curative

Pulmonary Arterial Hypertension (PAH) Prior Authorization Drug List A

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

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 is concomitantly receiving and is stabilized on maximum-tolerated therapies from all two (2) categories for at least 90 days or has a has a contraindication to each 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 maximum-tolerated therapies from all three (3) categories for at least 90 days or has a contraindication to each 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