Pharmacy Medical Necessity Guidelines: Pulmonary Hypertension Medications

Effective: January 14, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX/ MED	Department to Review	RXUM/ MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
Adcirca, Adempas, Letairis, Opsumit, Orenitram, Remodulin, Revatio, sildenafil, Tracleer, Tyvaso, Uptravi, Ventavis
RXUM: 617.673.0988
Epoprostenol, Flolan, Veletri
MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Adcirca (tadalafil) is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with New York Heart Association (NYHA) Functional Class II – III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).

Adempas (riociguat) is a soluble guanylate cyclase stimulator indicated:

- For the treatment of adults with PAH, (WHO Group 1), to improve exercise capacity, WHO functional class and to delay clinical worsening. Efficacy was shown in patients on Adempas (riociguat) monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominately patients with WHO functional class II–III and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (25%).
- For the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO functional class.

Flolan (epoprostenol sodium) is a prostacyclin vasodilator indicated for the treatment of PAH (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Letairis (ambrisentan) is an endothelin receptor antagonist (ERA) indicated for the treatment of PAH (WHO Group 1) to improve exercise ability and delay clinical worsening and in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability. Studies establishing effectiveness included predominantly patients with WHO Functional Class II–III symptoms and etiologies of idiopathic or heritable PAH (60%) or PAH associated with connective tissue diseases (34%).

Opsumit (macitentan) is an ERA indicated for the treatment of PAH (WHO Group I) to delay disease progression. Disease progression included: death, initiation of intravenous or subcutaneous prostanoids, or clinical worsening of PAH (decreased 6-minute walk distance, worsened PAH symptoms and need for additional PAH treatment). Opsumit (macitentan) also reduced hospitalization for PAH.

Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients were treated with Opsumit (macitentan) monotherapy or in combination with phosphodiesterase-5 inhibitors or inhaled prostanoids. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

Orenitram (treprostinil) is a prostacyclin vasodilator indicated for the treatment of PAH (WHO Group 1) to improve exercise capacity. The study that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (75%) or PAH associated with connective tissue disease (19%). When used as the sole vasodilator, the effect of Orenitram on exercise is about 10% of the deficit, and the effect, if any, on a background of another vasodilator is probably less than this. Orenitram (treprostinil) is probably most useful to replace subcutaneous, intravenous, or inhaled treprostinil, but this use has not been studied.

Remodulin (treprostinil sodium) is a prostacyclin vasodilator indicated:

- For the treatment of PAH (WHO Group 1) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%).
- In patients with PAH requiring transition from Flolan (epoprostenol sodium) to diminish the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition.

Revatio (sildenafil) is a PDE5 inhibitor indicated for the treatment of PAH (WHO Group I) in adults to improve exercise ability and delay clinical worsening. The delay in clinical worsening was demonstrated when Revatio (sildenafil) was added to background epoprostenol therapy. Studies establishing effectiveness were short-term (12 to 16 weeks), and included predominately patients with NYHA Functional Class II-III symptoms and idiopathic etiology (71%) or associated with connective tissue disease (CTD) (25%). Adding sildenafil to bosentan therapy does not result in any beneficial effect on exercise capacity.

Tracleer (bosentan) is an ERA indicated for the treatment of PAH (WHO Group 1)

- In adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to-right shunts (18%).
- In pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance, which is expected to result in an improvement in exercise ability.

Tyvaso (treprostinil) is a prostacyclin vasodilator, available as an inhalation solution and indicated for the treatment of PAH (WHO Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities. While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration.

Uptravi (selexipag) is a prostacyclin receptor antagonist indicated for the treatment of PAH (WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with WHO Functional Class II-III symptoms. Patients had idiopathic and heritable PAH (58%), PAH associated with connective tissue disease (29%), PAH associated with congenital heart disease with repaired shunts (10%).

Veletri (epoprostenol sodium) is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Ventavis (iloprost) is a synthetic analog of prostacyclin indicated for the treatment of PAH (WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration. Studies establishing effectiveness included predominately patients with

NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (65%) or PAH associated with connective tissue diseases (23%).

COVERAGE GUIDELINES

Pulmonary Arterial Hypertension (PAH)

The plan may authorize coverage of Adcirca (tadalafil), Adempas (riociguat), generic epoprostenol sodium, Flolan/Veletri (epoprostenol sodium), Letairis (ambrisentan), Opsumit (macitentan), Orenitram (treprostinil), Remodulin (treprostinil sodium), Tracleer (bosentan) tablets/tablets for oral suspension, Tyvaso (treprostinil), Uptravi (selexipag), Ventavis (loprost), or sildenafil tablets/oral suspension for Members when the following criteria are met:

See "Additional Coverage Criteria for Flolan/Veletri for PAH" below.

1. Documentation the Member has been evaluated by a specialist (i.e., cardiologist or pulmonologist)

AND

2. Definitive diagnosis of PAH (World Health Organization [WHO] Group I; see below) confirmed by right heart catheterization or echocardiogram

   WHO Classification of Pulmonary Hypertension
   Group 1:
   a. Idiopathic PAH (primary pulmonary hypertension)
   b. Heritable PAH
   c. Drug- and toxin-induced PAH
   d. PAH associated with other diseases and conditions (APAH)
      i. Connective tissue diseases
      ii. Human immunodeficiency virus infection
      iii. Portal hypertension
      iv. Congenital heart disease
      v. Schistosomiasis
   e. Pulmonary veno-occlusive disease and/or pulmonary capillary hemangiomatosis
   f. Persistent pulmonary hypertension of the newborn (PPHN)

AND

3. Documentation the Member has received, or documentation of clinical inappropriateness to an acute vasoreactivity test (e.g., New York Heart Association [NYHA] Class IV and those with right heart failure or hemodynamic instability)

AND

4. The medication used for treatment is consistent with its Food and Drug Administration (FDA) approved functional class (see corresponding chart below)

AND

5. Documentation of a positive acute vasoreactivity test AND documented prior failure to or clinical in appropriateness to calcium channel blockers AND documentation of one of the following:
   a. Documentation of NYHA Class IV OR
   b. If request is for sildenafil 20 mg tablets (Revatio) OR
   c. If request is for an oral medication (e.g., tablet) other than sildenafil 20 mg tablets (Revatio), documented prior failure of or clinical inappropriateness to sildenafil OR
   d. If request is for a non-oral medication (e.g., ampule for inhalation, intravenous, subcutaneous), documented prior failure of or clinical inappropriateness to two oral therapies, one of which must be sildenafil

OR

6. Documentation of a negative acute vasoreactivity test or of clinical inappropriateness to acute vasoreactivity testing AND documentation of one of the following:
   a. Documentation of NYHA Class IV OR
   b. Documentation of NYHA Class II or III AND at least one of the following:
      i. Request is for sildenafil 20 mg tablets (Revatio) OR
      ii. If request is for an oral medication (e.g., tablet) other than sildenafil 20 mg tablets (Revatio), documented prior failure of or clinical inappropriateness to sildenafil OR
      iii. If request is for a non-oral medication (e.g., ampule for inhalation, intravenous, subcutaneous), documented prior failure of or clinical inappropriateness to two oral therapies, one of which must be sildenafil

Drug	FDA Approved Functional Class of Symptoms
Adempas	WHO Class II and III (Pulmonary Arterial Hypertension)
epoprostenol	NYHA Class III and IV
Letairis	WHO Class II and III
Opsumit	WHO Class II and III
Orenitram	WHO Class II and III
Remodulin	NYHA Class II, III, and IV
sildenafil (Revatio)	NYHA Class II and III
tadalafil (Adcirca)	NYHA Class II and III
Tracleer	WHO Class II, III, and IV
Tyvaso	NYHA Class III
Uptravi	WHO Class II and III
Ventavis	NYHA Class III and IV

Note: Please refer to References Section for a description of NYHA and WHO Functional Class descriptions.

Additional Coverage Criteria for Flolan/Veletri (epoprostenol sodium) for PAH
The plan requires Members initiating treatment with epoprostenol sodium to utilize the generic version (provided that he/she meets the pharmacy coverage guidelines described above) prior to authorization of brand name Flolan (epoprostenol sodium) or Veletri (epoprostenol sodium). Coverage of Flolan/Veletri (epoprostenol sodium) will be considered for Members who have failed an adequate trial of or are unable to tolerate generic epoprostenol.

Chronic-Thromboembolic Pulmonary Hypertension
The plan may authorize coverage of Adempas (riociguat) for Members when the following criteria are met:

1. The Member has a definitive diagnosis of PAH (WHO group 4) confirmed by right heart catheterization or echocardiogram

AND

2. The prescriber is a cardiologist or pulmonologist

AND

3. Documentation Adempas (riociguat) is not being concomitantly administered with phosphodiesterase inhibitors or nitrates

AND

4. Documentation of one of the following:
    a. The chronic thromboembolic pulmonary hypertension persists or recurs after surgical treatment

    OR

    b. Member is diagnosed as inoperable by a center specializing in chronic thromboembolic pulmonary hypertension or pulmonary thromboendarterectomy

LIMITATIONS

None

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J1325	Injection, epoprostenol, 0.5mg
J3285	Injection, treprostinil
J7686	Treprostinil, inhalation solution, FDA-approved final product, noncompounded, administered through DME, unit dose form, 1.74 mg
Q4074	Iloprost, inhalation solution, administered through DME, up to 20mcg

REFERENCES

NYHA Pulmonary Arterial Hypertension Functional Classification of Symptoms

Class I	No limitation	Ordinary physical activity does not cause symptoms.
Class II	Slight limitation	Comfortable at rest. Ordinary physical activity causes symptoms.
Class III	Marked limitation	Comfortable at rest. Less than ordinary activity causes symptoms.
Class IV	Inability to carry on any physical activity	Symptoms present at rest. Discomfort is increased by any physical activity.

WHO Pulmonary Arterial Hypertension Functional Classification of Symptoms

Class I	No limitation	Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.
Class II	Slight limitation	Comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.
Class III	Marked limitation	Comfortable at rest. Less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope.
Class IV	Inability to carry on any physical activity	Dyspnea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

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APPROVAL HISTORY

July 17, 2008: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 13, 2013: Reviewed by the Pharmacy and Therapeutics Committee. Confirmation of WHO Group I, diagnosis confirmation via right heart catheterization or echocardiogram and vasoreactivity results. Trial and failure of sildenafil tablets prior oral treatment and trial and failure of two oral medications prior to non-oral medications (NYHA IV excluded).
2. June 4, 2014: Addition of Adempas, Opsimut and Orenitram to MRG. Included NYHA IV in patients with positive reactivity test. Added verbiage of provider indicating clinical inappropriateness to receiving an acute vasoreactivity test. Added criteria for brand name requests for Flolan and Veletri. Addition of criteria for chronic thromboembolic pulmonary hypertension.
3. December 2, 2014: Reviewed by the Pharmacy and Therapeutics Committee.
4. November 10, 2015: No changes.
5. January 1, 2016: Administrative change to rebranded template.
6. July 12, 2016: Effective October 1, 2016 - added Uptravi to Medical Necessity Guidelines.
7. April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
8. July 11: 2017: Removed the limitation "Initial approval will be for lifetime" as it is not needed per Medical Necessity Guideline template. Clarified that if documentation of clinical inappropriateness to acute vasoreactvity testing, calcium channel blockers are not required prerequisite trial. Added an "OR" statement for Chronic-Thromboembolic Pulmonary Hypertension criteria with regards to chronic disease that persists or recurs after surgical treatment OR inoperable disease as determined by a center specializing in chronic thromboembolic pulmonary hypertension or pulmonary thromboendarterectomy.
9. January 9, 2018: Added Tracleer (bosentan) tablets for oral suspension to the Medical Necessity Guideline.
10. January 14, 2020: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services