MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Health Plan of San Joaquin

POLICY:	Pulmonary Hypertension	**P&T DATE:**	12/21/2022
CLASS:	Respiratory Disorders	**REVIEW HISTORY:** (*month/year*)	12/21, 9/20, 5/19, 5/18, 12/16, 11/15, 5/13
LOB:	MCL		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ 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.

OVERVIEW

The purpose of this coverage policy is to review the available agents (Table 1) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

Table 1: Available Pulmonary Hypertension Agents *(Current as of 07/2022)*

CPT code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Calcium Channel Blockers (CCB)				
Dihydropyridine:				
--	**Amlodipine (Norvasc)** Dose range for PAH: 20 - 30 mg qd	Tablets: 2.5 mg, 5 mg, 10 mg	Yes	No
--	**Nifedipine (Adalat CC, Afeditab CR, Nifediac CC, Nifedical XL, Procardia XL)** Dose range for PAH: 180 – 240 mg qd	IR capsules: 10 mg, 20 mg 24 Hour ER Tablets: 30 mg, 60 mg, 90 mg XL Tablets: 30 mg, 60 mg, 90 mg	Yes	No
Non-Dihydropyridine:				
--	**Diltiazem (Cardizem, Cardizem CD, Cardizem LA, Cartia XT, Dilacor XR, Dilt-XR, Martizem LA, Tiazac XC)** Dose range for PAH: 720 – 960 mg qd	CD Capsules: 120 mg, 180 mg, 240 mg, 300mg, 360 mg XR capsules: 120 mg, 180 mg, 240 mg 12 Hour ER Capsules: 60 mg, 90 mg, 120 mg 24 Hour ER Capsules: 120 mg, 180 mg, 240 mg, 300 mg, 360 mg, 420 mg IR Tablets: 30mg, 60 mg, 90 mg, 120 mg ER Tablets: 180 mg, 240 mg, 300 mg, 360 mg Cardizem LA Tablets: 120 mg Cartia XT Capsules: 120 mg, 180 mg, 240 mg, 300 mg Taztia XT Capsules: 120 mg, 180 mg, 240 mg, 360 mg Matzim LA Tablets: 180 mg, 240 mg	Yes	No
Phosphodiesterase-5 Inhibitors (PDE-5i)				
S0090	**Sildenafil (Revatio)**	20 mg	Yes	Yes, for IV only

	Dose range for PAH: 20 mg every 8 hours, up to 80 mg every 8 hours			
--	**Tadalafil (Adcirca)**	5 MG 20 MG	Yes	No
Endothelin Receptor Antagonists (ERA)				
--	**Bosentan (Tracleer)**	Tablets: 62.5 mg, 125 mg Tablet, Dispersible: 32 mg	Yes	No
--	**Ambrisentan (Letairis)**	Tablets: 5 mg, 10 mg	Yes	No
--	**Macitentan (Opsumit)**	Tablets: 10 mg	Yes	No
Prostanoids				
J1325	**Epoprostenol (Flolan, Veletri)**	IV Solution: 0.5mg, 1.5mg	Yes	Yes (PA)
Q4074	**Iloprost Tromethamine (Ventavis)**	Inhalation Solution: 10 mcg/mL, 20 mcg/mL	Yes	No
J3285 for SQ or IV use	**Treprostinil (Orenitram; Remodulin; Tyvaso)**	Remodulin (IV or SQ): 1 mg/mL, 2.5 mg/mL, 5 mg/mL, 10 mg/mL Orenitram ER tablets: 0.125mg, 0.25 mg, 1 mg, 2.5mg, 5 mg Tyvaso Inhalation: Starter Kit (includes nebulizer). Refill Kit	Yes	Yes, for IV/SQ only (PA)
--	**Riociguat (Adempas)**	Tablets: 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg	Yes	No
--	**Selexipag (Uptravi)**	Tablets: 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,000 mcg, 1,200 mcg, 1,400 mcg, 1,600 mcg, 200 mcg- 800mcg Therapy Pack Solution (reconstituted):1800 mcg (per each)	Yes	Yes, for IV only (PA)

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 HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ will make the determination based on Medical Necessity criteria as described in HPSJ Medical Review Guidelines (UM06).

Basic Criteria: [1] Prescribed by a Cardiologist, Pulmonologist, or Critical care
[2] Diagnosis of Pulmonary Arterial Hypertension, WHO GROUP I
[3] WHO Functional Class (WHO FC) II-IV
[4] Right Heart Catheterization with Vasoreactivity test

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

Sildenafil (Revatio) IV

- ❒ **Coverage Criteria:** Reserved for patients with IPAH WHO FC II-IV with: (-) vasoreactivity test **OR** (+) vasoreactivity test and dose optimized 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 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), Iloprost (Ventavis), Treprostinil (Orenitram ,Remodulin)

- ❒ **Coverage Criteria:** [1] WHO FC IV **OR** [2] Inadequate response to dose optimized PDE-5i and ERA for 3 months for (-) vasoreactive patients **OR** [3] Inadequate response to dose optimized CCB plus PDE-5i AND 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
- ❒ **Non-Formulary: Orenitram ER tablets**

Treprostinil Inhalation (Tyvaso)

- ❒ **Coverage Criteria:** WHO FC III **AND one of the following:** [1] Inadequate response to dose optimized PDE-5i and ERA for 3 months for (-) vasoreactive patients **OR** [2] Inadequate response to dose optimized CCB plus PDE-5i AND ERA for 3 months for (+) vasoreactive patients **OR** [3] Contraindication to PDE-5i, Riociguat and 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 PDE-5i and ERA for 3 months for (-) vasoreactive patients **OR** [2] Inadequate response to dose optimized CCB plus PDE-5i AND ERA for 3 months for (+) vasoreactivity test **OR** [3] Contraindication to PDE-5i, Riociguat and 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.

Clinical Justification:

Diagnosis of Pulmonary Hypertension requires Right Heart Catheterization (RHC)[5]. Following the current Pulmonary Arteriole Hypertension recommendation, HPSJ formulary has set RHC and vasoreactivity test as a part of the requirements and restricts medications based on clinical evidence. Calcium channel blockers are the preferred agent in patients who can tolerate them, and who have shown good response during right heart catheterization, unless contraindicated. Drugs are restricted based on WHO Functional Class and patient's prior use of PAH medications. ERAs are not benign drugs. They are teratogenic, can potentially cause LFT elevations in patients who take them chronically, and can cause fluid retention. Sildenafil is widely available and relatively benign, thus carries few restrictions, while intravenous prostanoids carry significant risk, and should not be used unless all other therapeutic agents have been exhausted. Although 2019 Chest Guideline suggests Ambrisentan and Tadalafil as an initial therapy for WHO FC II and II, weak recommendation resulting from borderline clinically significant improvement in 6MWD, no change in WHO FC, variabilities of end points in clinical trial and studies, and the fact that the guideline does not prefer one regimen over the other in this treatment group, HPSJ has decided not to modify current PAH coverage criteria.

Triage:

- ***Appropriate diagnosis: WHO Group I, and WHO Functional Class II-IV***
- ***Right Heart Catheterization (RHC) with vasoreactivity test***
- ***Provider Specialty- cardiologist, pulmonologist, or critical care provider***
- ***Current Pulmonary Hypertension drugs***

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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

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy