Pharmacy Policy

Pulmonary Hypertension

Policy Number: 9.600
Version Number: 2
Version Effective Date: 3/1/2022

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Adempas (riociguat)**
- **ambrisentan (Letairis)**
- **bosentan (Tracleer)**
- **epoprostenol intravenous solution**
- **Opsumit (macitentan)**
- **sildenafil (Revatio)**
- **tadalafil (Adcirca)**
- **Tracleer (bosentan) soluble tablet**
- **Uptravi (selexipag)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Adempas, ambrisentan, bosentan, Opsumit, Tracleer: pregnancy
Required Medical Information	**ambrisentan, bosentan, epoprostenol, Opsumit, sildenafil, tadalafil, Tracleer soluble tablet, Uptravi:** Documentation of the following: 1. A diagnosis of Group 1 - PAH as defined by pulmonary artery pressure greater than 25 mmHg at

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	rest; **AND** 2. Symptoms of PAH have progressed despite general measures, supportive therapy, and treatment of any comorbid conditions. NYHA or WHO functional classification must be included; **AND** 3. A negative acute vasoreactivity testing, OR a treatment failure/contraindication with calcium channel blockers, OR a vasoreactivity test is not indicated (i.e. in patients with associated forms of PAH that are rarely vasoreactive) or is contraindicated; **OR** 4. Pediatric patient is 3 years of age or older with a diagnosis of idiopathic or congenital Pulmonary Hypertension (bosentan/**Tracleer only**) **Adempas:** Documentation of the following: 1. Will not be used with a phosphodiesterase 5 inhibitor, nitrates or other soluble guanylate cyclase (sGC) stimulators; **AND** 2. A diagnosis of one of the following: a. Persistent/ recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) when surgical treatment has failed or is inappropriate; **OR** b. Group 1 - PAH as defined by pulmonary artery pressure greater than 25 mmHg at rest; **AND** 3. Symptoms of PAH have progressed despite general measures, supportive therapy, and treatment of any comorbid conditions. NYHA or WHO functional classification must be included; **AND** 4. A negative acute vasoreactivity testing, OR a treatment failure/contraindication with calcium channel blockers, OR a vasoreactivity test is not indicated (i.e. in patients with associated forms of PAH that are rarely vasoreactive) or is contraindicated.
Age Restriction	Adempas, epoprostenol, Opsumit, Utravi: 18 years and older Tracleer/bosentan: 3 years and older
Prescriber Restriction	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Initial: 3 months Reauthorization: 12 months
Other criteria	Reauthorization: 1. Compliance with the requested therapy and the clinical condition has improved or stabilized without treatment-related adverse events

Applicable Coding:

Code	Medication
J1325	epoprostenol (Flolan, Veletri)
J3490	sildenafil (Revatio) injection 10mg/12.5ml

Clinical Background Information and References

1. 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://circ.ahajournals.org/content/119/16/2250.full.pdf+html.
2. Badesch DB, Abman SH, Ahearn GS, et al. Medical therapy for pulmonary arterial hypertension. ACCP evidence-based clinical practice guidelines. Chest 2007; 126(1 Suppl): 35S-62S.
3. Badesch DB, Abman SH, Ahearn GS, et al. Medical therapy for pulmonary arterial hypertension. ACCP evidence-based clinical practice guidelines. Chest 2004; 131(6): 1917-28.
4. Galiè N, Hoeper MM, Humbert M, et al. Guidelines for the diagnosis and treatment of pulmonary hypertension: 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 the International Society of Heart and Lung Transplantation (ISHLT). Eur Heart J 2009; 30:2493 -2537.
5. Galie N, Humbert M, Vachiery JL, Gibbs S, Lang I, Torbicki A, et al. 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. Eur Heart J. 2015. doi:10.1093/eurheartj/ehv317.
6. Hopkins W, Rubin LJ. Treatment of pulmonary hypertension in adults. Up to Date®, Topic last updated: December 1, 2017. Accessed December 2017; available from: http://www.uptodate.com
7. Hopkins, W. and Rubin, L. Treatment of pulmonary hypertension in adults. UpToDate. Last updated September 26, 2018. Accessed December 12,2018.
8. Huertas A, Girerd B, Dorfmuller P. et al. Pulmonary veno-occlusive disease: advances in clinical management and treatments. Expert Review of Respiratory Medicine, Apr 2011, Vol. 5, No. 2, Pages 217-231.
9. Peter F Fedullo, Chronic thromboembolic pulmonary hypertension: Medical treatment. Up to Date®, accessed December 2013; available from: http://www.uptodate.com
10. Product Information. Adcirca® (tadalafil). Eli Lilly, Indianapolis, IN, 46285. Available from: http://pi.lilly.com/us/adcirca-pi.pdf. Accessed Nov 24, 2015.
11. Product Information. Adempas® (riociguat). Bayer Healthcare Pharmaceuticals, Inc. Whippany, NJ 07981. Available from: http://labeling.bayerhealthcare.com/html/products/pi/Adempas_PI.pdf. Accessed Dec 14, 2015.
12. Product Information. Opsumit® (macitentan). Actelion Pharmaceuticals US, Inc. South San Francisco, CA 94080. Available from: http://opsumit.com/sites/opsumit/files/OPSUMIT-Full-Prescribing-Information.pdf. Accessed Dec 15, 2015.
13. Product Information. Orenitram® (treprostinil). United Therapeutics Corp. Research Triangle Park, NC 27709. Available from: file:///H:/CV/20141020_8ed2003a-c801-411e-831e-d06079bb0d7c.pdf. Accessed Dec 14, 2015.
14. Product Information. Remodulin® (treprostinil). United Therapeutics Corp. Research Triangle Park, NC 27709. Available from: http://www.remodulin.com/patient/. Accessed Dec 14, 2015.
15. Product Information: Revatio® (sildenafil). Pfizer Labs. New York, NY 10017. Available from: http://labeling.pfizer.com/ShowLabeling.aspx?id=645. Accessed Dec 15, 2015.
16. Product Information: Tracleer® (bosentan). Actelion Pharmaceuticals US, Inc. South San Francisco, CA 94080. Available from: https://www.tracleer.com/docs/Tracleer_Full_Prescribing_Information.pdf. Accessed Dec 15, 2015.
17. Product Information: Tyvaso® (treprostinil). United Therapeutics Corp. Research Triangle Park, NC 27709. Available from: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022387s009lbl.pdf. Accessed Dec 15, 2015.

18. Product information: Uptravi ® (selexipag). Actelion Pharmaceuticals US, Inc. South San Francisco, CA 94080. Available from: https://www.uptravi.com/assets/pdf/UPTRAVI-full-prescribing-information.pdf. Accessed December 19, 2016.
19. Product Information: Veletri® (epoprostenol). Actelion Pharmaceuticals US, Inc. South San Francisco, CA 94080. Available from: https://www.veletri.com/pdf/veletri_full_prescribing_information_2nd_gen.pdf. Accessed Dec 15, 2015.
20. Product Information: Ventavis® (iloprost). Actelion Pharmaceuticals US, Inc. South San Francisco, CA 94080. Available from: https://www.4ventavis.com/pdf/Ventavis_PI.pdf. Accessed Dec 15, 2015.
21. Rubin LJ, Hopkins W. Overview of pulmonary hypertension. Up to Date®, accessed December 2014; available from: http://www.uptodate.com
22. Simoneau G, Galie N, Rubin LJ, et al. Clinical classification of pulmonary hypertension. J Am Coll Cardiol 2004; 43:5S.
23. Simonneau, G, Gatzoulis, M, Adiata, I et al. Updated Clinical Classification of Pulmonary Hypertension. J Am Coll Cardiol 2013; 62: S34
24. Taichman DB et al. Pharmacologic Therapy for Pulmonary Arterial Hypertension in Adults: CHEST Guideline and Expert Panel Report. Chest 2014; 146(2): 449-75. Available at: http://journal.publications.chestnet.org/data/Journals/CHEST/930614/chest_146_2_449.pdf

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.128 Pulmonary Hypertension Policy retired, new policy created	1/1/2021	P&T Committee
11/11/2021	Annual review: Tadalafil (Adcirca) added to policy, updated Adempas criteria to labeling, added cardiologist as a prescriber	3/1/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.