arterial Hypertension (PAH)**
   - The following criteria must be met for all PAH agents:
   - Must be prescribed by a cardiologist or pulmonologist
     - Requests for a prostacyclin therapy OR combination therapy with two or more PAH agents must be prescribed by or in consultation with a pulmonary hypertension specialist.
   - Must have a diagnosis of PAH (WHO Group 1) confirmed by right heart catheterization
     - Must include chart documentation of right heart catheterization that indicates that the member has the following hemodynamic values:
       - Mean pulmonary arterial pressure (mPAP) >25 mmHg
       - Pulmonary capillary wedge pressure (PCWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) ≤15 mmHg
       - Pulmonary vascular resistance >3 Wood units

In addition to the above, the below criteria applies per drug:

Phosphodiesterase-5 Inhibitors:

Revatio (sildenafil) tablet

- Must have a confirmed diagnosis of PAH (WHO Group 1) with WHO functional class II-IV symptoms
- Must NOT currently be taking a nitrate product or Adempas (riociguat)

Revatio (sildenafil) oral suspension

- Must have a confirmed diagnosis of PAH (WHO Group 1) with WHO functional class II-IV symptoms
- Must NOT currently be taking a nitrate product or Adempas (riociguat)
- Must have chart documentation of the clinical rationale for why sildenafil tablet cannot be used

Adcirca (tadalafil)

- Must have a confirmed diagnosis of PAH (WHO Group 1) with WHO functional class II-IV symptoms

- Must NOT currently be taking a nitrate product or Adempas (riociguat)

Soluble Guanylate Cyclase Stimulator:

Adempas (riociguat)

- Must have a confirmed diagnosis of PAH (WHO group 1)
- Must have a baseline negative pregnancy test prior to initiation of therapy if a woman of childbearing potential
- Must NOT currently be taking a nitrate product or phosphodiesterase inhibitor
- Must previously have had an inadequate response or intolerance to sildenafil (Revatio)

Endothelin Receptor Antagonists:

Letairis (ambrisentan)

- Must have a confirmed diagnosis of PAH (WHO Group 1) with WHO functional class II or III symptoms
- Must have a baseline negative pregnancy test prior to initiation of therapy if a woman of childbearing potential

Tracleer (bosentan)

- Must have a confirmed diagnosis of PAH (WHO Group 1) with WHO functional class II-IV symptoms
- Adult patients must previously have had an inadequate response or intolerance to ambrisentan (Letairis)
    - Trial of Letairis not required for pediatric patients
- Must NOT currently be taking glyburide or cyclosporine
- Must evaluate baseline liver function tests (ALT, AST) prior to initiation of therapy
- Must evaluate baseline hemoglobin level prior to initiation of therapy
- Must have a baseline negative pregnancy test prior to initiation of therapy if a woman of childbearing potential

Opsumit (macitentan)

- Must have a confirmed diagnosis of PAH (WHO Group 1)
- Must previously have had an inadequate response or intolerance to ambrisentan (Letaris)
- Must evaluate baseline liver function tests (ALT, AST) prior to initiation of therapy
- Must evaluate baseline hemoglobin level prior to initiation of therapy
- Must have a baseline negative pregnancy test prior to initiation of therapy if a woman of childbearing potential

Prostacyclins:

- All prostacyclins must be prescribed by a pulmonary hypertension specialist

Flolan (epoprostenol)

- Must have a confirmed diagnosis of PAH (WHO Group 1) with WHO functional class III or IV symptoms and idiopathic or heritable PAH or PAH associated with connective tissue diseases

Veletri (epoprostenol)]

- Must have a confirmed diagnosis of PAH (WHO Group 1) with WHO functional class III or IV symptoms and idiopathic or heritable PAH or PAH associated with connective tissue diseases

Remodulin (treprostinil)

- Must have a confirmed diagnosis of PAH (WHO Group 1) with WHO functional class II-IV symptoms

Tyvaso (treprostinil)

- Must have a confirmed diagnosis of PAH (WHO Group 1) with WHO functional class III symptoms

Ventavis (iloprost)

- Must have a confirmed diagnosis of PAH (WHO Group 1) with WHO functional class III or IV symptoms

Orenitram (treprostinil)

- Must have a confirmed diagnosis of PAH (WHO Group 1) with WHO functional class II or III symptoms
- Must not have severe hepatic impairment
    - Member must meet one of the following criteria:
    - Member is currently maintained on an inhaled or parenteral prostacyclin product and has been assessed for switch to oral treprostinil therapy by a pulmonary hypertension specialist
    - Member was started on oral treprostinil in a clinical trial and pulmonary hypertension specialist recommends maintaining patient on oral treprostinil following conclusion of clinical trial

Prostacyclin Receptor Agonists:
All prostacyclin receptor agonists must be prescribed by a pulmonary hypertension specialist

Uptravi (selexipag)

- Must have a confirmed diagnosis of PAH (WHO Group 1)

Combination Therapy:

- The use of two or more PAH agents together in combination must be prescribed by a pulmonary hypertension specialist

2. For Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Soluble Guanylate Cyclase Stimulator:
Adempas (riociguat)

- Must be prescribed by a cardiologist or pulmonologist
- Must have a diagnosis of CTEPH, confirmed through BOTH of the following:
    - Chart documentation of right heart catheterization that indicates that the member has both of the following hemodynamic values at least 90 days after the start of full anticoagulation OR 180 days after pulmonary endarterectomy (PEA) unless there is clinical evidence of right heart failure and pulmonary hypertension on clinical exam and echocardiogram:
        - Mean pulmonary arterial pressure (mPAP) >25 mmHg
        - Pulmonary vascular resistance >3 Wood units
- Documentation that CTEPH was confirmed through ventilation-perfusion scanning (VQ scan) or pulmonary angiography
- Must be refractory to surgical treatment (e.g. PEA) or have inoperable CTEPH
- Must have a baseline negative pregnancy test prior to initiation of therapy if a woman of childbearing potential
- Must NOT currently be taking a nitrate product or a phosphodiesterase inhibitor

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorizations may be extended at one-year intervals based upon chart documentation from the prescriber indicating that the member's condition has improved as a result of therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Criteria Update	*06/16, 01/18*