Cohere Medical Policy - Peripheral Intravascular Lithotripsy (IVL)

Clinical Guidelines for Medical Necessity Review

Version: 2
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Revision: Not applicable
Next Annual Review: July 10, 2026

Important Notices

Notices & Disclaimers:

GUIDELINES SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION MAKING OF END USERS.

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Other Notices:

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Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Cohere Medical Policy - Peripheral Intravascular Lithotripsy (IVL)
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Peripheral Intravascular Lithotripsy (IVL)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
    - The medical necessity of each individual request
    - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
    - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the

patient's primary symptoms can be adequately assessed with a single study or procedure.

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 safely through soft tissue.[4,5] The waves produce vapor bubbles that, upon collapse, create high-energy shocks to calcified plaques.[6]

Medical Necessity Criteria

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.

Level of Care Criteria

None

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
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

Medical Evidence

In their prospective, multicenter, cohort study of twelve-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 a comparison of IVL with angioplasty for popliteal and infrapopliteal arterial disease.[7]

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 stent rates. In addition, the presence of vascular calcification limits the success rates of endovascular interventions.[3]

Adams et al. (2020) conducted an observational study to assess the Shockwave Peripheral IVL System, which is labeled to treat calcified, stenotic lower limb arteries. A total of 200 patients from 18 sites were included. Follow-up occurred post-discharge. Intravascular lithotripsy was used with additional balloon-based technologies in 54% of the target lesions studied. IVL was used less often with concomitant atherectomy (19.8%) or stenting (29.9%).[4]

Armstrong et al. (2020) conducted a cohort analysis (2020) of IVL for treating calcified, stenotic iliac arteries. A total of 200 lesions were evaluated among 20 sites; 101 patients sought treatment for claudication or critical limb ischemia, and 17 sought treatment for optimization of the iliac vasculature for large-bore access. Limitations of the study included site-reported data. The study was also a single-arm study without a control arm.[8]

Madhavan et al. (2020) performed a meta-analysis on the efficacy of IVL for patients with PAD. Five prospective studies were included. The analysis included individual patient-level data that was compared to existing studies on the use of IVL for patients with PAD. A total of 336 patients were included and underwent endovascular revascularization using IVL.

Limitations include a need for comparators in single-arm studies, which did not allow for a proper comparison of the safety and efficacy of IVL in combination with other endovascular PAD treatments. Over 12% of the patients were receiving adjunctive device therapy, which makes isolating the benefits of IVL difficult. A limited number of patients were also available in key subgroups; future studies should include larger cohorts.[9]

References

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Disrupt PAD III Study. *Cardiovasc Revasc Med*. 2020;21(10):1262-1268. https://doi.org/10.1016/j.carrev.2020.02.026

9. 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. PMID: 31957955; PMCID: PMC7187419

Policy Revision History/Information

Original Date: March 29, 2024		
Review History		
Version 2	07/10/2025	Annual Review Added procedure description (page 4). The medical evidence section has been updated to include Nugteren et al. (2023). References added (Sogbadji et al., 2025; Wong et al., 2022; Gruslova et al., 2024; Nugteren et al., 2023).