Coronary intravascular lithotripsy

Clinical Policy ID: CCP.1498

Recent review date: 10/2025

Next review date: 2/2027

Policy contains: Atherosclerosis; coronary intravascular lithotripsy; drug-eluting stent; percutaneous coronary intervention; Shockwave®.

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Coverage policy

Coronary intravascular lithotripsy is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Atherectomy.
- Balloon angioplasty (high-pressure noncompliant, cutting, or scoring types).
- Drug-eluting intracoronary stent.

Background

Percutaneous coronary intervention with drug-eluting stents is an established mode of coronary revascularization in patients presenting with both stable angina and acute coronary syndromes. Heavily calcified, fibrotic coronary stenosis increases procedural complexity and is associated with a high risk of major adverse cardiac events. To optimize stent delivery and implantation in native coronary arteries, vessel preparation relies on tissue compression or debulking alternatives that apply direct vascular tissue injury for plaque modification. These alternatives include atherectomy, high-pressure noncompliant balloon angioplasty, and cutting or scoring balloon angioplasty. However, the presence of deep, thick, or eccentric calcifications may reduce the success of these procedures and increase the risk for procedural complications such as slow or obstructed flow, reflow, coronary spasm, perforation, dissection, and myocardial infarction requiring emergent surgical revascularization (Yeoh, 2019).

Coronary intravascular lithotripsy is a novel method for native coronary vessel preparation for stent placement The equipment includes a generator, connecting cable, and a single-use balloon catheter containing emitters for the localized delivery of acoustically driven pulse pressure therapy. This method applies ultrasound waves to the surrounding tissue to selectively break up superficial and deep calcium deposits that have adhered within the vessel, resulting in better vessel compliance. Intravascular imaging (e.g., intravascular ultrasound and optical coherence imaging) is essential for defining the calcium density, depth, and circumferential extent, delineating the best lesion modification strategy, and evaluating procedural success. This procedure has the ability to modify calcium deposits across and encircling the vessel promoting stent expansion and cohesion (Butt, 2021; Forero, 2019).

Reported benefits of coronary intravascular lithotripsy are circumferential plaque targeting and reduction in the potential for distal embolization and bias while passing the guidewire. Balloon expansion pressure used is low, which reduces the need for aggressive high-pressure balloon dilatation prior to stent delivery and reduces the potential for soft tissue injury. Finally, the technique can be performed by a majority of interventional cardiologists (Butt, 2021; Forero, 2019).

The U.S. Food and Drug Administration (2021a) has approved one coronary intravascular lithotripsy system — Shockwave Medical Intravascular Lithotripsy System (Shockwave Medical Inc., Santa Clara, California). This class 3 device is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.

Approval was based on the results of the Disrupt CAD III single-arm clinical study conducted in the United States and in Europe comprising 431 adult enrollees in 47 investigational sites (ClinicalTrials.gov identifier NCT03595176; U.S. Food and Drug Administration, 2021b). Approval also stipulated two post-approval data collection requirements: 1) registry data for assessment of real-world use, and 2) long-term (two-year) safety and effectiveness data collection from the Disrupt CAD III follow-up study.

Findings

Across contemporary guidelines, systematic reviews, and meta-analyses, coronary intravascular lithotripsy consistently improves stent deliverability and expansion in severely calcified coronary lesions with high procedural success and low acute complication rates. Quantitatively, procedural success routinely approaches 92–97%, in-hospital and 30-day major adverse cardiovascular events cluster near 4–8%, and device-related complications such as perforation or abrupt closure remain uncommon. Imaging-directed selection of lesions with thick or circumferential calcium predicts the greatest benefit, while heterogeneity of lesion morphology, operator discretion, and nonrandomized designs limit definitive comparative effectiveness against atherectomy or high-pressure balloon strategies.

Guideline

Major societies place coronary intravascular lithotripsy within a broader, imaging-guided calcium modification strategy for percutaneous coronary intervention of calcified disease. The American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions guideline issues a weak recommendation to consider intracoronary lithotripsy to facilitate stent delivery and expansion in select circumstances, with the rationale that intravascular imaging evidence of calcium thickness > 0.5 mm or an arc > 270 degrees predicts the need for lesion modification (Lawton, 2022).

The Society for Cardiovascular Angiography and Interventions expert consensus specifies imaging-based criteria that trigger calcium modification and positions intravascular lithotripsy as particularly effective for circumferential calcium in balloon-crossable lesions, with synergy alongside atherectomy for long or heterogeneous calcific segments and a very low rate of slow flow or no reflow. It emphasizes routine intravascular imaging to define arc, length, and thickness, and it notes multiple randomized trials in progress comparing intravascular lithotripsy with cutting balloons and rotational atherectomy (Riley, 2023).

In 2025, the National Institute for Health and Care Excellence issued an interventional procedures overview covering ~8,400 patients from 38 studies and multiple registries. Procedural success consistently ranged from 92–100%, with pooled procedural success at 97% and clinical success at 93%. Major adverse cardiovascular events at 30 days occurred in ~8%, myocardial infarction in 5%, and mortality in 2%, with perforation and dissection each <2%. NICE concluded that intravascular lithotripsy provides effective plaque modification and favorable safety outcomes, though evidence remains limited by heterogeneity, short follow-up, and predominance of nonrandomized data. NICE highlighted ongoing randomized controlled trials comparing intravascular lithotripsy with rotational atherectomy and specialty balloons as critical for defining its role in routine practice (NICE, 2025).

Systematic reviews

A systematic review focused on left coronary artery calcific disease synthesized 4 studies (N = 282) and found that intravascular lithotripsy increased lumen diameter by up to 4.16 mm, reduced the luminal calcium angle, and had a low overall complication rate, while calling for randomized trials and longer follow-up before routine adoption (Sattar, 2021).

Meta-analyses

A pooled analysis of Disrupt CAD studies reported high procedural success and low short-term complications in patients with de novo severely calcified lesions; patient-level data showed 30-day major adverse cardiovascular events near 7% and procedural success near 92%, with prior myocardial infarction, bifurcation treatment, and long lesions predicting lower success or higher events (Kereiakes, 2021).

An updated meta-analysis that added 3 studies summarized 760 participants and reported pooled clinical and angiographic success of 94.4% and 94.8%, a significant increase in minimal lumen diameter, and low 30-day adverse event rates; heterogeneity and lack of direct randomized comparisons remained prominent limitations (Sattar, 2022).

The largest recent meta-analysis aggregated 38 studies (N = 2,977) and found overall clinical success 93% and procedural success 97%, with in-hospital and 30-day major adverse cardiovascular events 8%, myocardial infarction 5%, and death 2%. Diameter stenosis fell markedly after intravascular lithotripsy and further after stenting; perforation and dissection were rare (about 1–2%). These findings generalize across concentric and eccentric calcification and support intravascular lithotripsy as an effective lesion-preparation strategy prior to stenting (Sagris, 2024).

Other evidence

Evidence outside formal meta-analyses reinforces both feasibility in complex anatomy and the trajectory of adoption toward higher-risk presentations. Patient-level pooled data across Disrupt CAD studies quantified safety and effectiveness in 628 participants with severe calcification, with 30-day major adverse cardiovascular events 7.3%, procedural success 92.4%, and very low rates of serious angiographic complications; bifurcation treatment, prior myocardial infarction, and lesion length ≥ 25 mm predicted less favorable short-term outcomes (Kereiakes, 2021).

Independent registries in broader practice settings, including cohorts with under-expanded stents or chronic total occlusion subsets, show high technical success and low acute complication rates across primary and secondary applications. Prospective and retrospective series reported favorable lumen gain and low rates of perforation or abrupt closure when intravascular lithotripsy was used as a primary strategy or after balloon failure (Aksoy, 2019; Umapathy, 2021). In calcific in-stent restenosis and stent underexpansion, intravascular lithotripsy has been used off-label with high success in otherwise undilatable segments when guided by intravascular imaging (Ielasi, 2020).

A contemporary international, multicenter registry of 454 patients reported device, technical, and procedural success of 98%, 91%, and 89%, intravascular lithotripsy-related complications in 1%, and 1-year major adverse cardiovascular events in 13%. Notably, use increased over time in acute coronary syndrome, with frequent use of intravascular imaging and treatment of complex subsets such as left main, bifurcation, in-stent, and chronic total occlusion lesions (van Oort, 2025).

Adjunctive or staged use with atherectomy appears effective when atherectomy alone leaves resistant calcium or when the initial strategy fails. In a multinational registry of 160 patients who underwent intravascular lithotripsy after rotational atherectomy for severe calcification, procedural success was 96.9%, with freedom from serious angiographic complications 90.6% and very low in-hospital major adverse cardiovascular and cerebrovascular events (Sardella, 2023). Observational comparisons restricted to balloon-crossable lesions show similar technical success between intravascular lithotripsy and rotational atherectomy with low complication rates, while emphasizing device selection based on lesion morphology rather than a single default strategy (Mousa, 2023).

In 2025 we updated the findings section to include the new National Institute for Health and Care Excellence interventional procedures guidance (NICE, 2025), the Society for Cardiovascular Angiography and Interventions consensus statement (Riley, 2023), a large systematic review and meta-analysis (Sagris, 2024), and a multinational registry (van Oort, 2025). No policy changes warranted.

References

On September 10, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "percutaneous coronary intervention" (MeSH), "lithotripsy" (MeSH), "heart" (MeSH), and "coronary lithotripsy." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

10/2021: initial review date and clinical policy effective date: 11/2021

10/2022: Policy references updated.

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