Cohere Medicare Advantage Policy - Pulmonary Artery Denervation

Clinical Guidelines for Medical Necessity Review

Version: 1
Revision Date: April 3, 2025

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.
Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine the medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice. This policy may be superseded by existing and applicable Centers for Medicare & Medicaid Services (CMS) statutes.

Other Notices:

Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Pulmonary Artery Denervation

Date of last literature review: 03/22/2025
Document last updated: 04/01/2025
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17 yo)

Table of Contents

Medical Necessity Criteria

Service: Pulmonary Artery Denervation (PADN)

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- There are no applicable NCDs or LCDs for pulmonary artery denervation (PADN).

Recommended Clinical Approach

This service is clinically unproven and not medically necessary. Pulmonary arterial hypertension (PAH) is a disease with a poor prognosis and high mortality that leads to right ventricular failure and sudden cardiac death. Current therapy consists of combination pharmacological treatments, which yield mixed results.[1]

Pulmonary artery denervation (PADN) is a minimally invasive, catheter based procedure to reduce pulmonary artery pressure in patients with pulmonary arterial hypertension (PAH).[2] The most common method of PADN is catheter-directed thermal ablation.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of pulmonary artery denervation. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Although PADN is a minimally invasive procedure with reasonable pathophysiology, it is subject to procedural risk and iatrogenic injury.[3]
- Disproportionate increased costs.[3]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- PADN can significantly increase the 6-minute walk distance in patients with PAH.[4, 5]
- Significant Improvements in hemodynamic parameters.[5]
- Improvement in cardiac function.[5]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous

clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Pulmonary artery denervation (PADN)** is considered appropriate if **ANY** of the following is **TRUE**[6, 7]:
  - This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

- ➔ **Pulmonary artery denervation (PADN)** is not considered appropriate if **ANY** of the following is **TRUE**[6,7]:
  - This is not applicable as there are no indications.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance.
0632T	Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance.

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Pulmonary arterial hypertension (PAH) is a disease with a poor prognosis and high mortality that leads to right ventricular failure and sudden cardiac death. Chin et al (2024) recently outlined the current treatment algorithm for PAH, with maximal medical therapy now involving four drugs.[6] Current therapy consisting of combination pharmacological treatments yields mixed results.[1]

Pulmonary artery denervation (PADN) is a relatively new, minimally invasive endovascular catheter-based interventional procedure for the treatment of patients with PAH.[2] In a prospective, randomized, sham-controlled trial (the PADN-5 trial), Zhang et al (2019) studied the benefits of PADN in combined pre- and post-capillary pulmonary hypertension (CpcPH) patients. This was the first randomized, sham-controlled trial to determine the benefits of PADN treatment in these patients. The results showed that patients treated with PADN had significant improvements in hemodynamic and clinical outcomes.[4]

In another randomized, sham-controlled trial (the PADN-CFDA trial), Zhang et al (2023) studied 128 treatment-naïve patients with PAH. Patients received either PADN along with drug monotherapy or a sham procedure with drug monotherapy. They found that the patients treated with PADN and drug monotherapy improved exercise capacity and hemodynamic outcomes at 6 months compared to the sham group.[5] This trial was done in China, and the response to PADN treatment could differ in other populations.

Davies et al (2022) and Xie et al (2022) also note the potential of PADN as a treatment for patients with PAH; however, additional research is needed.[2, 9]

A recent review guideline for the treatment of PAH does not mention PADN.[6] Most clinical studies and reviews agree that larger clinical trials are needed to define and confirm the efficacy of PADN.

The European Society of Cardiology (ESC) and the European Respiratory Society (ERS) published guidelines in 2022 for the Diagnosis and Treatment of Pulmonary Hypertension (PH). The guidelines mention that although potentially promising, PADN should be considered experimental.[7]

References

1. Le T, Makar C, Morway P, et al. Pulmonary artery denervation: a novel treatment modality for pulmonary hypertension. *J Thorac Dis.* 2019 Apr;11(4):1094-1096. doi: 10.21037/jtd.2019.02.93. PMID: 31179049; PMCID: PMC6531721.
2. Davies MG, Miserlis D, Hart JP. Current status of pulmonary artery denervation. *Front Cardiovasc Med.* 2022 Oct 3;9:972256. doi: 10.3389/fcvm.2022.972256. PMID: 36262207; PMCID: PMC9573987.
3. Zheng Z, Chen R, Sun X, et al. A meta-analysis of the efficacy of pulmonary artery denervation in the treatment of pulmonary hypertension. *Heart Lung*. 2022 May-Jun;53:42-50. doi: 10.1016/j.hrtlng.2022.01.020. Epub 2022 Feb 7. PMID: 35144042.
4. Zhang H, Zhang J, Chen M, et al. Pulmonary artery denervation significantly increases 6-min walk distance for patients with combined pre- and post-capillary pulmonary Hypertension associated with left heart failure: The PADN-5 study. *JACC Cardiovasc Interv.* 2019 Feb 11;12(3):274-284. doi: 10.1016/j.jcin.2018.09.021. Epub 2018 Oct 23. PMID: 30732732.
5. Zhang J, Kan J, Wei Y, et al. Treatment effects of pulmonary artery denervation for pulmonary arterial hypertension stratified by REVEAL risk score: Results from PADN-CFDA trial. *J Heart Lung Transplant.* 2023 Aug;42(8):1140-1151. doi: 10.1016/j.healun.2023.03.015. Epub 2023 Mar 28. PMID: 36990173.
6. Chin KM, Gaine SP, Gerges C, et al. Treatment algorithm for pulmonary arterial hypertension. *Eur Respir J.* 2024 Oct 31;64(4):2401325. doi: 10.1183/13993003.01325-2024. PMID: 39209476; PMCID: PMC11525349.
7. Humbert M, Kovacs G, Hoeper MM, et al. ESC/ERS Scientific Document Group. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J.* 2022 Oct 11;43(38):3618-3731. doi:

10.1093/eurheartj/ehac237. Erratum in: *Eur Heart J.* 2023 Apr 17;44(15):1312. doi: 10.1093/eurheartj/ehad005. PMID: 36017548.

8. Chin KM, Gaine SP, Gerges C, et al. Treatment algorithm for pulmonary arterial hypertension. *Eur Respir J.* 2024 Oct 31;64(4):2401325. doi: 10.1183/13993003.01325-2024. PMID: 39209476; PMCID: PMC11525349.
9. Xie Y, Liu N, Xiao Z, et al. The progress of pulmonary artery denervation. *Cardiol J.* 2022;29(3):381-387. doi: 10.5603/CJ.a2020.0186. Epub 2021 Jan 13. PMID: 33438182; PMCID: PMC9170319.

Clinical Guideline Revision History/Information

Original Date: April 3, 2025		
Review History		