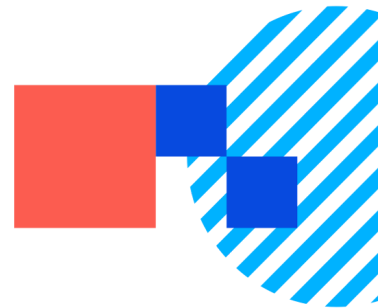




## Pulmonary Arterial Hypertension (PAH) Prior Authorization

|                         |                                                                                                                                                                      |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Drug(s) Applied:</b> | <b>ambrisentan, sildenafil, tadalafil, Alyq (tadalafil), treprostinil, Tyvaso (treprostinil), Opsumit (macitentan), Uptravi (selexipag), Winrevair (sotatercept)</b> |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

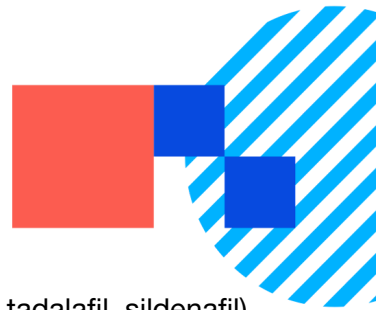
### Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

#### I. Initial Therapy Criteria

##### A. Pulmonary Arterial Hypertension (PAH), WHO Group 1 as indicated by chart notes within past 180 days

1. Diagnosis has been confirmed by right heart catheterization (medical records required) **and**
2. Patient's World Health Organization (WHO) Group 1 with WHO Functional Class of II, III, or IV **and**
3. If request is for Tyvaso, patient must meet one of the following:
  - a) Patient has tried and had an inadequate response or intolerance to treprostinil injection (IV or SQ), **or**
  - b) Patient is not a suitable candidate for treprostinil injection (IV or SQ) **and**
4. If request is for Uptravi, patient must meet all of the following:
  - a) Patient is at least 18 years old, **and**
  - b) Patient has tried or is currently receiving therapies from all two (2) categories for at least 60 days or has a has a contraindication or intolerance to combination therapy:
    - (1) A phosphodiesterase 5 inhibitor (PDE5i) (e.g. tadalafil, sildenafil)
    - (2) An endothelin receptor antagonist (ERA) (e.g. ambrisentan), **and**
  - c) Patient is not planned to concurrently use Uptravi with a prostacyclin therapy (e.g. treprostinil), **and**
5. If request is for Winrevair, patient must meet all of the following:
  - a) Patient is at least 18 years old **and**
  - b) Labs showing Hg and Platelet monitoring within past 180 days **and**
  - c) Patient is concomitantly receiving and is stabilized on therapies from all three (3) categories for at least 90 days or has a contraindication or intolerance to combination therapy:



- (1) A phosphodiesterase 5 inhibitor (PDE5i) (e.g. tadalafil, sildenafil)
  - (2) An endothelin receptor antagonist (ERA) (e.g. ambrisentan)
  - (3) A prostacyclin therapy (e.g., treprostinil) or a prostacyclin receptor agonist (e.g., selexipag) **and**
6. Prescriber is a specialist (e.g., cardiology, pulmonology) **and**
  7. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug including but not limited to:
    - a) For tadalafil or sildenafil, concurrent use with organic nitrates (e.g., nitroglycerin, isosorbide dinitrate) or guanylate cyclase stimulators (e.g., riociguat)
    - b) For ambrisentan, pregnancy or idiopathic pulmonary fibrosis
    - c) For Opsumit (macitentan), pregnancy
    - d) For Uptravi (selexipag), concurrent use with strong CYP2C8 inhibitors (e.g., gemfibrozil)

**Approval Duration:** 12 months

## II. Continued Therapy Criteria

### A. Pulmonary Arterial Hypertension (PAH), WHO Group 1 as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit since starting the requested agent (i.e., improvement in symptoms of right heart failure, exercise tolerance, six-minute walk distance (6MWD), resting and ambulatory oximetry) **and**
3. For Winrevair, labs showing Hg and Platelet monitoring within past 180 days **and**
4. Prescriber is a specialist (e.g., cardiology, pulmonology) **and**
5. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug including but not limited to:
  - a) For tadalafil or sildenafil, concurrent use with organic nitrates (e.g., nitroglycerin, isosorbide dinitrate) or guanylate cyclase stimulators (e.g., riociguat)
  - b) For ambrisentan, pregnancy or idiopathic pulmonary fibrosis
  - c) For Opsumit (macitentan), pregnancy
  - d) For Uptravi (selexipag), concurrent use with strong CYP2C8 inhibitors (e.g., gemfibrozil)

**Approval Duration:** 12 months

**Policy Owned by:** Curative PBM team