cohere HEALTH

Cohere Medical Policy -Coronary Intravascular Lithotripsy (IVL) Clinical Guidelines for Medical Necessity Review

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Guideline Information:

Specialty Area: Cardiovascular Disease Guideline Name: Coronary Intravascular Lithotripsy (IVL) (Single Service) Literature review current through: 12/9/2024 Document last updated: 12/19/2024 Type: [X] Adult (18+ yo) | [X] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Coronary Intravascular Lithotripsy (IVL)

Recommended Clinical Approach

This service is clinically unproven and not medically necessary. The current coronary lithotripsy device received premarket approval from the US Food and Drug Administration (FDA) on February 12th, 2021, for use on severely calcified, stenotic de novo coronary artery lesions. Coronary lithotripsy is intended to disrupt calcified coronary plaques with sonic pressure waves in order to facilitate coronary stenting. Because IVL does not yet have long-term efficacy results, nor a diverse range of randomized, controlled, double-blinded trials of statistical rigor, it is premature to presume clinical outcomes and benefits.

Medical Necessity Criteria

Indications

- → Coronary 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.¹⁻¹⁶

Non-Indications

- → Coronary Intravascular Lithotripsy may not be appropriate if ANY of the following is TRUE:
 - This is not applicable, as there are no indications.

Level of Care Criteria

None

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description	
C1761	Catheter, transluminal intravascular lithotripsy, coronary	
92972	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary	

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Medical Evidence

As of December 6th, 2024, an Investigational Device Exemption (IDE) study is currently recruiting up to 145 patients to further evaluate the safety and efficacy of IVL (ClinicalTrials.gov identifier NCT05966662). This prospective, multicenter, single-arm study aims to quantify the rate of major adverse cardiac events among patients who undergo IVL at several intervals post-procedure up to one year. It will also evaluate procedural efficacy by capturing the number of patients with residual stenosis after undergoing IVL. The estimated study completion date is November 2025. As such, the study is ongoing and does not yet have published results.^{15,16} Because IVL does not yet have long-term efficacy results, nor a diverse range of randomized, controlled, double-blinded trials of statistical rigor, it is premature to presume clinical outcomes and benefits.

The Society for Cardiovascular Angiography Interventions (SCAI) published an expert consensus statement in February 2024 to guide the management of calcified coronary lesions. The statement discussed IVL in a number of clinical capacities and concluded that IVL is safe and effective with the explicit caveat that there is presently limited available data and no comparative studies. IVL is included in their treatment algorithm for calcified coronary disease alongside atherectomy and specialty balloons. A number of multicenter studies – including randomized controlled trials – examining the use of IVL are underway and will further illuminate the role of IVL in this high-risk patient population. Ultimately, although it appears likely that IVL will become an adjunct tool in the management of challenging calcified coronary disease, it lacks the long-term safety and efficacy data that are needed to robustly recommend its use at this time.^{12,13}

A 2023 review of 747 IVL patients from Michigan's BMC2 registry found a procedural success rate of 91.4%, while 1.91% of patients suffered perforation, myocardial infarction, or death.⁴

A 2020 study of 57 patients found procedural success of 98%, although the lithoplasty balloon ruptured in 13% of cases, and 2 patients experienced significant dissection. In addition, more than 75% of lesions were dilated before and after lithotripsy with the current standard technology of either rotational atherectomy or cutting/scoring balloons, limiting the conclusions that can be drawn about the effect of IVL itself.⁵

A 2024 study examining sex differences between 454 IVL patients (75% males, 25% females) found relative parity of procedural success and adverse events. At one year post-procedure, 13% of all patients had experienced a major adverse cardiac event (cardiac death, myocardial infarction, or target vessel repeat revascularization). Again, other plaque disruption techniques were employed in 17% of all patients.⁶

Kereiakes et al. (2020) reported 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 the only current FDA-approved device that 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 a non-randomized study design.¹ The preliminary results of this study were published in 2020, which found no major adverse cardiac event in 92% of patients at 30 days following IVL. At one year post-procedure, that number decreased to 86.2%. At two years, 81.1% of patients remained free of major adverse cardiac events. Target lesion failure had occurred in 16.1% of patients at this time. In 2023, a larger post-approval study was published by the same study team involving 1,212 patients. The authors found a 0.25% mortality rate, lower than the predicted 0.31% rate, but acknowledged the study's weakness of lacking long-term data. A 2024 review of post-IVL in-hospital events, published by the same team, studied 17,681 higher-risk patients who were excluded from the prior post-approval study, with a total population of 18,893. 21.7% of patients also required atherectomy; post-procedure residual stenosis was observed at a rate of 4.0 ± 12%. In-hospital mortality and major procedural complications remained low (<1%), but no long-term data were presented.⁷⁻¹¹

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

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Clinical Guideline Revision History/Information

Original Date: March 22, 2024		
Review History		
Version 2	 Policy review and restructure. Updated recommended clinical approach to current format Removed retired T-code Added current CPT code Updated medical evidence to reflect current knowledge base and progress in literature Updated references 	