

Pulmonary Arterial Hypertension (PAH) Prior Authorization Drug List A

Drug(s) Applied:	ambrisentan, sildenafil, tadalafil, Alyq (tadalafil), treprostinil, Tyvaso (treprostinil), Opsumit (macitentan), Upravi (selexipag), Winrevair (sotatercept), Adempas (riociguat), bosentan
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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 Upravi, 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 Upravi 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:



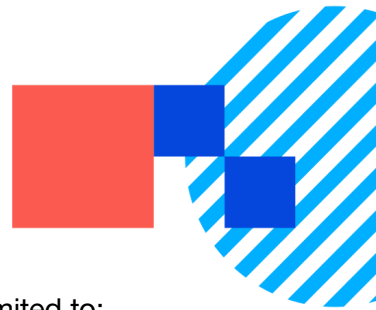
- (1) A phosphodiesterase 5 inhibitor (PDE5i) (e.g. tadalafil, sildenafil)
- (2) An endothelin receptor antagonist (ERA) (e.g. ambrisentan)
- (3) A prostacyclin therapy (e.g., treprostinil) or a prostacyclin receptor agonist (e.g., selexipag) **and**
6. If request is for bosentan, must have documented failure to ambrisentan **and**
7. If for Adempas, must have documented failure to, or be concurrently taking, all of the following:
 - a) A phosphodiesterase 5 inhibitor (PDE5i) (e.g. tadalafil, sildenafil) **and**
 - b) An endothelin receptor antagonist (ERA) (e.g. ambrisentan) **and**
 - c) A prostacyclin therapy (e.g., treprostinil) or a prostacyclin receptor agonist (e.g., selexipag) **and**
8. Prescriber is a specialist (e.g., cardiology, pulmonology) **and**
9. 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 bosentan, pregnancy or concurrent use of cyclosporine or glyburide
 - d) For Opsumit (macitentan), pregnancy
 - e) For Uptravi (selexipag), concurrent use with strong CYP2C8 inhibitors (e.g., gemfibrozil)
 - f) For Adempas (riociguat), concurrent use with organic nitrates (e.g., nitroglycerin, isosorbide dinitrate), PDE5 inhibitors (e.g., sildenafil, tadalafil, dipyridamole, theophylline), or pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP)

Approval Duration: Bosentan: 6 months; Adempas: 3 months; All others: 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 bosentan, pregnancy or concurrent use of cyclosporine or glyburide
- d) For Opsumit (macitentan), pregnancy
- e) For Uptravi (selexipag), concurrent use with strong CYP2C8 inhibitors (e.g., gemfibrozil)
- f) For Adempas (riociguat), concurrent use with organic nitrates (e.g., nitroglycerin, isosorbide dinitrate), PDE5 inhibitors (e.g., sildenafil, tadalafil, dipyridamole, theophylline), or pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP)

Approval Duration: Bosentan: 6 months; Adempas: 3 months; All others: 12 months

Policy Owned by: Curative PBM team