Cohere Medicare Advantage Policy - Coronary Intravascular Lithotripsy (IVL)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: December 19, 2024

© 2024 Cohere Health, Inc. All Rights Reserved.

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine the medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice. This policy may be superseded by existing and applicable Centers for Medicare & Medicaid Services (CMS) statutes.

©2024 Cohere Health, Inc. All Rights Reserved.

Other Notices:

HCPCS® and CPT® copyright 2024 American Medical Association. All rights reserved.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

HCPCS and CPT are registered trademarks of the American Medical Association.

Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Cohere Medicare Advantage Policy - Coronary Intravascular Lithotripsy
Date of last literature review: 12/10/2024
Document last updated: 12/19/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

© 2024 Cohere Health, Inc. All Rights Reserved.

Table of Contents

© 2024 Cohere Health, Inc. All Rights Reserved.

Medical Necessity Criteria

Service: *Coronary Intravascular Lithotripsy (IVL)*

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- There are no NCDs and/or LCDs for coronary intravascular lithotripsy.

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.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of coronary intravascular lithotripsy. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- No long-term data is available regarding the safety and efficacy of IVL.

© 2024 Cohere Health, Inc. All Rights Reserved.

- There is a lack of randomized controlled trials with statistical rigor to determine the superiority or inferiority of IVL relative to the current standard of care.
- Several of the existing studies included patients who underwent other plaque disruption methods, including before and after IVL. This limits the conclusions that can be drawn regarding IVL efficacy from these studies and therefore reduces generalizability.[5,6]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- IVL represents a possible treatment option for patients with severely calcified and/or undilatable coronary arteries that are not receptive to traditional treatment methods, such as rotational atherectomy or orbital atherectomy. Traditional tools may be insufficient to address "deep" (medial or intimal) circumferential calcification and may result in unsuccessful treatment.[18]
- The SCAI includes IVL in their 2024 expert consensus statement treatment algorithm for calcified coronary disease alongside specialty balloons and atherectomy.[12,13]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

➔ **Coronary Intravascular Lithotripsy** is considered appropriate if **ANY** of the following is **TRUE**:

© 2024 Cohere Health, Inc. All Rights Reserved.

- 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 (CPT/HCPCS)

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

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

© 2024 Cohere Health, Inc. All Rights Reserved.

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.[12,13]

A 2023 review of 747 IVL patients from Michigan's BMC2 registry found a procedural success rate of 91.4%, while an aggregate 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

© 2024 Cohere Health, Inc. All Rights Reserved.

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]

© 2024 Cohere Health, Inc. All Rights Reserved.

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]

© 2024 Cohere Health, Inc. All Rights Reserved.

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.
4. Sukul D, Seth M, Madder R, Basir MB, Menees DS, Kaki A, Azzalini L, Lee DT, Gurm HS. THE REAL-WORLD SAFETY AND EFFECTIVENESS OF CORONARY INTRAVASCULAR LITHOTRIPSY: INSIGHTS FROM THE BMC2 REGISTRY. Journal of the American College of Cardiology. 2023 Mar 7;81(8_Supplement):1052-.
5. Cubero-Gallego H, Millan R, Fuertes-Barahona M, Amat-Santos I, Quiroga X, Gomez-Lara J, Salvatella N, Tizon-Marcos H, Negrete A, Vaquerizo B. REAL-WORLD DATA FROM A MULTICENTER REGISTRY OF CORONARY LITHOTRIPSY FOR TREATMENT OF CALCIFIED CORONARY LESIONS. Journal of the American College of Cardiology. 2020 Mar 24;75(11_Supplement_1):1233-.
6. van Oort MJ, Oliveri F, Bingen BO, Claessen BE, Dimitriu-Leen AC, Vossenberg TN, Kefer J, Girgis H, van der Kley F, Jukema JW, Montero-Cabezas JM. Sex Differences in a Real-World Registry Examining Coronary Lithotripsy for Calcified Lesions. The American Journal of Cardiology. 2025 Feb 1;236:49-55.
7. Hill, J, Kereiakes, D, Shlofmitz, R. et al. Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Artery Disease. JACC. 2020 Dec, 76 (22) 2635–2646. https://doi.org/10.1016/j.jacc.2020.09.603
8. Kereiakes DJ, Hill JM, Shlofmitz RA, Klein AJ, Riley RF, Price MJ, Herrmann HC, Bachinsky W, Waksman R, Stone GW, Disrupt CAD III Investigators. Intravascular lithotripsy for treatment of severely calcified coronary lesions: 1-year results from the Disrupt CAD III study. Journal of the Society for Cardiovascular Angiography & Interventions. 2022 Jan 1;1(1):100001.
9. Kereiakes DJ, Hill JM, Shlofmitz RA, Klein AJ, Riley RF, Price MJ, Herrmann HC, Bachinsky W, Waksman R, Stone GW, Disrupt CAD III Investigators. Intravascular Lithotripsy for Treatment of Severely Calcified Coronary

© 2024 Cohere Health, Inc. All Rights Reserved.

Arteries: 2-Year Results—Disrupt CAD III Study. Cardiovascular Interventions. 2023 Oct 9;16(19):2472-4.
10. Kereiakes DJ, Hill JM, Shlofmitz RA, et al. A-54| The Disrupt CAD III Post-Approval Study: Real-World Safety and Effectiveness of Coronary Intravascular Lithotripsy from the ACC NCDR CathPCI Registry. *JSCAI*. 2023 May 1;2(3). DOI: 10.1016/j.jscai.2023.10071
11. Kereiakes DJ, Hill JM, Shlofmitz RA, et al. OR4-1| In-hospital Results with Intravascular Lithotripsy in the Real-World: Outcomes from the ACC NCDR® CathPCI Registry®. *JSCAI*. 2024 May 1;3(5). DOI: 10.1016/j.jscai.2024.101424
12. Riley RF, Patel MP, Abbott JD, et al. SCAI expert consensus statement on the management of calcified coronary lesions. *JSCAI*. 2024 Feb 1;3(2):101259. https://doi.org/10.1016/j.jscai.2023.101259
13. Ali ZA, Shin D, Barbato E. Between a Rock and a Hard Place: A Consensus Statement on the Management of Calcified Coronary Lesions. *JSCAI*. 2024 Feb 1;3(2). DOI: 10.1016/j.jscai.2023.101265
14. Rempakos A, Simsek B, Kostantinis S, et al. Adverse events with intravascular lithotripsy after coronary use: A report from the FDA MAUDE database. *J Invasive Cardiol*. 2023 Sep 1;35(9). https://doi.org/10.25270/jic/23.00111
15. Food and Drug Administration. Summary of Safety and Effectiveness Data: P200039 - Shockwave Intravascular Lithotripsy System with Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter. https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200039B.pdf Updated February 12, 2021. Accessed December 6, 2024.
16. Shockwave C2+ 2Hz Coronary IVL Catheter in Calcified Coronary Arteries (Disrupt CAD DUO) ClinicalTrials.gov identifier: NCT05966662. Updated October 9, 2024. Accessed December 6, 2024. https://clinicaltrials.gov/study/NCT05966662?term=NCT05966662&rank=1
17. Centers for Medicare and Medicaid Services. Approved IDE Studies: G230172-NCT05966662. Published November 9, 2023. Accessed December 9, 2024. https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved/g230172-nct05966662
18. Gonzálvez-García A, Jiménez-Valero S, Galeote G, et al. "RotaTripsy": combination of rotational atherectomy and intravascular lithotripsy in heavily calcified coronary lesions: a case series. *Cardiovascular Revascularization Medicine*. 2022 Feb 1;35:179-84. https://doi.org/10.1016/j.carrev.2021.04.011
19. Gupta A, Shrivastava A, Dugal JS, et al. Coronary intravascular lithotripsy in contemporary practice: challenges and opportunities in coronary

© 2024 Cohere Health, Inc. All Rights Reserved.

intervention. *Therapeutic Advances in Cardiovascular Disease*. 2024 Jul;18:17539447241263444. https://doi.org/10.1177/17539447241263444

© 2024 Cohere Health, Inc. All Rights Reserved.

Clinical Guideline Revision History/Information

Original Date: December 19, 2024		
Review History		

© 2024 Cohere Health, Inc. All Rights Reserved.