Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Pulmonary Hypertension Medications: Epoprostenol Products, Remodulin (Treprostinil)

Effective: September 15, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration - Approved Indications

Flolan (epoprostenol) is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly (97%) patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (49%) or PAH associated with connective tissue diseases (51%).

Remodulin (treprostinil) is a prostacyclin vasodilator indicated for

- 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 epoprostenol to diminish the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition.

Veletri (epoprostenol) 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.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of a Pulmonary Hypertension Medication for Members when the following criteria are met:

1. Documented diagnosis of pulmonary arterial hypertension (PAH) - World Health Organization Group 1

AND

2. Prescribed by or in consultation with a cardiologist or pulmonologist

AND

3. Documentation diagnosis is confirmed by right heart catheterization with **one (1)** of the following parameters:

a. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg at rest or greater than 30 mmHg with exertion
b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
c. Pulmonary vascular resistance (PVR) greater than 3 Wood units

AND

4. Documentation of **one (1)** of the following:
    a. The patient is currently taking a phosphodiesterase-5 inhibitor or an endothelin receptor antagonist
    b. The patient has tried and failed a phosphodiesterase-5 inhibitor or an endothelin receptor antagonist
    c. Contraindication to a phosphodiesterase-5 inhibitor and an endothelin receptor antagonist

Brand Flolan (epoprostenol) or Veletri (epoprostenol)

In addition to the coverage criteria above for coverage of a Pulmonary Hypertension Medication:

1. Documented failure of an adequate trial of or inability to tolerate generic epoprostenol

Brand Remodulin (treprostinil)

In addition to the coverage criteria above for coverage of a Pulmonary Hypertension Medication:

1. Documented failure of an adequate trial of or inability to tolerate generic treprostinil

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1325	Injection, epoprostenol, 0.5mg
J3285	Injection, treprostinil, 1mg

References

1. 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.
2. 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.
3. 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.
4. Bishop BM, Mauro VF, Khouri SJ. Practical considerations for the pharmacotherapy of pulmonary arterial hypertension. *Pharmacotherapy.* 2012 Sep; 32(9): 838-855.
5. Daly, Richard C., MD., “Lung transplantation for Pulmonary Hypertension”, Mayo Foundation for Medical Education and Research, August 1997.
6. Fishman, Alfred P. MD. Pulmonary Hypertension -Beyond Vasodilator Therapy. *NEJM.* Volume 338, Number 5, January 29, 1998.
7. Flolan (epoprostenol sodium) for Injection [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2023.
8. 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.
9. 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.
10. 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.
11. 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.
12. 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.
13. Hoeper MM, Mayer E, Simonneau G et al. Chronic Thromboembolic Pulmonary Hypertension. *Circulation*. 2006; 113: 2011-2020.
14. McGoon MD, Kane GC. Pulmonary Hypertension: Diagnosis and Management. Mayo Clin Proc. 2009; 84(2): 191-207.
15. 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.
16. McLaughlin VV, Davis M, Cornwell W. Pulmonary Arterial Hypertension. *Curr Probl Cardiol*. 2011; 36:461-517.
17. McLaughlin VV, Gaine SP, Howard LS et al. Treatment goals of pulmonary hypertension. *J Am Coll Cardiol.* 2013; 62(25 Suppl):D42-50.
18. McLaughlin VV, Shah SJ, Souza R et al. Management of pulmonary arterial hypertension. *J Am Coll Cardiol.* 2015; 65(18):1976-97.
19. McNeil K, Dunning J. Chronic Thromboembolic Pulmonary Hypertension (CTEPH). *Heart;* 93: 1152- 1158.
20. National Heart, Lung, and Blood Institute, National Institute of Health: "Primary Pulmonary Hypertension," November 1996, NIH Publication No. 96-3291 Pages 1-11.
21. Remodulin (treprostinil) injection [package insert]. Research Triangle Park, NC: United Therapeutics, Corp; April 2026.
22. Piazza G, Goldhaber SZ. Chronic Thromboembolic Pulmonary Hypertension. *N Engl J Med*. 2011; 364: 351-360.
23. Remodulin (treprostinil) Injection [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; July 2018.
24. Rubin LJ. Introduction: Diagnosis and management of pulmonary arterial hypertension: ACCP Evidenced-Based Clinical Practice Guidelines. *Chest*. 2004; 126: 7S-10S.
25. 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.
26. 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.
27. Veletri (epoprostenol for injection) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; July 2022.
28. Wilkins MR. Pulmonary hypertension: the science behind the disease spectrum. *Eur Respir Rev.* 2012; 21(123):19-26.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Removed the Limitation The Plan will not authorize coverage of epoprostenol sodium injection, Flolan (epoprostenol sodium), Remodulin (treprostinil sodium), treprostinil sodium injection, or Veletri (epoprostenol sodium) 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, or Obstructive sleep apnea or other sleep disorders involving breathing or alveolar hyperventilation disorders. Expanded provider requirements to "prescribed by or in consultation." Defined criteria for right heart catheterization. Added step through phosphodiesterase-5 inhibitor and an endothelin receptor antagonist. Added step through generic epoprostenol for brand Flolan and Veletri (effective 2/1/24).
- September 10, 2024: Added a step through generic treprostinil for brand Remodulin (eff 12/1/24).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- September 9, 2025: No changes (eff 9/9/25).
- September 15, 2026: Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from "Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans" to "Tufts Health Together- MassHealth Accountable Care Partnership Plans."

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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