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/ PRECERT /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, Revatio, sildenafil, Tracleer, Uptravi
RXUM: 617.673.0988

Epoprostenol, Flolan, Remodulin, Tyvaso, Veletri, Ventavis
All plans except Tufts Health Direct – Health Connector
PRECERT: 617.972.9409

Tufts Health Direct – Health Connector Only
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. The Member must have a definitive diagnosis of PAH (World Health Organization [WHO] Group I; see below) from a cardiologist or pulmonologist and confirmed by right heart catheterization

   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)
      - Connective tissue diseases
      - Human immunodeficiency virus infection
      - Portal hypertension
      - Congenital heart disease
      - Schistosomiasis
   e. Pulmonary veno-occlusive disease and/or pulmonary capillary hemangiomatosis
   f. Persistent pulmonary hypertension of the newborn (PPHN)

AND

2. The pulmonary hypertension has progressed despite surgical treatment and/or maximal medical treatment of the underlying condition

AND

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

Drug	FDA Approved Functional Class of Symptoms
Adempas	WHO Class II and III (Pulmonary Arterial Hypertension)
epoprostenol (Flolan/Veletri)	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 they meet 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

AND

2. The prescriber is a cardiologist or pulmonologist

AND

3. Documentation of one of the following:
    a. The chronic thromboembolic pulmonary hypertension persists or recurs after surgical treatment
    b. Member is diagnosed as inoperable by a center specializing in chronic thromboembolic pulmonary hypertension or pulmonary thromboendarterectomy

LIMITATIONS

- The plan will not authorize coverage of generic epoprostenol sodium, Flolan/Veletri (epoprostenol sodium), Adempas (riociguat), Letairis (ambrisentan), Opsumit (macitentan), Orenitram (treprostinil), Remodulin (treprostinil sodium), Tracleer (bosentan), Tyvaso (treprostinil), Uptravi (selexipag), Ventavis (loprost), Adcirca (tadalafil) and sildenafil tablets/oral suspension for pulmonary hypertension secondary to the following conditions:
    - Diseases of the left atrium and ventricle such as congestive heart failure or cardiomyopathy
    - Diseases of the mitral and aortic valves
    - Chronic lung diseases such as chronic obstructive pulmonary disease, restrictive pulmonary disease or interstitial pulmonary disease
    - Obstructive sleep apnea or other sleep disorders involving breathing or alveolar hyperventilation disorders
- Adempas (riociguat) will not be approved if administered concomitantly with phosphodiesterase inhibitors or nitrates.

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

New York Heart Association 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.

World Health Organization 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.

REFERENCES

1. Adcirca (tadalafil) [package insert]. Indianapolis, IN: Eli Lilly and Company; May 2017.
2. Adempas (riociguat) [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; January 2018.
3. Ambrisentan (*Letairis*) For Pulmonary Arterial Hypertension, Medical Letter, October 22, 2007, Vol. 49 Issue 1272.
4. Badesch DB, Abman SH, Simonneau G, et al. Medical therapy for pulmonary arterial hypertension: Updated ACCP evidence-based clinical practice guidelines. *Chest*. 2007; 131:1917-28.
5. Barst RJ, Gibbs JS, Ghofrani HA, et al. Updated evidence-based treatment algorithm in pulmonary arterial hypertension. *J Am Coll Cardiol* 2009; 54: S78–S84.
6. Benza RL, Miller DP, Barst RJ et al. An evaluation of long-term survival from time of diagnosis in pulmonary arterial hypertension from the REVEAL Registry. *Chest*. 2012; 142(2):448-56.
7. Benza RL, Seeger W, McLaughlin VV et al. Long-term effects of inhaled treprostinil in patients with pulmonary arterial hypertension: the Treprostinil Sodium Inhalation Used in the Management of Pulmonary Arterial Hypertension (TRIUMPH) study open-label extension. *J Heart Lung Transplant*. 2011 Dec; 30(12):1327-33.
8. Bishop BM, Mauro VF, Khouri SJ. Practical considerations for the pharmacotherapy of pulmonary arterial hypertension. *Pharmacotherapy.* 2012 Sep; 32(9): 838-855.
9. Daly, Richard C., MD., "Lung transplantation for Pulmonary Hypertension", Mayo Foundation for Medical Education and Research, August 1997.
10. FDA Talk Paper, FDA Approves First Oral Medication for Pulmonary Arterial Hypertension, November 20, 2001.
11. Fishman, Alfred P. MD. Pulmonary Hypertension -Beyond Vasodilator Therapy. *NEJM.* Volume 338, Number 5, January 29, 1998.
12. Flolan (epoprostenol sodium) for Injection [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2018.
13. Fox BD, Shimony A, Langleben D. Meta-analysis of monotherapy versus combination therapy for pulmonary arterial hypertension. *Am J Cardiol*. 2011 Oct 15; 108(8):1177-82.
14. Frost AE, Badesch DB, Barst RJ et al. The changing picture of patients with pulmonary arterial hypertension in the United States: how REVEAL differs from historic and non-US contemporary registries. *Chest.* 2011; 139:128-37.
15. Galiè N, Barberà JA, Frost AE, et al. Initial Use of Ambrisentan plus Tadalafil in Pulmonary Arterial Hypertension. *N Engl J Med*. 2015 Aug 27;373(9):834-44.
16. Galie N, Corrie PA, Frost A et al. Updated treatment algorithm of pulmonary arterial hypertension. *J Am Coll Cardiol.* 2013; 62(25 Suppl):D60-72.
17. Galie N, Hoeper MM, Humbert M, et al. Guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J.* 2009a; 30(20):2493-2537.
18. Ghofrani, "Combination Therapy with Oral Sildenafil and Inhaled Iloprost for Severe Pulmonary Hypertension", Annals of Internal Medicine, April 2002, volume 136, Pages 515-522.
19. Ghofrani HA, Armini AM, Grimminger F, et al. Riociguat for the treatment of chronic thromboembolic pulmonary hypertension. *N Engl J Med*. 2013a; 364(4): 319-329.
20. Ghofrani HA, Galie N, Grimminger F, et al. Riociguat for the treatment of pulmonary arterial hypertension. *N Engl J Med*. 2013b; 369(4): 330-340.
21. He B, Zhang F, Li X et al. Meta-analysis of randomized controlled trials on treatment of pulmonary arterial hypertension. *Circ J*. 2010 Jul; 74(7):1458-64.
22. Hoeper MM, Mayer E, Simonneau G et al. Chronic Thromboembolic Pulmonary Hypertension. *Circulation*. 2006; 113: 2011-2020.
23. Letairis (ambrisentan) [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2018.

24. McGoon MD, Kane GC. Pulmonary Hypertension: Diagnosis and Management. Mayo Clin Proc. 2009; 84(2): 191-207.
25. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension: A report of the American College of Cardiology Foundation Task Force on expert consensus documents and the American Heart Association: Developed in collaboration with the American College of Chest Physician, American Thoracic Society, Inc. and the Pulmonary Hypertension Association. *Circulation*. 2009; 119: 2250-2294.
26. McLaughlin VV, Davis M, Cornwell W. Pulmonary Arterial Hypertension*. Curr Probl Cardiol*. 2011; 36:461-517.
27. McLaughlin VV, Gaine SP, Howard LS et al. Treatment goals of pulmonary hypertension. *J Am Coll Cardiol.* 2013; 62(25 Suppl):D42-50.
28. McLaughlin VV, Shah SJ, Souza R et al. Management of pulmonary arterial hypertension. *J Am Coll Cardiol.* 2015; 65(18):1976-97.
29. McNeil K, Dunning J. Chronic Thromboembolic Pulmonary Hypertension (CTEPH). *Heart;* 93: 1152-1158.
30. National Heart, Lung, and Blood Institute, National Institute of Health: "Primary Pulmonary Hypertension," November 1996, NIH Publication No. 96-3291 Pages 1-11.
31. Opsumit (macitentan) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; October 2018.
32. Orenitram (treprostinil) [package insert]. Research Triangle Park, NC; United Therapeutics Corp.; January 2017.
33. Oudiz RJ, Brundage BH, Galiè N et al. Tadalafil for the treatment of pulmonary arterial hypertension: a double-blind 52-week uncontrolled extension study. *J Am Coll Cardiol*. 2012 Aug 21; 60(8):768-74.
34. Piazza G, Goldhaber SZ. Chronic Thromboembolic Pulmonary Hypertension*. N Engl J Med*. 2011; 364: 351-360.
35. Pulido T, Adzerikho I, Channick R, et al. Macitentan and morbidity and mortality in pulmonary arterial hypertension. *N Engl J Med*. 2013 Aug 29; 369(9):809-818.
36. Remodulin (treprostinil) Injection [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; July 2018.
37. Revatio (sildenafil) [package insert]. New York, NY: Pfizer Labs; February 2018.
38. Rosenzweig EB, Ivy DD, Widlitz A et al. Effects of long-term bosentan in children with pulmonary arterial hypertension. *J Am Coll Cardiol*. 2005; 46:697-704.
39. Rubin LJ. Introduction: Diagnosis and management of pulmonary arterial hypertension: ACCP Evidenced-Based Clinical Practice Guidelines. *Chest*. 2004; 126: 7S-10S.
40. Sitbon O, Channick R, GRIPHON Investigators at al. Selexipag for the Treatment of Pulmonary Arterial Hypertension. *N Engl J Med*. 2015 Dec 24;373(26):2522-33.
41. Taichman DB, Ornelas J, Chung L et al. Pharmacologic therapy for pulmonary arterial hypertension in adults: CHEST guideline and expert panel report. *Chest*. 2014; 146(2):449-75.
42. Tapson VF, Jing ZC XU KF et al. Oral treprostinil for the treatment of pulmonary arterial hypertension in patients receiving background endothelin receptor antagonist and phosphodiesterase type 5 inhibitor therapy (the FREEDOM-C2 study): a randomized controlled trial. *Chest*. 2013 Sep; 144(3):952-8.
43. Tracleer (bosentan) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; May 2018.
44. Tuder RM, Archer SL, Dorfmuller P et al. Relevant issues in the pathology and pathobiology of pulmonary hypertension. J Am Coll Cardiol. 2013; 62(25 Suppl):D4-12.
45. Tyvaso (treprostinil) [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; October 2017.
46. Uptravi (selexipag) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; December 2017.
47. Veletri (epoprostenol for injection) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; December 2018.
48. Ventavis (iloprost) [package insert]. South San Francisco: Actelion Pharmaceuticals US, Inc.; October 2017.
49. Wilkins MR. Pulmonary hypertension: the science behind the disease spectrum. *Eur Respir Rev.* 2012; 21(123):19-26.

APPROVAL HISTORY

May 2003: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 10, 2005: No changes.
2. September 13, 2005: Add Ventavis (iloprost) to the TOPIC, CLINICAL COVERAGE CRITERIA and LIMITATIONS. Change criteria #1 from "The Member must have the definitive diagnosis of either Primary or Secondary symptomatic Pulmonary Hypertension (PH) from a cardiologist or pulmonologist confirmed by the two diagnostic tests, Right-heart cardiac catheterization and Echocardiogram showing right atrial and ventricular enlargement" to "The Member must have a definitive diagnosis of pulmonary artery hypertension (WHO group I) from a cardiologist or pulmonologist and confirmed by right heart catheterization". Add criteria #3, "The Member's symptoms are New York Heart Association (NYHA) class III to IV" (see table above).
3. November 8, 2005: Change the brand name "Viagra" in the Topic, Coverage Criteria and Coverage Limitations to sildenafil. Add the coverage limitations: "Tufts Health Plan may authorize coverage of Viagra for pulmonary hypertension when the dosage for sildenafil exceeds 20mg three times a day."
4. October 10, 2006: No changes.
5. November 13, 2007: Add Letairis (ambrisentan) to the Overview, Pharmacy Coverage Guidelines, and Limitations. Add description of WHO Pulmonary Arterial Hypertension Functional Classes
6. November 11, 2008: No changes.
7. September 8, 2009: For effective date December 1, 2009: Added guidelines for "*Coverage for Flolan" Added WHO class II to FDA approved functional class for Tracleer.
8. November 10, 2009: Added Adcirca to Pharmacy Coverage Guidelines. Added dispensing limitation for Adcirca and Revatio to Pharmacy Medical Necessity Guidelines. Updated FDA Approved Functional Class of Symptoms for sildenafil. Revised WHO Classification of Pulmonary Hypertension Group I
9. January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred)
10. January 12, 2010: Added Tyvaso (treprostinil) inhalation solution to Medical Necessity Guidelines
11. May 11, 2010: Clarified dosage form of sildenafil and Revatio as tablets
12. January 1, 2011: Administrative Update: Added reimbursement code J7686. Removed discontinued code Q4080
13. January 11, 2011: Added Veletri (epoprostenol for injection) to Medical Necessity Guidelines
14. January 10, 2012: No changes.
15. January 15, 2013: Added quantity limitation for sildenafil 20mg tablets.
16. October 15, 2013: Removed quantity limitation from Adcirca, Revatio and sildenafil. Updated table of FDA Approved Functional Class of Symptoms to reflect current FDA-approved prescribing information.
17. February 11, 2014: Added Adempas (riociguat) and Opsumit (macitentan) to Medical Necessity Guidelines.
18. June 10, 2014: Added Orenitram (treprostinil) to Medical Necessity Guidelines, and Updated WHO Group I classifications under criteria #1: Removed: Chronic hemolytic anemias and Added: Pulmonary veno-occlusive disease and/or pulmonary capillary hemangiomatosis and Persistent pulmonary hypertension of the newborn (PPHN). Updated criterion #4 under Chronic-Thromboembolic Pulmonary Hypertension to "Member is diagnosed as inoperable by a center specializing in chronic thromboembolic pulmonary hypertension or pulmonary thromboendarterectomy."
19. December 9, 2014: Added sildenafil oral suspension to Medical Necessity Guidelines. Removed authorization of coverage of Viagra tablets when the dosage for sildenafil exceeds 20mg three times a day.
20. November 10, 2015: No changes.
21. January 1, 2016: Administrative change to rebranded template.
22. July 12, 2016: Added Uptravi (selexipag) to Medical Necessity Guidelines.
23. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
24. July 11, 2017: No changes.
25. January 9, 2018: Added Tracleer (bosentan) tablets for oral suspension to the Medical Necessity Guideline.
26. January 8, 2019: No changes.
27. 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