Coronary intravascular lithotripsy

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

First Choice Next has developed clinical policies to assist with making coverage determinations. First Choice Next's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case by case basis, by First Choice Next when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. First Choice Next's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. First Choice Next's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, First Choice Next will update its clinical policies as necessary. First Choice Next's clinical policies are not guarantees of payment.

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

A joint guideline by the American College of Cardiology, American Heart Association, and the Society for Cardiovascular Angiography & Interventions issued a weak recommendation for considering intracoronary lithotripsy for treatment of calcified lesions to improve stent placement procedural success in select circumstances, inferring that the benefits may outweigh the risks. Their rationale is that presence of calcium deposits thicker than 500 μm or calcium involving an arc of the vessel > 270° on intravascular imaging predicts the need for lesion modification to facilitate stent delivery. The supportive evidence for coronary intravascular lithotripsy consists of nonrandomized studies, observational studies, and registry analyses, and meta-analyses of such studies (Lawton, 2022).

We included results of two pooled analyses (Kereiakes, 2021; Sattar, 2021), two independent registry studies (Aksoy, 2019; Umapathy, 2021), one single-site observational study (Brunner, 2021), and no guidelines for this policy. The preponderance of evidence of safety and effectiveness is derived from four prospective, nonrandomized, manufacturer-sponsored, multisite studies: Disrupt CAD I (ClinicalTrials.gov identifier NCT02650128); Disrupt CAD II (ClinicalTrials.gov identifier NCT03328949); Disrupt CAD III; and Disrupt CAD IV (ClinicalTrials.gov identifier NCT04151628). Multiple articles from these studies have been published, which can increase the potential for publication bias. To avoid duplicating results from these trials and hyperinflating the actual study base, we included two recent secondary analyses that pooled individual patient outcome data from these and other trials (Kereiakes, 2021; Sattar, 2021). Real-world clinical data from additional independent registry analyses and a single-site case series further inform this policy.

The evidence from single-arm observational studies is derived primarily from men in their 70s with native coronary artery disease (including stable or unstable angina or silent ischemia) suitable for percutaneous coronary intervention of a single de novo target lesion stenosis. The main treated target vessels were the left anterior descending coronary artery, circumflex coronary artery, and right coronary artery. In the Disrupt CAD trials, 30% had a bifurcation lesion with side branch involvement.

The results suggest coronary intravascular lithotripsy is safe and feasible in the short term as an adjunct to percutaneous coronary intervention for treating calcified, complex lesions in de novo coronary arteries prior to stenting. Coronary intravascular lithotripsy is associated with low in-hospital and 30-day procedural complications and low rates of major adverse cardiovascular events.

However, lack of a randomized comparator precludes definitive direct comparisons to available balloon-based or atheroablative alternatives. Application of coronary intravascular lithotripsy in other lesion subsets such as in-stent restenosis, under-expanded stents, and with other calcium-modifying therapies represent potential off-label uses. Long-term event-free survival outcomes at 24 months follow-up are the subject of the ongoing Disrupt CAD III and IV trials.

Kereiakes (2021) pooled the cumulative safety and effectiveness data for coronary intravascular lithotripsy from the four Disrupt CAD studies. Data comprised 628 participants enrolled at 72 sites in 12 countries. Presence of severe calcification was confirmed in 97.0% of target lesions with an average calcified segment length of 41.5 ± 20.0 millimeters and an average diameter stenosis of 63.7% ± 11.8%. The primary safety endpoint was freedom from major adverse cardiovascular events (composite of cardiac death, all myocardial infarction, or target vessel revascularization) at 30 days. The primary effectiveness endpoint was procedural success, defined as stent delivery with a residual stenosis ≤ 30% by quantitative coronary angiography without in-hospital major adverse cardiovascular events. Secondary outcomes included serious angiographic complications, target lesion failure, cardiac death, and stent thrombosis at 30 days.

The primary safety and effectiveness endpoints were achieved in 92.7% and 92.4% of participants, respectively. The rate of in-hospital major adverse cardiovascular events was 6.5% (4.7% to 8.8%), driven by non-Q-wave myocardial infarction (5.7%, 4.1% to 7.9%). The rate of 30-day major adverse cardiovascular events was 7.3% (5.4% to 9.7%), also driven by non-Q-wave myocardial infarction (5.9%, 4.2% to 8.1%). At 30 days, the rates of target lesion failure, cardiac death, and stent thrombosis were 7.2%, 0.5%, and 0.8%, and rates of post-procedure and final serious angiographic complications were 2.1% and 0.3%, respectively, with no procedure-associated perforations, abrupt closure, or episodes of no reflow, suggesting procedural success in treating both eccentric and concentric calcified lesions. Results of multivariate logistic regression show that treatment of bifurcation lesion (P = .006), prior myocardial infarction (P = .04), and lesion length ≥ 25 mm (P = .049) were independent predictors of 30-day major adverse cardiovascular events. Prior myocardial infarction (P = .016) and treatment of bifurcation lesion (P = .015) were predictors of lack of procedural success (Kereiakes, 2021).

A systematic review and meta-analysis (Sattar, 2021) examined the safety and efficacy of coronary intravascular lithotripsy for left coronary calcific disease from four studies (n = 282 participants). Their analysis included the results from a registry study (Aksoy, 2019) and two publications from the Disrupt CAD I and II trials. In left coronary artery calcific disease, intravascular lithotripsy can yield significant lumen gain of up to 4.16 millimeters by disrupting the calcium in the media and intima coronary arteries. The overall post-procedure lumen diameter was significantly higher than the pre-procedure diameter with a significant reduction in luminal calcium angle after intravascular lithotripsy of the stented coronary arteries (P = .01). Coronary intravascular lithotripsy appears to be associated with a low incidence of overall complications, but the authors recommend randomized controlled trials and longer-term follow-up before recommending routine use in these patients.

Two independent registry studies (Aksoy, 2019, n = 78 lesions; Umapathy, 2021, n = 50 lesions in 45 participants) analyzed lesion data from three subgroups who underwent coronary intravascular lithotripsy for

application: 1) as a primary procedure with de novo lesions; 2) as a secondary procedure following noncompliant balloon dilation failure; and (3) as a secondary procedure to under-expanded stents. A case series (Brunner, 2021, n = 6 participants) examined the feasibility, safety, and acute and mid-term angiographic outcomes of coronary intravascular lithotripsy for the treatment of calcium-mediated coronary in-stent restenosis. Although the defined outcomes varied across these three studies, their preliminary results suggest a high success rate, minimal procedural complications, and low major adverse cardiovascular event rates for expanded cohorts representing off-label uses. Intravascular lithotripsy is a safe and effective therapy to break up coronary calcium deposits for optimum stent vessel expansion and placement (Gardiner, 2022).

In 2023, we added an updated meta-analysis (Sattar, 2022), a new guideline (Lawton, 2022), and two observational studies. Prospective, randomized trials comparing clinical outcomes of various plaque debulking procedures are needed before recommending for routine use. The results confirm previous findings and no policy changes are warranted.

In an update of their previous 2021 meta-analysis, Sattar (2022) added three new studies (n = 760 total patients). The rates of pooled clinical/procedural success and angiographic success were 94.4% and 94.8%, respectively. Coronary intravascular lithotripsy significantly increased minimal lumen diameter (P < .0001) and changed overall diameter stenosis (−0.84, 95% confidence interval −7.63 to 5.96), but it was not associated with a change in diameter stenosis or calcium angle at any vessel point except maximum calcium thickness at the minimal luminal area. In 669 participants, the most common complication was major adverse cardiovascular events at 30-day follow-up (n = 48) and in-hospital (n = 39). Direct comparison with other calcium debulking procedures in randomized, blinded studies are needed to assess relative safety and efficacy.

A retrospective subanalysis (n = 21) of the ROTA.shock multicenter randomized controlled trial (ClinicalTrials.gov identifier NCT04047368) used high-resolution optical coherence tomography to compare the acute effects of preparation of severely calcified lesions by coronary intravascular lithotripsy or rotational atherectomy. Both procedures modify calcified plaques by producing acute luminal gain and creating plaque fractures. Rotational atherectomy was associated with greater acute lumen gain (0.46 ± 0.16 mm^2 vs 0.17 ± 0.14 mm^2, P = .03) but shorter fracture length (0.48 ± 0.27 mm^3 vs. 1.47 ± 0.40 mm^3, P = .003). Post-procedural dissection rates were similar, but mean flap lengths were greater with coronary intravascular lithotripsy (P = .03). The effects of these differences on stent expansion and clinical outcome require further study (Blachutzik, 2023).

A multinational registry study (n = 160) examined the safety and efficacy of elective or salvage coronary intravascular lithotripsy after rotational atherectomy for treatment of severe coronary artery calcification. The majority of participants experienced rotational atherectomy failure (57.5%), in whom balloon under-expansion was the most common reason. The primary efficacy end point of procedural success was observed in 96.9% of participants. The primary safety end point of freedom from serious angiographic complications occurred in 90.6% of participants. For secondary safety endpoints, freedom from in-hospital major adverse cardiac and cerebrovascular events occurred in 98.7% of participants, and stent under-expansion and malapposition occurred in 7.10% of participants each (Sardella, 2023).

In 2024, we found a comprehensive review of coronary intravascular lithotripsy, three clinical trials (total participants = 564) involving patients with severely calcified coronary lesions were analyzed. Coronary intravascular lithotripsy was used as the primary treatment modality to modify calcified plaques before stent placement. The first trial (DISRUPT CAD I) enrolled 60 patients, achieving 95% clinical success with Coronary Intravascular Lithotripsy reducing stenosis to 12.2%. The second trial (DISRUPT CAD II) enrolled 120 patients, with Coronary Intravascular Lithotripsy achieving a clinical success rate of 94.2%. The third trial (DISRUPT CAD III), involving 384 patients, reported a procedural success rate of 92.4% using coronary intravascular lithotripsy. Across these trials, major adverse cardiac event rates within 30 days ranged from 5% to 7.8%, highlighting the safety and effectiveness of coronary intravascular lithotripsy in treating calcified lesions. These findings

collectively support the statement that coronary intravascular lithotripsy is a clinically appropriate option for managing patients with heavily calcified coronary lesions, offering high procedural success rates and low complication rates when used to facilitate stent delivery and expansion in calcified coronary arteries (Jazar, 2022).

References

On September 10, 2024, 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

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