

Cohere Medicare Advantage Policy – Peripheral Intravascular Lithotripsy (IVL)

Clinical Policy for Medical Necessity Review

CHP-310-1 Version 1

Cohere Health UMC Approval Date January 29, 2026

Last Annual Review January 29, 2026

Revision Date Not applicable

Next Annual Review January 29, 2027

Level of care Inpatient, Outpatient

Specialty Cardiovascular disease

Population type Adult (18+ years old), Pediatric (0-17 years old)

Table of contents

Procedure Codes (CPT/HCPCS)	3
Important Notices	4
Service: Peripheral Intravascular Lithotripsy (IVL) - Description	5
Service: Peripheral Intravascular Lithotripsy (IVL) - Medical Necessity Criteria	6
Evaluation of Clinical Harms and Benefits	7
Medical Evidence	8
References	9
Policy Revision History/Information	10

Procedure Codes (CPT/HCPCS)

Service: Peripheral Intravascular Lithotripsy (IVL)	
Code	Description
37262	Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)
37279	Intravascular lithotripsy(ies), femoral and popliteal vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)
C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed
C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed
C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed

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. To the extent that applicable state laws, regulations, or regulatory guidance impose requirements that differ from or supersede the provisions of these Guidelines, such state laws and regulations shall control. Diagnostic and therapeutic interventions addressed in these Guidelines are to be performed using pharmaceuticals, biologics, radiotracers, and medical devices that are FDA-approved or conditionally approved for their intended purpose. FDA approval status alone does not determine medical necessity or confer eligibility for coverage or reimbursement.

© 2026 Cohere Health, Inc. All Rights Reserved.

Other Notices:

HCPCS ® and CPT ® copyright 2026 American Medical Association. All rights reserved.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

HCPCS and CPT are registered trademarks of the American Medical Association.

Service: Peripheral Intravascular Lithotripsy (IVL) - Description

Peripheral intravascular lithotripsy (IVL) is a minimally invasive procedure that uses acoustic pulses to treat moderate to severe calcific peripheral arterial disease.¹⁻³ During IVL, lithotripsy emitters, embedded in a balloon catheter, create sonic pressure waves that travel through soft tissue.^{4,5} The waves produce vapor bubbles that, upon collapse, create high-energy shocks to calcified plaques.⁶⁻¹¹

Service: Peripheral Intravascular Lithotripsy (IVL) - Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no applicable NCDs and/or LCDs for peripheral intravascular lithotripsy (IVL).

Indications

- **Peripheral intravascular lithotripsy** is considered appropriate if **ANY** of the following is **TRUE**:
 - This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

- **Peripheral intravascular lithotripsy** is not considered appropriate if **ANY** of the following is **TRUE**:
 - This is not applicable, as there are no indications.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

Potential Harms of applying the clinical criteria in this policy include, but are not limited to, denying opportunities to improve health outcomes for individuals and populations suffering from calcified peripheral artery disease. For example, restricting access to this procedure may increase patient and population dependence on excessive pain medication, including opioids, reduced functionality leading to additional medical problems, and a decrease in economic opportunity.

Potential Benefits of applying the clinical criteria in this policy include, but are not limited to, safeguarding patients from unproven technologies, procedures, and medical treatments until the proposed treatment's safety, efficacy are thoroughly validated via peer-reviewed scientific literature. This protects patients from balloon dislodgment, rupture, or perforation.¹²

Medical Evidence

In their prospective multicenter cohort study of 12-month outcomes of intravascular lithotripsy (IVL) treatment in patients with chronic limb-threatening ischemia, Nugteren et al. (2023) concluded that IVL showed promising safety and efficacy results. The study, which included a complex patient population of 29 patients, documented few major adverse events (4) and had a low rate of bailout stenting (12.5%). These results, according to the authors, warrant caution, as the study has several limitations, including a small patient size, the absence of a control group, and heterogeneity in the postdilatation technique.¹³

According to Kereiakes et al. (2021), endovascular treatment of calcific peripheral artery disease (PAD) remains an ongoing challenge for interventionalists, as calcification in the peripheral arteries is associated with an increased risk of dissection, perforation, and increased stenting rates. In addition, the presence of vascular calcification limits the success rates of endovascular interventions.³

Armstrong et al. (2020) conducted a cohort analysis of IVL for treating calcified, stenotic iliac arteries. A total of 200 lesions were evaluated; 101 patients sought treatment for claudication or critical limb ischemia, and 17 sought treatment for optimization of the iliac vasculature for large-bore access. The authors concluded that IVL in calcified iliac lesions was both safe and effective for the treatment of stenotic iliac disease. Limitations of the study included site-reported data. Furthermore, the study was a single-arm study without a control arm.¹⁴

Madhavan et al. (2020) conducted a meta-analysis on the efficacy of IVL for patients with PAD. Five prospective studies were included. The analysis included individual patient-level data, which were compared to existing studies on the use of IVL in patients with PAD. A total of 336 patients were included and underwent endovascular revascularization using IVL. The authors concluded that the use of IVL for significantly calcified PAD lesions is safe and effective. However, as over 12% of the study's patients received adjunctive device therapy, isolating the benefits of IVL was difficult.¹⁵

References

1. Fanelli F, Cannavale A, Gazzetti M, et al. Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease. *Cardiovasc Intervent Radiol*. 2014; 37(4):898–907. doi:10.1007/s00270-014-0904-3
2. Sogbadji J, Kadry K, Poletti G, et al. Impact of lesion preparation-induced calcified plaque defects in vascular intervention for atherosclerotic disease: In silico assessment. *Biomech Model Mechanobiol*. 2025;24(2):539–552. doi:10.1007/s10237-024-01923-6
3. Kereiakes DJ, Virmani R, Hokama JY, et al. Principles of intravascular lithotripsy for calcific plaque modification. *JACC Cardiovasc Interv*. 2021;14(12):1275–1292. doi: 10.1016/j.jcin.2021.03.036
4. Adams G, Shammas N, Mangalmurti S, et al. Intravascular lithotripsy for treatment of calcified lower extremity arterial stenosis: Initial analysis of the Disrupt PAD III Study. *J Endovasc Ther*. 2020;27(3):473–480. doi:10.1177/1526602820914598
5. Wong CP, Chan LP, Au DM, et al. Efficacy and safety of intravascular lithotripsy in lower extremity peripheral artery disease: A systematic review and meta-analysis. *Eur J Vasc Endovasc Surg*. 2022;63(3):446–456. doi:10.1016/j.ejvs.2021.10.035
6. Gruslova AB, Inanc IH, Cilingiroglu M, et al. Review of intravascular lithotripsy for treating coronary, peripheral artery, and valve calcifications. *Catheter Cardiovasc Interv*. 2024;103(2):295–307. doi:10.1002/ccd.30933
7. Giannopoulos S, Speziale F, Vadalà G, et al. Intravascular lithotripsy for treatment of calcified lesions during carotid artery stenting. *J Endovasc Ther*. 2021;28(1):93–99. doi:10.1177/1526602820954244
8. Diaz O, Gerstner Saucedo J, Carmona I, et al. Intravascular lithotripsy-assisted carotid artery stenting in heavily calcified lesions: A case series. *Radiol Case Rep*. 2025;20(12):5977–5983. doi:10.1016/j.radcr.2025.08.087
9. Evans AR, Reid AR, Kharbat AF, et al. Carotid artery stenting with intravascular lithotripsy for calcific carotid stenosis: A systematic literature review. *J Int Med Res*. 2025;53(8):3000605251343871. doi:10.1177/03000605251343871
10. Fazzini S, Turriziani V, Lomazzi C, et al. Mid-term outcomes of Shockwave intravascular lithotripsy in the IVLIAC registry for the treatment of calcified iliac occlusive disease. *J Vasc Surg*. 2025;82(4):1366–1374.e3. doi:10.1016/j.jvs.2025.04.025
11. Suruagy-Motta R, Cabeça L, Da Silva A, et al. Intravascular lithotripsy versus rotational atherectomy for calcified coronary lesions: A systematic review and an updated meta-analysis of clinical outcomes. *Catheter Cardiovasc Interv*. 2025;106(1):563–572. doi:10.1002/ccd.31591
12. Chugh Y, Khatri J, Shishehbor MH et al. Adverse events with intravascular lithotripsy after peripheral and off-label coronary use: A report from the FDA MAUDE database. *J Invasive Cardiol*. 2021;33(12):E974–E977. doi:10.25270/jic/21.00034
13. Nugteren M, Hazenberg C, Akkersdijk G, et al. Twelve-month outcomes of intravascular lithotripsy for treatment of calcified popliteal and infrapopliteal lesions in patients with chronic limb-threatening ischemia. *J Endovasc Ther*. 2025;32(4):1127–1134. doi:10.1177/15266028231205421
14. Armstrong EJ, Soukas PA, Shammas N, et al. Intravascular lithotripsy for treatment of calcified, stenotic iliac arteries: A cohort analysis from the Disrupt PAD III Study. *Cardiovasc Revasc Med*. 2020;21(10):1262–1268. <https://doi.org/10.1016/j.carrev.2020.02.026>
15. Madhavan MV, Shahim B, Mena-Hurtado C, et al. Efficacy and safety of intravascular lithotripsy for the treatment of peripheral arterial disease: An individual patient-level pooled data analysis. *Catheter Cardiovasc Interv*. 2020;95(5):959–968. doi: 10.1002/ccd.28729

Policy Revision History/Information

Clinical Guideline Version	Date	Review History
Version 1	01/29/2026	Original Date.