JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS004
		Effective Date	07/20/2022
		Approval Date	07/27/2017
	Subject **Pulmonary Arterial Hypertension Agents (Adcirca [tadalafil], Revatio [sildenafil], Flolan, Letairis, Remodulin, Tracleer, Tyvaso, Ventavis, Opsumit, Veletri, Orenitram, Uptravi, Adempas)**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: agents, DPAHC, hypertension, pulmonary, tracleer

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I. POLICY

A. Pulmonary Arterial Hypertension (PAH) Agents will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20. Adcirca, Revatio, Letairis, Tracleer, Opsumit, Flolan, Veletri, Orenitram, Remodulin, Tyvaso, Ventavis, Uptravi and Adempas will require prior authorization for outpatient prescription drug benefit coverage to ensure this medication is used only when clinically appropriate.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **PAH agents** may be approved when all the following criteria have been met:
   1. Documentation that member has a definitive diagnosis of pulmonary artery hypertension from a cardiologist or pulmonologist and confirmed by right heart catheterization.
   2. Pulmonary hypertension has progressed despite surgical treatment and/or maximal medical treatment of the underlying condition. If appropriate, treatment failure with oral calcium channel blockers:
      a. Patients who have substantial reductions in pulmonary arterial pressure from short acting vasodilators at the time of catheterization may require high doses (e.g.; nifedipine 240 mg/day or amlodipine 20 mg/day).
   3. The medication used for treatment is consistent with its FDA approved functional class.
   4. *New therapy initiation caveats:
      1. All new starts will require a trial of generic sildenafil (Revatio) or tadalafil (Adcirca) as initial treatment when the above criteria are met, unless their use is contraindicated.
      2. Product-specific requirements:
         1. New starts for Opsumit will require documented trial and inadequate response to generic sildenafil or tadalafil, followed by trials with Letairis and Tracleer, unless contraindicated.
         2. New starts for Ventavis will require documented trial and inadequate response to generic sildenafil or tadalafil, followed by a trial with Tyvaso, unless contraindicated.

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PAH Agent Category	Drug/Formulation	FDA Approved WHO Functional Class of Symptoms
Phosphodiesterase Type 5 Inhibitors (PDE-5)	Tadalafil (Adcirca)-Tablet	II, III
	Sildenafil (Revatio)-Tablet, Oral Susp	II, III
Endothelin Receptor Antagonists	Letairis- Tablet	II, III
	Tracleer-Tablet	II, III, IV
	Opsumit-Tablet	II, III
Prostanoids	Epoprostenol (Flolan)-IV Inj.	III, IV
	Remodulin- IV/SQ Inj.	II, III, IV
	Tyvaso- Inhalation	III
	Ventavis- Inhalation	III, IV
	Veletri- IV Inj	III, IV
	Orenitram- Tablet	II, III
	Uptravi- Tablet	II, III
Soluble Guanylate Cyclase Stimulator	Adempas- Tablet	II, III

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be restricted to 6 months of therapy.

B. Approval for continuation of therapy may be extended in 12-month intervals with clinical documentation showing the patient has experienced improved exercise capacity or a delay in symptom worsening.

IV. EXCLUSIONS

A. If the request is for a diagnosis not listed above, a letter may be sent to the requesting physician to provide additional information. Coverage is NOT provided for sildenafil (Revatio) and tadalafil (Adcirca) in situations where patients are receiving nitrate therapy. Coverage of brand formulation will be considered for Members who have failed an adequate trial of or are unable to tolerate the generic formulation (if available). Coverage is provided for combination use of two or more drugs with different pharmacology in patients who have not adequately responded to monotherapy.

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Adcirca prescribing information. Indianapolis, IN: Eli Lilly and Company; April 2015.
2. Flolan prescribing information. Research Triangle Park, NC: GlaxoSmithKline; April 2015.
3. Letairis prescribing information. Foster City, CA: Gilead Sciences, Inc; October 2015.
4. Opsumit prescribing information. San Francisco, CA: Actelion Pharmaceuticals US, Inc. February 2016.
5. Remodulin prescribing information. Indianapolis, IN: Eli Lilly and Company; December 2014.
6. Revatio prescribing information. New York, NY: Pfizer Labs; April 2015.
7. Tracleer prescribing information. South San Francisco, CA: Actelion Pharmaceuticals US, Inc; December 2015.

8. Tyvaso prescribing information. Research Triangle Park, NC: United Therapeutics Corp.; May 2014.
9. Uptravi prescribing information. San Francisco, CA: Actelion Pharmaceuticals US, Inc. December 2015.
10. Ventavis prescribing information. South San Francisco, CA: Actelion Pharmaceuticals US, Inc; November 2013.
11. Adempas prescribing information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc., April 2014.
12. Orenitram prescribing information. Research Triangle Park, NC: United Therapeutics Corp. January 2016.
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14. Rubin LJ, Hopkins W. Overview of pulmonary hypertension. Up to Date®, accessed March 2016; available from: http://www.uptodate.com.
15. Hopkins W, Rubin LJ. Treatment of pulmonary hypertension. Up to Date®, accessed March 2016; available from: http://www.uptodate.com.
16. 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. Available at: http://content.onlinejacc.org/cgi/reprint/53/17/1573.pdf.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Added Uptravi, Updated criteria to include all meds in class including Opsumit, Adempas, Orenitram, and Veletri. Removed background information & recommended dose. Updated references & clarified FDA approved indication/functional classes per package inserts.
07/27/2017	Updated Exclusion section regarding physician samples.
07/01/2018	Removed EHP Line of Business.
08/20/2018	Clarified policy criteria
05/13/2021	Updated authorization guidance
07/20/2022	Revised policy layout

Review Dates: 07/01/2010, 1/15/2014, 03/01/2014, 04/20/2016, 07/27/2017

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