



# Peripheral Intravascular Lithotripsy (IVL) - Single Service

*Clinical Guidelines for Medical Necessity Review*

**Version:** 1  
**Effective Date:** March 29, 2024

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## Guideline Information:

**Specialty Area:** Cardiovascular Disease

**Guideline Name:** Peripheral Intravascular Lithotripsy (IVL) (Single Service)

**Literature review current through:** 3/29/2024

**Document last updated:** 3/29/2024

**Type:**  Adult (18+ yo) |  Pediatric (0-17yo)

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# Medical Necessity Criteria

## ***Service: Peripheral Intravascular Lithotripsy (IVL)***

### General Guidelines

- **Units, Frequency, & Duration:** This service is experimental/investigational.
- **Criteria for Subsequent Requests:** This service is experimental/investigational.
- **Recommended Clinical Approach:** This service is experimental/investigational.
- **Exclusions:** This service is experimental/investigational.

### Medical Necessity Criteria

#### Indications

- **Peripheral Intravascular Lithotripsy** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Currently, there are no evidence-based indications for this service in the peer-reviewed, published literature.

#### Non-Indications

- **Peripheral Intravascular Lithotripsy** may not be appropriate if **ANY** of the following is **TRUE**:
- ◆ Service is considered experimental/investigational.

### Level of Care Criteria

Outpatient.

### Procedure Codes (HCPCS/CPT)

HCPCS/CPT 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 Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except

	<p>tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed</p> <p>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</p> <p>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</p> <p>Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed</p> <p>Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, includes and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed</p> <p>Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed</p> <p>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</p>
C9765	<p>Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed</p> <p>Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and</p>

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C9767	<p>Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed</p> <p>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</p>

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C9775	<p>Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed</p> <p>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</p> <p>Revascularization endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and</p>

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# Medical Evidence

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.<sup>1</sup> Intravascular lithotripsy is a novel method to treat patients with moderate to severe calcific PAD. The mechanism of intravascular lithotripsy (IVL) action utilizes acoustic pressure waves that safely travel circumferentially through soft tissue to modify calcific PAD, leading to improved vascular compliance.<sup>2</sup>

Adams et al. (2020) report on the Disrupt PAD III Observational Study (ClinicalTrials.gov identifier NCT02923193) 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. In contrast, IVL was used less often with concomitant atherectomy (19.8%) or stenting (29.9%).<sup>3</sup>

Armstrong et al. (2020) report on IVL for treating calcified, stenotic iliac arteries. Results of a cohort analysis from the Disrupt PAD III Study are included. 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 include site-reported data; this was also a single-arm study without a control arm.<sup>4</sup>

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.<sup>5</sup>

## References

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# Clinical Guideline Revision History/Information

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<b>Review History</b>	