Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Veletri® (epoprostenol) for injection

Effective: December 12, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988
☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ 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

Pulmonary arterial hypertension (PAH) is a rare but life-threatening disorder characterized by hypertension in the arteries of the lungs and shortness of breath and fatigue following exertion. Interstitial lung disease (ILD) is a group of diseases characterized by marked scarring or fibrosis of the lungs.

Food and Drug Administration (FDA) Approved Indications:

VELETRI (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 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 cover Veletri (epoprostenol) when all the following clinical criteria is met:

1. The member has a documented diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)

Limitations

- Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1325	Injection, epoprostenol, 0.5 mg

Appendix:
WHO classification of pulmonary hypertension (PH):

- Group 1 PAH: Pulmonary arterial hypertension (PAH)
- Group 2 PH: Pulmonary hypertension owing to left heart disease
- Group 3 PH: Pulmonary hypertension owing to lung diseases and/or hypoxia
- Group 4 PH: Chronic thromboembolic pulmonary hypertension (CTEPH)
- Group 5 PH: Pulmonary hypertension with unclear multifactorial mechanisms

World Health Organization (WHO) Functional Assessment Classification

- Class I: Patients with PH but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.
- Class II: Patients with PH resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.
- Class III: Patients with PH resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope.
- Class IV: Patients with PH with inability to carry out any physical activity without symptoms. These patients' manifest signs of right-heart failure. Dyspnea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

References:

1. Veletri (epoprostenol for injection) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; January 2021.
2. Humbert M, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. European Heart Journal. 2022 Oct;43(38):3618–31.
3. Klinger JR, et al. Therapy for Pulmonary Arterial Hypertension in Adults 2018: Update of the CHEST Guideline and Expert Panel Report. Chest. 2019 Mar;155(3).
4. McLaughlin VV, et al. Results of an Expert Consensus Survey on the Treatment of Pulmonary Arterial Hypertension With Oral Prostacyclin Pathway Agents. Chest. 2020;157(4):955-965
5. McLaughlin VV, et al. ACCF/AHA 2009 Expert Consensus Document on Pulmonary Hypertension. JACC. 2009;53(17):1573–619.

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)

December 12, 2023: No changes. Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule. Retire Veletri Medical Necessity Guideline effective 2/29/2024. Defer to Pulmonary Hypertension Medications: Epoprostenol products, Remodulin, Tyvaso, Veletri, Ventavis Medical Necessity Guidelines effective March 1, 2024.

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria

within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

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.