MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Pulmonary Hypertension	**P&T DATE:**	3/10/2026
CLASS:	Respiratory Disorders	**REVIEW HISTORY:** (*month/year*)	3/25, 12/22, 12/21, 9/20, 5/19, 5/18, 12/16, 11/15, 5/13
LOB:	Medi-Cal/Medicare		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the Health Plan of San Joaquin/Mountain Valley Health Plan (Health Plan) Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medi-calrx.dhcs.ca.gov/home/ for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.
All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

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Any biosimilars pending litigations or not officially available in the US Market for consumer use is not an available treatment option or covered on the medical benefit. Biosimilars that are FDA approved and available in the US Market for consumer use will follow the reference brand name criteria as available per our PH05 - Prior Authorizations processes. Certain biosimilars may be subject to alternative criteria based on the preferences of Health Plan.

This coverage policy is updated on an annual basis. For more recent or up-to-date criteria, reference the Medi-Cal Provider Manual and/or the Medicare National Coverage Determination/Local Coverage Determination (NCD/LCD) for specific criteria. If the Medi-Cal Provider Manual and/or the Medicare NCD/LCD do not have medical necessity criteria, please refer to the "Evaluation Criteria" section in this policy for specific criteria. It is also important to reference the Medicare Benefit Manuals - Chapter 15 and Chapter 16 - when determining benefit coverage and criteria for review of physician administered drugs on the Medicare benefit.

OVERVIEW

For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

Guidelines used in the creation of this policy include the following (please review the references section for all the relevant literature used):

- 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).
- Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report

⌗ MEDI-CAL EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the Health Plan Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, Health Plan will make the determination based on Medical Necessity criteria as described in Health Plan Medical Review Guidelines (UM06).

Phosphodiesterase-5 Inhibitors (PDE-5i): Sildenafil, Tadalafil

Sildenafil (Revatio) IV

- ❒ **Coverage Criteria:** Reserved for patients with WHO FC II-IV with: (-) vasoreactivity test **OR** (+) vasoreactivity test and dose optimized Calcium Channel Blocker (CCB) for 3 months.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Basic criteria as listed above plus all of the following: clinical documentation of inadequate response to dose optimized Calcium Channel Blocker (CCB) for 3 months evidenced by worsening of symptoms (i.e. decline in 6MWD) and pharmacy fill history.

Prostanoids: Epoprostenol, Iloprost, Tresprostinil

Epoprostenol (Flolan, Veletri), Treprostinil (Remodulin)

- ❒ **Coverage Criteria:**
  - [1] WHO FC IV **OR**
  - [2] Inadequate response to dose optimized PDE-5i and Endothelin Receptor Antagonists (ERA) for 3 months for (-) vasoreactive patients **OR**
  - [3] Inadequate response to dose optimized Calcium Channel Blocker (CCB) plus Phosphodiesterase-5 Inhibitors (PDE-5i) AND Endothelin Receptor Antagonists (ERA) for 3 months for (+) vasoreactivity test **OR**
  - [4] Patients with clinical evidence of Right Ventricle (RV) failure or moderate to rapid rate of progression of symptoms/disease
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Basic criteria as listed above, clinical documentation of inadequate response evidenced by worsening of symptoms (i.e. decline in 6MWD), and pharmacy fill history or clinical evidence of Right Ventricle (RV) failure or moderate to rapid rate of progression of symptoms/disease

Treprostinil Inhalation (Tyvaso)

- ❒ **Coverage Criteria:** WHO FC III **AND one of the following:**
  - [1] Inadequate response to dose optimized Phosphodiesterase-5 Inhibitors (PDE-5i) and Endothelin Receptor Antagonists (ERA) for 3 months for (-) vasoreactive patients **OR**
  - [2] Inadequate response to dose optimized Calcium Channel Blocker (CCB) plus Phosphodiesterase-5 Inhibitors (PDE-5i) AND Endothelin Receptor Antagonists (ERA) for 3 months for (+) vasoreactive patients **OR**
  - [3] Contraindication to Phosphodiesterase-5 Inhibitors (PDE-5i), Riociguat and Endothelin Receptor Antagonists (ERA).
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Basic criteria as listed above, clinical documentation of inadequate response evidenced by worsening of symptoms (i.e. decline in 6MWD), and pharmacy fill history +/- documentation of the nature of contraindication

Prostacyclin IP Receptor Agonist: Selexipag (Uptravi)

Selexipag (Uptravi)

- ❒ **Coverage Criteria:** WHO FC III to IV **AND one of the following:**
  - [1] Inadequate response to dose optimized Phosphodiesterase-5 Inhibitors (PDE-5i) and Endothelin Receptor Antagonists (ERA) for 3 months for (-) vasoreactive patients **OR**

- [2] Inadequate response to dose optimized Calcium Channel Blocker (CCB) plus Phosphodiesterase-5 Inhibitors (PDE-5i) AND Endothelin Receptor Antagonists (ERA) for 3 months for (+) vasoreactivity test **OR**
- [3] Contraindication to PDE-5i, Riociguat, and Endothelin Receptor Antagonists (ERA).

❒ **Limits:** None

❒ **Required Information for Approval:** Basic criteria plus specific coverage criteria clinical documentation of inadequate response evidenced by worsening of symptoms (i.e. decline in 6MWD), and pharmacy fill history +/- documentation of the nature of contraindication.

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REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	PAH Class Review 5-21-2013.docx	5/2013	Jonathan Szkotak, PharmD BCACP
Update Policy	Drug Class Review – Respiratory disorders – Pulmonary Hypertension 2015-11.docx	11/2015	Johnathan Yeh, PharmD
Update Policy	HPSJ Coverage Policy – Respiratory disorders – Pulmonary Hypertension 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update Policy	HPSJ Coverage Policy – Respiratory disorders – Pulmonary Hypertension 2018-05.docx	5/2018	Johnathan Yeh, PharmD
Update Policy	HPSJ Coverage Policy – Respiratory disorders – Pulmonary Hypertension 2019-05.docx	5/2019	Matthew Garrett, PharmD
Review of Policy	Pulmonary Hypertension	9/2020	Matthew Garrett, PharmD
Review of Policy	Pulmonary Hypertension	12/2021	Matthew Garrett, PharmD
Review of Policy	Pulmonary Hypertension	12/2022	Matthew Garrett, PharmD
Review of Policy	Pulmonary Hypertension	01/2024	Matthew Garrett, PharmD
Review of Policy	Pulmonary Hypertension	03/2025	Matthew Garrett, PharmD
Review of Policy	Pulmonary Hypertension	03/2026	Matthew Garrett, PharmD

are approved by the Health Plan P&T Committee before incorporation into the utilization policy