



Coronary Intravascular Lithotripsy (IVL) - Single Service

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Coronary Intravascular Lithotripsy (IVL) (Single Service)

Literature review current through: 3/22/2024

Document last updated: 3/22/2024

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

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Medical Necessity Criteria

Service: Coronary 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

- **Coronary 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

- **Coronary 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
C1761	Catheter, transluminal intravascular lithotripsy, coronary
0715T	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)

Medical Evidence

Kereiakes et al. (2020) report on the design and rationale for the Disrupt CAD III trial (ClinicalTrials.gov identifier NCT03595176). The study assessed the Shockwave Coronary IVL catheter, which is indicated to optimize coronary stent deployment in patients with de novo calcified coronary stenoses. Follow-up was to continue for two years after enrollment ended in 2020. The authors noted that limitations include a lack of a concurrent control group, and the study is non-randomized.¹

Mhanna et al. (2022) performed a meta-analysis to evaluate the utility of adjunctive intravascular lithotripsy (IVL) for treating calcified coronary lesions. Eight single-arm observational studies with 980 patients (1011 lesions) were included. Almost half of the patients had a diagnosis of acute coronary syndrome. Severe calcification was found in 97% of all lesions. Additional studies should focus on evaluating IVL against other calcium/plaque modifying techniques.²

Sattar et al. (2022) evaluated the use of IVL for calcified lesions in 760 patients in seven studies. While positive outcomes were reported, limitations were identified. One single-arm observational study was included. The authors note the need for randomized, double-blind studies. Also, the definition of 'severe calcification' is needed to bring uniformity to the studies (e.g., imaging use, including intravascular ultrasounds and optical coherence tomography). Adjunct therapy was also not included.³

References

1. Kereiakes DJ, Hill JM, Ben-Yehuda O, et al. Evaluation of safety and efficacy of coronary intravascular lithotripsy for treatment of severely calcified coronary stenoses: Design and rationale for the Disrupt CAD III trial. *Am Heart J*. 2020 Jul;225:10-18. doi: 10.1016/j.ahj.2020.04.005. PMID: 32470635.
2. Mhanna M, Beran A, Nazir S, et al. Efficacy and safety of intravascular lithotripsy in calcified coronary lesions: A systematic review and meta-analysis. *Cardiovasc Revasc Med*. 2022;36:73-82. doi: 10.1016/j.carrev.2021.05.009.
3. Sattar Y, Almas T, Arshad J, et al. Clinical and angiographic success and safety comparison of coronary intravascular lithotripsy: An updated meta-analysis. *Int J Cardiol Heart Vasc*. 2022 Feb 24;39:100975. doi: 10.1016/j.ijcha.2022.100975. PMID: 35242998; PMCID: PMC8881660.

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