



Drug Use Evaluation: Pulmonary Hypertension Drugs

Plain Language Summary: How many people are prescribed sildenafil for pulmonary hypertension?

- Sildenafil is a medicine that is approved by the Food and Drug Administration for both pulmonary hypertension and erectile dysfunction. Pulmonary hypertension is a condition caused by high blood pressure in the lungs. This high blood pressure can lead to difficulty breathing, heart failure, and death. Erectile dysfunction, or impotence, is the inability to get and keep an erection.
- The Oregon Health Plan (OHP) covers sildenafil, and similar medicines, for treatment of pulmonary hypertension. Erectile dysfunction is not covered by the OHP.
- In people with claims for pulmonary hypertension medicines, only 16% of people had a diagnosis for pulmonary hypertension. More than 90% of people had claims for sildenafil.
- The average dose of sildenafil, patient gender, and prescriber type indicate that sildenafil may be prescribed for erectile dysfunction.
- We recommend the Oregon Health Authority require a prior authorization (PA) to limit use for erectile dysfunction in people on the Oregon Health Plan.

Research Questions:

1. In the fee-for-service (FFS) program, what proportion of people prescribed medication for pulmonary arterial hypertension (PAH) have a diagnosis of PAH present in medical claims?
2. In the FFS program, what proportion of people prescribed medications for PAH are prescribed more than one drug class of PAH therapy?
3. What proportion of FFS members are prescribed medication for PAH from a pulmonary specialist?
4. What is the average dose of phosphodiesterase (PDE)-5 inhibitor prescribed for fee-for-service (FFS) members?

Conclusions:

- Of FFS members prescribed PAH drugs, only 16% of members had a diagnosis of pulmonary hypertension in the 6 months before or 3 months after the first paid FFS claim for PAH therapy.
- Only 4% of members were prescribed more than one class of drugs for PAH.
- Most members had claims for preferred PDE-5 inhibitors (99%) and most members were male (90.5%). These demographics are inconsistent with epidemiologic data for PAH. It is estimated that PAH is 1.5 to 3 times more common in females than males.¹
- Only 10% of members had prescriptions written by a cardiopulmonary specialist.
- In members with claims for a PDE-5 inhibitor, most members were prescribed lower doses (<60 mg daily) which is consistent with a diagnosis of erectile dysfunction (47%).

Recommendations:

- Implement prior authorization (PA) for preferred PDE-5 inhibitors to limit use for erectile dysfunction. Auto-approve prescriptions for any of the following criteria:

- PAH;
- Prior claims for other PAH drug classes;
- Identified female gender; OR
- Prescriptions written by a pulmonologist.

Background

Pulmonary hypertension is classified into 5 groups: pulmonary arterial hypertension (PAH; World Health Organization [WHO] group 1), pulmonary hypertension due to left heart disease (WHO group 2), pulmonary hypertension due to lung disease and hypoxia (WHO group 3), chronic thromboembolic pulmonary hypertension (CTEPH, WHO group 4) and pulmonary hypertension with an unclear multifactorial cause (WHO group 5). Each type of pulmonary hypertension has a unique etiology, pathology and management strategy. Epidemiologic studies indicate that about 1% of people have some type of pulmonary hypertension with incidence increasing with age.² Left heart disease and lung disease are the most common causes of pulmonary hypertension.² Diagnosis of PAH requires ruling out alternative causes of pulmonary hypertension. It is estimated that PAH is 1.5 to 3 times more common in females than males.^{1,3}

Pulmonary hypertension symptoms are often classified according to WHO functional classes (**Table 1**). In PAH (WHO group 1), current guidelines recommend targeted medications for people with WHO functional class II-IV symptoms.^{3,4} Current PAH-specific treatment options include the following drugs:

- PDE-5 inhibitors: sildenafil (oral, intravenous) and tadalafil (oral)
- Endothelial receptor antagonists (ERAs): bosentan (oral), macitentan (oral), and ambrisentan (oral)
- soluble guanylate cyclase stimulators: riociguat (oral)
- prostacyclin receptor agonists: selexipag (oral, intravenous)
- prostanoids: epoprostenol (intravenous), treprostinil (inhaled, oral, subcutaneous, intravenous), and iloprost (inhaled)
- activin receptor protein: sotatercept (subcutaneous)

Guidelines recommend initial combination treatment with tadalafil and ambrisentan to improve 6MWD in treatment-naïve patients with WHO functional class II and III symptoms who are not candidates for calcium channel blockers (weak recommendation, moderate quality evidence).⁴ If patients are unable to tolerate combination treatment then monotherapy with an ERA, PDE-5 inhibitor, or soluble guanylate cyclase inhibitor is suggested.⁴ Targeted treatments (riociguat and inhaled treprostinil) are also FDA-approved for CTEPH (WHO group 4) and pulmonary hypertension due to interstitial lung disease (WHO group 3), respectively.

Table 1. WHO functional classes

WHO Class	Description
Class I	No limitations in physical activity; physical activity does not cause symptoms
Class II	Slight limitations in physical activity; ordinary physical activity causes symptoms
Class III	Limitations of physical activity; less than ordinary activity causes symptoms
Class IV	Symptoms at rest and/or with any physical activity

Guidelines for management of PAH published in 2019 recommend initial combination treatment with tadalafil and ambrisentan to improve exercise capacity in treatment-naïve patients with WHO functional class II and III symptoms who are not candidates for calcium channel blockers (weak recommendation, moderate quality evidence).⁴ There is evidence that PDE-5 inhibitors can improve exercise capacity in people with PAH, and that high doses of sildenafil may be associated with improved mortality in adults with PAH.^{4,5} Use of PDE-5 inhibitors is not routinely recommended for other types of pulmonary hypertension (WHO groups 2-

5). PDE-5 inhibitors have also been FDA-approved for erectile dysfunction and benign prostatic hyperplasia. Treatment for benign prostatic hyperplasia is funded. Treatment for erectile dysfunction is unfunded and coverage is not included in the Medicaid state plan.

In FFS, prior authorization (PA) is required for non-preferred agents; preferred products are available without PA. Preferred products include oral sildenafil 20 mg tablets (with indications for PAH), bosentan tablets, and epoprostenol injection. The purpose of this policy evaluation is to evaluate whether the current policy appropriately restricts utilization to covered indications in the FFS population.

Methods:

OHP members were identified for inclusion in this evaluation based on paid FFS pharmacy claims for targeted PAH therapies over a 2-year evaluation window (from 4/1/22 to 03/31/24). The first paid claim was identified as the index event (IE). For each patient, the 6 months before the IE was used to define the baseline period (inclusive of the IE) and the 3 months after the IE was used to define the follow-up period (exclusive of the IE).

Inclusion Criteria:

- OHP members with paid FFS pharmacy claims for drugs in the Pulmonary Arterial Hypertension preferred drug list (PDL) classes (including oral, inhaled and parenteral drugs) from 4/1/22 to 03/31/24

Exclusion Criteria:

- Members with <75% continuous OHP eligibility in the baseline or follow up periods
- Members with Medicare eligibility, primary insurance (e.g, third-party liability), or a limited Medicaid drug benefit in the baseline or follow-up period.

Claims data for these members may be incomplete. Members were identified based on the following benefit packages:

Category	Benefit Package	Description
Medicare Part D coverage	BMM	Qualified Medicare Beneficiary + Oregon Health Plan with Limited Drug
	BMD	Oregon Health Plan with Limited Drug
	MED	Qualified Medicare Beneficiary
Limited or no Medicaid drug benefit	MND	Transplant package
	CWM	Citizenship Waived Emergency Medical
	SMF	Special Low-Income Medicare Beneficiary Only
	SMB	Special Low-Income Medicare Beneficiary Only

Outcomes

- Proportion of members with a diagnosis of PAH in the baseline or follow-up periods.
- Proportion of members with paid FFS or Coordinated Care Organization (CCO) pharmacy or medical claims for PAH therapy in the follow-up period.
- Proportion of members with an IE claim from a pulmonary specialist (defined based on provider taxonomy in **Appendix 1; Table A3**).
- Daily dose prescribed for PDE-5 inhibitors on the IE

Descriptors and definitions

- Drugs were categorized based on mechanism of action (**Appendix 1; Table A1**)
- Dose of PDE-5 inhibitors was categorized based on expected doses for PAH and calculated based on quantity and days' supply submitted on the index event (**Appendix 1; Table A2**)

Results:

Of 131 members with paid FFS claims for PAH treatment over a 2-year period, 74 members (56.5%) were included in the analysis (**Table 2**). Most members were adults (97%), male (90%), and Native American or Alaskan Native (68%). About 72% of members did not have any prior claims for PAH drug therapy. All identified members had claims for oral drugs, most were for preferred products, and 99% of members had claims for a PDE-5 inhibitor (**Table 3**). Preferred PDE-5 inhibitors include brand and generic formulations of REVATIO® which are FDA-approved for pulmonary arterial hypertension. Brand and generic formulations of Viagra® are non-preferred and not covered by OHP.

Only 16% of members had a diagnosis of pulmonary hypertension in the 6 months before or 3 months after the IE (**Table 4**). About 15% of members had comorbid diagnoses which are known causes of WHO Groups 2-4 pulmonary hypertension. Twenty-eight percent of members lacked a pulmonary hypertension diagnosis but did have a diagnosis of erectile dysfunction. Very few members (4%) had claims for more than one class of PAH drugs in the 3-month follow-up period (**Table 5**) and most prescriptions were written by general practitioners (**Table 6**). Only 10% of members had prescriptions written by a cardiopulmonary specialist.

The recommended total daily dose of sildenafil when prescribed for pulmonary arterial hypertension is 60 to 240 mg (divided three times daily).⁶ The typical dose when prescribed for erectile dysfunction is 25 to 100 mg as needed up to one time per day.⁶ In members with claims for a PDE-5 inhibitor, most members were prescribed lower daily doses which were consistent with a diagnosis of erectile dysfunction (47%; **Table 7**).

Table 2. Included members

	#	%
Members with paid claims for PAH treatment	131	
After exclusion of members with Medicare, TPL, or limited benefit plans	89	67.9%
After exclusion of members with <75% Medicaid eligibility in the baseline period	75	57.3%
After exclusion of members with <75% Medicaid eligibility in the follow-up period	74	56.5%

Table 3. Baseline demographics

	Members	
	74	%
Average Age (min-max)	47	(0-63)
<18	2	2.7%
>=18	72	97.3%
Sex		
Male	67	90.5%
Female	7	9.5%

Race		
Native American/Alaskan Native	50	67.6%
White	16	21.6%
Other	5	6.8%
Unknown	3	4.1%
Prior Treatment (PAH claims in the baseline period)		
New start (no prior treatment)	53	71.6%
Previous claims	21	28.4%
IE PDL Status		
Preferred	69	93.2%
Non-preferred	5	6.8%
IE Drug Route		
Oral	74	100.0%
Injectable	0	0.0%
Inhaled	0	0.0%
IE Drug Category		
PDE-5 inhibitor	73	98.6%
ERA	1	1.4%
Guanylate cyclase stimulator	0	0.0%
Prostanoid/prostacyclin receptor agonist	0	0.0%

Table 4. Diagnoses in the baseline or follow up periods. Categories are mutually exclusive

Indication	Total IE	
	74	%
Pulmonary Hypertension	12	16.2%
No pulmonary hypertension diagnosis but relevant comorbid conditions for pulmonary hypertension	11	14.9%
Group 1 conditions (e.g., connective tissue disorders, rheumatoid arthritis)	0	0.0%
Group 2 conditions (e.g., heart failure and valvular heart disease)	3	4.1%
Group 3 conditions (e.g., COPD, interstitial lung disease, sleep apnea)	3	4.1%
Group 4 conditions (e.g., pulmonary embolism, cancer)	5	6.8%

No pulmonary hypertension diagnosis AND no comorbid diagnosis for pulmonary hypertension	23	31.1%
Erectile dysfunction	21	28.4%
Benign prostatic hyperplasia	2	2.7%

Table 5. Concomitant PAH treatment

	Members	
	74	%
Number of PAH drug classes (by mechanism) in the follow-up period (including the IE)		
1	71	95.9%
2	2	2.7%
3	1	1.4%

Table 6. Provider taxonomy

	Members	
	74	%
Provider Taxonomy (IE)		
Cardiopulmonary specialty	7	9.5%
Other	67	90.5%
Top 10 provider taxonomies		
207Q00000X: PHYSICIAN-FAMILY MEDICINE	19	25.7%
207R00000X: PHYSICIAN-INTERNAL MEDICINE	16	21.6%
363A00000X: PHYSICIAN ASSISTANT	11	14.9%
363LF0000X: NURSE PRACTITIONER - FAMILY	10	13.5%
207RP1001X: PHYSICIAN-INTERNAL MEDICINE- PULMONARY DISEASE	5	6.8%
363LA2200X: NURSE PRACTITIONER - ADULT HEALTH	3	4.1%
2080P0202X: PHYSICIAN-PEDIATRICS-PEDIATRIC CARDIOLOGY	2	2.7%
207RI0200X: PHYSICIAN-INTERNAL MEDICINE-INFECTIOUS DISEASE	2	2.7%
363AM0700X: PHYSICIAN ASSISTANT - MEDICAL	1	1.4%
208800000X: PHYSICIAN-SURGERY-UROLOGY	1	1.4%
2084P0800X: PHYSICIAN-PSYCHIATRY&NEUROLOGY-PSYCHIATRY	1	1.4%
207RN0300X: PHYSICIAN-INTERNAL MEDICINE-NEPHROLOGY	1	1.4%
207P00000X: PHYSICIAN-EMERGENCY MEDICINE	1	1.4%

Table 7. Average dose per day for oral PDE-5 inhibitors

IE Daily Dose	Members with PDE-5 inhibitor IE	
	73	%
Sildenafil		
<= 59 mg daily (ED dose only)	34	46.6%
60-100 mg daily (ED and PAH dose)	35	47.9%
>=101 mg daily (PAH dose only)	3	4.1%
Tadalafil		
<20 mg daily (ED dose only)	0	0.0%
20-25 mg daily (ED and PAH dose)	0	0.0%
>=26 mg daily (PAH dose only)	1	1.4%

Abbreviations: ED = erectile dysfunction; PAH = pulmonary arterial hypertension

Limitations and Discussion:

This analysis is based on claims data which has several inherent limitations.

- Provider taxonomies may be inaccurate or incomplete. For example, providers with multiple specialties may not be accurately categorized and taxonomy does not capture the setting in which the provider practices. Classification of providers based on taxonomy may be most inaccurate for general practitioners (like nurse practitioners or physician assistants) who are working in a pulmonary or cardiology clinic and consult regularly with providers specializing in pulmonary disease.
- Diagnoses were only evaluated in the 6 months before or 3 months after the first identified claim which may not accurately categorize members who have a chronic condition like pulmonary hypertension.
- Daily dose relies on information submitted on the pharmacy claim and may not reflect the actual dose prescribed or dose taken by the member. This analysis evaluated daily dose for only one claim in the reporting period and did not attempt to quantify medication possession ratio for members over time. For example, routine prescriptions may be more indicative of use for PAH, whereas intermittent claims may be more indicative of “as needed” use for erectile dysfunction. However, despite these limitations, the relatively low daily doses on the IE are consistent with use for erectile dysfunction instead of PAH.

The results of this analysis strongly suggest that most pharmacy claims for oral PDE-5 inhibitors are prescribed for erectile dysfunction and are not prescribed for PAH. Evidence to support this conclusion is based on the following factors:

- While only 131 members were identified over a 2-year period, most members did not have a diagnosis of pulmonary hypertension.
- Over 90% of claims were for males, and these demographics are inconsistent with epidemiologic data for PAH which is more common in female patients.

- Most members were prescribed PDE-5 inhibitors and were not prescribed other drugs for PAH. PDE-5 inhibitors are one of the first-line agents recommended for pulmonary arterial hypertension (WHO group 1). However, guidelines recommend combination treatment with a PDE-5 inhibitor and ERA for newly diagnosed patients with PAH and WHO functional class II-IV symptoms.⁴
- The prescribed daily dose is more consistent with utilization for erectile dysfunction than pulmonary hypertension.
- Only 10% of prescriptions were written by a provider with a cardiology or pulmonary specialty.

References:

1. Hoeper MM, Badesch DB, Ghofrani HA, et al. Phase 3 Trial of Sotatercept for Treatment of Pulmonary Arterial Hypertension. *The New England journal of medicine*. 2023;388(16):1478-1490.
2. Pulmonary Hypertension Classification and Treatment. DynaMed [internet database]. Ipswich, MA: EBSCO Publishing. Accessed October 09, 2024.
3. Humbert M, Kovacs G, Hoeper MM, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. *European heart journal*. 2022;43(38):3618-3731.
4. 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(3):565-586.
5. Revatio (sildenafil) [package label]. Morgantown, WV: Viatris Specialty LLC; January 2023.
6. Sildenafil Citrate In: Merative Micromedex® DRUGDEX® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: October 21, 2024).

Appendix 1: Drug Codes

<u>HSN</u>	<u>Generic</u>	<u>Mechanism of Action</u>
022990	bosentan	ERA
034849	ambrisentan	ERA
040677	macitentan	ERA
026287	iloprost tromethamine	Prostanoid
036537	treprostinil/nebulizer/accesor	Prostanoid
036539	treprostinil/neb accessories	Prostanoid
036541	treprostinil	Prostanoid
040827	treprostinil diolamine	Prostanoid
042922	selexipag	prostacyclin receptor agonist
018084	sildenafil citrate	PDE-5 inhibitor
024859	tadalafil	PDE-5 inhibitor
040644	riociguat	Guanylate cyclase stimulator
049475	sotatercept-csrk	Activin receptor protein
007323	epoprostenol sodium	Prostanoid
023650	treprostinil sodium	Prostanoid
037760	epoprostenol sodium (glycine)	Prostanoid

Table A2. Strength for Daily Dose calculations of PDE-5 inhibitors

<u>GSN</u>	<u>Route</u>	<u>Generic</u>	<u>Strength</u>	<u>Strength Per Unit</u>
059211	PO	sildenafil citrate	20 mg	20
069921	PO	sildenafil citrate	10 mg/mL	10
084720	PO	sildenafil citrate	10 mg/mL	10
039189	PO	sildenafil citrate	25 mg	25
039190	PO	sildenafil citrate	50 mg	50
039191	PO	sildenafil citrate	100 mg	100
065368	PO	tadalafil	20 mg	20
083592	PO	tadalafil	20 mg/5 mL (4 mg/mL)	4

Table A3. Taxonomy codes for cardiopulmonary specialists

<u>Taxonomy</u>	<u>Taxonomy Description</u>
207RA0001X	ADVANCED HEART FAILURE AND TRANSPLANT CARDIOLOGY
207RC0000X	PHYSICIAN-INTERNAL MEDICINE-CARDIOVASCULAR DISEASE
207RI0011X	PHYSICIAN-INTERNAL MEDICINE-INTERVENTIONAL CARDIOLOGY
207RP1001X	PHYSICIAN-INTERNAL MEDICINE- PULMONARY DISEASE
207UN0901X	PHYSICIAN-NUCLEAR MEDICINE-NUCLEAR CARDIOLOGY
2080P0202X	PHYSICIAN-PEDIATRICS-PEDIATRIC CARDIOLOGY

2080P0214X	PHYSICIAN-PEDIATRICS-PEDIATRIC PULMONOLOGY
208G00000X	PHYSICIAN-SURGERY-THORACIC SURGERY(CARDIOTHORACIC VASCULAR SURGERY)
2251C2600X	PHYSICAL THERAPIST - CARDIOPULMONARY
225B00000X	PULMONARY FUNCTION TECHNOLOGIST
227800000X	RESPIRATORY THERAPIST
2278C0205X	RESPIRATORY THERAPIST
2278E0002X	RESPIRATORY THERAPIST
2278E1000X	RESPIRATORY THERAPIST
2278G0305X	RESPIRATORY THERAPIST
2278G1100X	RESPIRATORY THERAPIST
2278H0200X	RESPIRATORY THERAPIST
2278P1004X	RESPIRATORY THERAPIST
2278P1005X	RESPIRATORY THERAPIST
2278P1006X	RESPIRATORY THERAPIST
2278P3800X	RESPIRATORY THERAPIST
2278P3900X	RESPIRATORY THERAPIST
2278P4000X	RESPIRATORY THERAPIST
2278S1500X	RESPIRATORY THERAPIST
227900000X	RESPIRATORY THERAPIST
2279C0205X	RESPIRATORY THERAPIST
2279E0002X	RESPIRATORY THERAPIST
2279E1000X	RESPIRATORY THERAPIST
2279G0305X	RESPIRATORY THERAPIST
2279G1100X	RESPIRATORY THERAPIST
2279H0200X	RESPIRATORY THERAPIST
2279P1004X	RESPIRATORY THERAPIST
2279P1005X	RESPIRATORY THERAPIST
2279P1006X	RESPIRATORY THERAPIST
2279P3800X	RESPIRATORY THERAPIST
2279P3900X	RESPIRATORY THERAPIST
2279P4000X	RESPIRATORY THERAPIST
2279S1500X	RESPIRATORY THERAPIST
246X00000X	TECHNOLOGISTS-SPECIALIST TECH CARDIO
246XC2901X	TECHNOLOGIST-SPECIALIST CARDIO-CARDIOVASCULAR INVASIVE SPECIALIST
246XC2903X	TECHNOLOGIST-SPECIALIST CARDIO-VASCULAR SPECIALIST
246XS1301X	TECHNOLOGIST-SPECIALIST CARDIO-SONOGRAPHY

Table A4. Diagnoses

<u>Description</u>	<u>ICD-10 codes</u>	<u>Category</u>
Pulmonary hypertension and pulmonary heart disease	I27x	Pulmonary Hypertension
Pulmonary hypertension of the newborn	P2930	Pulmonary Hypertension
Systemic connective tissue disorders	M30x-M36x	Group 1 comorbidities
Rheumatoid arthritis	M05x-M06x	Group 1 comorbidities
Heart failure	I50x	Group 2 Comorbidities
Valvular heart disorders	I32x-I39x	Group 2 Comorbidities
COPD, Emphysema	J43x-J44x	Group 3 Comorbidities
Interstitial pulmonary diseases	J84x	Group 3 Comorbidities
Sleep apnea	G473x	Group 3 Comorbidities
Pulmonary embolism	I26x	Group 4 Comorbidities
Malignant and non-malignant cancer	Cx-Dx	Group 4 Comorbidities
Erectile dysfunction	N52x-N53x	Other
BPH	N40x	Other

Appendix 2: Proposed Prior Authorization Criteria

Pulmonary Hypertension Agents, Oral/Inhaled

Goals:

- Restrict use to appropriate patients with World Health Organization (WHO) Functional Class II-IV symptoms and WHO pulmonary classifications with demonstrated clinical benefit in clinical trials (e.g., pulmonary arterial hypertension (PAH), chronic thromboembolic pulmonary hypertension, or interstitial lung disease).
- Restrict use to conditions funded by the Oregon Health Plan (OHP). Note: erectile dysfunction is not covered by the OHP.

Length of Authorization:

- Up to 12 months

Requires PA:

- Non-preferred drugs

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the drug being prescribed by <u>, or in consultation with,</u> a pulmonologist or cardiologist?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness.
3. Is the request for riociguat (Adempas®) or ambrisentan (Letairis®)?	Yes: Go to #4	No: Go to #5
4. Is there documentation that the patient has a medical history of PAH associated with idiopathic interstitial pneumonias or idiopathic pulmonary fibrosis?	Yes: Pass to RPh. Deny; medical appropriateness.	No: Go to #5
5. Is the patient classified as having World Health Organization (WHO) Functional Class II-IV symptoms?	Yes: Go to #6	No: Pass to RPh. Deny; medical appropriateness.
6. Is there a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1; ICD10 I27.0)?	Yes: Go to #7	No: Go to #8
7. Will the prescriber consider a change to a preferred product? <u>Note:</u> preferred products do not require PA.	Yes: Inform prescriber of preferred alternatives in class.	No: Approve for 12 months
8. Is the request for riociguat in a patient with a diagnosis of chronic thromboembolic pulmonary hypertension (WHO Group 4; ICD10 I27.24)?	Yes: Approve for 12 months	No: Go to #9
9. Is the request for nebulized treprostinil (Tyvaso®) in a patient with <u>WHO Group 3 pulmonary hypertension (ICD10 I27.23)</u> <u>and</u> a diagnosis of interstitial lung disease (WHO Group 3; ICD10 I27.23 J84.0-J84.9)? Note: treprostinil <u>is not approved</u> has not been studied and is not recommended in patients with pulmonary hypertension due to chronic obstructive pulmonary disease <u>and may increase risk of exacerbations</u> .	Yes: Approve for 12 months	No: Go to #10

Approval Criteria		
10. <u>Is the request for treatment of erectile dysfunction, sexual dysfunction, or infertility?</u>	<u>Yes:</u> Pass to RPh; Deny; not covered by OHP.	<u>No:</u> Go to #11
11. RPh Only: <u>For other indications and other types of pulmonary hypertension,</u> Prescriber must provide supporting literature for use.	Yes: Approve for length of treatment.	No: Pass to RPh. Deny; medical appropriateness.

P&T Review: 12/24; 10/21 (SS); 9/18; 3/16; 7/14; 3/14; 2/12; 9/10

Implementation: 1/1/2022; 11/1/2018; 10/13/16; 5/1/16; 5/14/12; 1/24/12; 1/1/11