Iloprost (Ventavis®)	Place of Service Infusion Center Administration Home Infusion Administration Office Administration Outpatient Facility Administration HCPCS: **Q4074** per 20 mcg

Condition(s) listed in policy (*see criteria for details*)

- Pulmonary arterial hypertension (PAH) WHO Group 1

AHFS therapeutic class: Vasodilating Agent (respiratory tract)

Mechanism of action: a synthetic analog of prostacyclin (PGI_2), is a vasodilating agent and a platelet-aggregation inhibitor.

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Ventavis® (iloprost) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Pulmonary arterial hypertension

1. WHO Group I classification

Covered Doses
Up to 5 mcg inhaled up to 9 times per day

Coverage Period
Indefinite

ICD-10:
I27.0 [Primary], I27.2, I27.89 [Secondary]

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Ventavis® (iloprost) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety

Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied: 1 mL ampules

10 mcg (single-use ampule) – supplies single 2.5 mcg or 5 mcg dose

20 mcg (single-use ampule) – supplies single 5 mcg dose

Clinical classification of pulmonary hypertension (6th World Symposium on Pulmonary Hypertension)

1 PAH
1.1 Idiopathic PAH
1.2 Heritable PAH
1.3 Drug- and toxin-induced PAH (table 3)
1.4 PAH associated with:
1.4.1 Connective tissue disease
1.4.2 HIV infection
1.4.3 Portal hypertension
1.4.4 Congenital heart disease
1.4.5 Schistosomiasis
1.5 PAH long-term responders to calcium channel blockers
1.6 PAH with overt features of venous/capillaries (PVOD/PCH) involvement
1.7 Persistent PH of the newborn syndrome
2 PH due to left heart disease
2.1 PH due to heart failure with preserved LVEF
2.2 PH due to heart failure with reduced LVEF
2.3 Valvular heart disease
2.4 Congenital/acquired cardiovascular conditions leading to post-capillary PH
3 PH due to lung diseases and/or hypoxia
3.1 Obstructive lung disease
3.2 Restrictive lung disease
3.3 Other lung disease with mixed restrictive/obstructive pattern
3.4 Hypoxia without lung disease
3.5 Developmental lung disorders
4 PH due to pulmonary artery obstructions (table 6)
4.1 Chronic thromboembolic PH
4.2 Other pulmonary artery obstructions
5 PH with unclear and/or multifactorial mechanisms (table 7)
5.1 Haematological disorders
5.2 Systemic and metabolic disorders
5.3 Others
5.4 Complex congenital heart disease

(6) References

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- Humbert M, Kovacs G, Hoeper M, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: Developed by the task force for the diagnosis and treatment of pulmonary hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Endorsed by by the International Society for Heart and Lung Transplantation (ISHLT) and the European Reference Network on rare respiratory distress (ERN-LUNG). European Heart Journal, 2022; 43 (38): 3618-3731. https://doi.org/10.1093/eurheartj/ehac237
- Klinger JR, Elliott CG, Levine DJ, et al. Therapy for pulmonary arterial hypertension in adults: update of the CHEST guideline and expert panel report. Chest 2019; 155:565-586.
- 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 Physicians, American Thoracic Society, Inc., and the Pulmonary Hypertension Association. Circulation 2009;119(16):2250-94.
- 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.
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(7) Policy Update

Date of initial review: 4Q2023

Date of next review: 4Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee