Cohere Medicare Advantage Policy - Coronary Artery Atherectomy

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Cohere Medicare Advantage Policy - Coronary Artery Atherectomy and Intracoronary Lithotripsy

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Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Coronary Artery Atherectomy

Benefit Category

Not applicable.

Recommended Clinical Approach

Coronary artery atherectomy is a percutaneous interventional technique that removes or ablates coronary plaque. Three atherectomy devices are FDA-approved: 1) rotational (RotaPro, Boston Scientific); 2) orbital (Diamondback, CSI); and 3) excimer laser (ELCA, Phillips). These devices are typically used as adjuncts to balloon angioplasty and stenting procedures and are rarely used as a stand-alone treatment. They improve procedural success in patients with fibrotic and/or moderate to severely calcified lesions and in lesions that are unable to be crossed or adequately expanded with a balloon.[1-7] Atherectomy may also be useful to improve procedural success in lesions that are eccentric, lesions that are due to in-stent restenosis (rotational or laser)[8-11], aorto-ostial or branch ostial (bifurcation) lesions, and in under-expanded stents (rotational or laser).[11-13] Additional procedures sometimes used with atherectomy or to treat similar lesions include atherotomy devices (cutting and scoring balloons) and intracoronary lithotripsy.[14-17]

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of coronary artery atherectomy procedures. 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, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Adverse effects from delayed or denied treatment: Delays or denials in the use of coronary artery atherectomy can lead to increased

symptoms and complications, especially in patients with severe calcified coronary lesions. The 2021 ACC/AHA/SCAI Coronary Artery Revascularization guideline emphasizes the importance of timely intervention to prevent adverse outcomes in patients with significant heart conditions.[1]

- Risks with inappropriate surgical procedures: This includes infection, bleeding, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to complications. The ROTAXUS trial highlights the importance of appropriate patient selection to minimize surgical risks and enhance the benefits of coronary artery atherectomy.[2]
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Proper use of coronary artery atherectomy criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The guidelines for the management of coronary artery disease support the necessity of appropriate diagnostic and treatment procedures to prevent unnecessary healthcare utilization.[1]

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to coronary artery atherectomy procedures for the patients selected for best outcomes. The goal is to provide accurate diagnostics and effective treatment planning, reducing the risk of complications and improving overall patient health. The guidelines for the management of coronary artery disease revascularization emphasize the diagnostic accuracy of imaging and monitoring procedures in managing patients with heart conditions.[1]
- Enhanced diagnostic accuracy: This is crucial for complex cardiovascular conditions where traditional diagnostic methods may pose additional risks. Advanced imaging and monitoring techniques offer the advantage of detailed vascular assessment, aiding in decision-making regarding interventions.[5]
- Reduction in complications and adverse effects: Proper use of coronary artery atherectomy criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Studies on

the use of coronary artery atherectomy procedures emphasize the importance of accurate diagnostics in preventing complications.[6]
- Enhanced overall patient satisfaction: Ensuring that coronary artery atherectomy procedures are used appropriately leads to better procedural outcomes in certain clinical settings and higher satisfaction rates due to effective treatment and reduced complications.[7]

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 and to ensure 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 artery atherectomy** is considered appropriate if **ALL** of the following are **TRUE**[19-20]:
- ◆ The patient has an indication for a percutaneous coronary intervention; **AND**
- ◆ **ANY** of the following**:**
  - Rotational atherectomy may be used to treat patients undergoing PCI of fibrotic or heavily calcified lesions (see Note below) in order to achieve plaque modification to improve procedural success[2-3,7,10-11]; **OR**
  - Orbital atherectomy may be used to treat patients undergoing PCI of fibrotic or heavily calcified lesions (see Note below) to achieve plaque modification in order to improve procedural success[1,4-6,18]

NOTE: Heavy (severe) calcification is most commonly defined by invasive angiography as radiopacities seen without cardiac

motion before contrast injection, usually affecting both sides of the arterial lumen.

Intravascular ultrasound (IVUS) or optical coherence tomography (OCT) criteria may predict non-dilatable lesions or impaired stent delivery and expansion (e.g., calcium thickness greater than 670 um by OCT or greater than 270-degree arc of calcium by IVUS or OCT or other proposed scoring system that predicts stent underexpansion).[21-22]

Non-Indications

- ➔ **Coronary Artery Atherectomy** is not considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ There are no current non-indications in the literature.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

HCPCS Code	Code Description/Definition
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch
+92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
+92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery
92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft,

	any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel
+92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)
C1724	Catheter, transluminal atherectomy, rotational
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
+C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel
+C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of

	drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)

Medical Evidence

Lawton et al. (2022) published a clinical practice guideline for the American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions for coronary artery revascularization. It was recommended that in patients with significant left main disease, surgical revascularization is indicated. Percutaneous revascularization is a reasonable option to improve survival compared with medical therapy in selected patients with low to medium anatomic complexity of coronary artery disease and left main disease that is suitable for revascularization. In patients with stable ischemic heart disease, normal left ventricular ejection fraction, and triple vessel coronary artery disease, surgical revascularization may be reasonable, and percutaneous revascularization survival benefit is uncertain.[1]

Mehanna et al. (2018) discuss the use of optical coherence tomography (OCT) in guiding percutaneous coronary intervention (PCI) for calcified lesions. The authors highlight the challenges associated with treating calcified coronary lesions, which can lead to suboptimal stent deployment and increased risk of adverse cardiovascular events. They emphasize the importance of understanding lesion morphology and composition to improve procedural outcomes. The utility of OCT is reviewed, a high-resolution imaging modality, in assessing lesion characteristics such as calcium distribution, thickness, and morphology. By providing detailed visualization of the vessel wall, OCT enables better lesion assessment and facilitates optimal stent selection and deployment. The authors discuss the role of atherectomy devices in modifying calcified plaques prior to stent placement. They argue that OCT-guided atherectomy can improve procedural success by optimizing lesion preparation and ensuring adequate stent expansion. The group overall advocates for the integration of OCT into routine clinical practice for PCI in calcified lesions, citing its potential to enhance procedural outcomes and reduce the risk of complications.[21]

Whiteside and colleagues (2019), present evidence regarding the use of rotational atherectomy (RA) for the treatment of underexpanded and undilatable coronary stents. The authors address the clinical challenge of managing stent underexpansion, a condition associated with increased risk of adverse cardiovascular events. They propose RA as a potential solution to

improve stent expansion and optimize procedural outcomes. The study reviews the outcomes of patients undergoing stent ablation with RA, focusing on procedural success rates, safety, and long-term efficacy. By analyzing data from a cohort of patients with under expanded or undilatable stents, the authors evaluate the effectiveness of RA in achieving adequate stent expansion and restoring optimal coronary flow. Key findings from the study include improvements in angiographic parameters such as minimal lumen diameter and percent diameter stenosis following RA. Additionally, the authors report favorable clinical outcomes with low rates of major adverse cardiovascular events during follow-up. The importance of appropriate patient selection and meticulous procedural technique in achieving successful stent ablation with RA is emphasized. Potential challenges and complications associated with the technique are discussed, emphasizing the need for careful risk assessment and management strategies. Overall, the evidence presented in the article suggests that RA represents a valuable therapeutic option for the management of underexpanded and undilatable coronary stents, offering the potential to improve clinical outcomes and reduce the need for repeat revascularization procedures.[13]

References

1. Lawton JS, Tamis-Holland JE, Bangalore S, Bates ER, Beckie TM, Bischoff JM, Bittl JA, Cohen MG, DiMaio JM, Don CW, Fremes SE, Gaudino MF, Goldberger ZD, Grant MC, Jaswal JB, Kurlansky PA, Mehran R, Metkus TS Jr, Nnacheta LC, Rao SV, Sabik JF, Sellke FW, Sharma G, Yong CM, Zwischenberger BA. 2021 ACC/AHA/SCAI guideline for coronary artery revascularization: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145:e18–e114. doi: 10.1161/CIR.0000000000001038.
2. Abdel-Wahab M, Richardt G, Joachim Büttner H, et al. High-speed rotational atherectomy before paclitaxel-eluting stent implantation in complex calcified coronary lesions: the randomized ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) trial. JACC Cardiovasc Interv. 2013;6:10–19.
3. Abdel-Wahab M, Toelg R, Byrne RA, et al. High-speed rotational atherectomy versus modified balloons prior to drug-eluting stent implantation in severely calcified coronary lesions. Circ Cardiovasc Interv. 2018;11:e007415.
4. Chambers JW, Feldman RL, Himmelstein SI, Bhatheja R, Villa AE, Strickman NE, Shlofmitz RA, Dulas DD, Arab D, Khanna PK, Lee AC, Ghali MG, Shah RR, Davis TP, Kim CY, Tai Z, Patel KC, Puma JA, Makam P, Bertolet BD, Nseir GY. Pivotal trial to evaluate the safety and efficacy of the orbital atherectomy system in treating de novo, severely calcified coronary lesions (ORBIT II). JACC Cardiovasc Interv. 2014 May;7(5):510-8.
5. Shlofmitz E, Martinsen BJ, Lee M, Rao SV, Généreux P, Higgins J, Chambers JW, Kirtane AJ, Brilakis ES, Kandzari DE, Sharma SK, Shlofmitz R. Orbital atherectomy for the treatment of severely calcified coronary lesions: evidence, technique, and best practices. Expert Rev Med Devices. 2017 Nov;14(11):867-879.
6. Fernandez JP, Hobson AR, McKenzie D et al. Beyond the balloon: excimer coronary laser atherectomy used alone or in combination with rotational atherectomy in the treatment of chronic total occlusions, non-crossable and non-expansible coronary lesions. Eurointervention 2013;9:243-250.

7. Armstrong EJ, et al. Coronary atherectomy is associated with improved procedural and clinical outcomes among patients with calcified coronary lesions: Insights from the VA CART program. Catheter Cardiovasc Interv 2018;91:1009-1017.
8. Noble S, Bilodeau L. High energy excimer laser to treat coronary in-stent restenosis in an underexpanded stent. Catheter Cardiovasc Interv 2008;71:803-807.
9. Lee T, Shlofmitz RA, Song L, et al. The effectiveness of excimer laser angioplasty to treat coronary in-stent restenosis with peri-stent calcium as assessed by optical coherence tomography. EuroIntervention. 2019;15:e279–e288.
10. Tomey MI, Kini AS, Sharma SK. Current status of rotational atherectomy. *JACC Cardiovasc Interv* 2014;7:345-53.
11. Barbato E, Carrie D, Dardas P, et al. European expert consensus on rotational atherectomy. Eurointervention 2015;11:30-36.
12. Latib A, Takagi K, Chizzola G, et al. Excimer laser lesion modification to expand non-dilatable stents: the ELLEMENT registry. Cardiovasc Revasc Med. 2014;15:8–12.
13. Whiteside HL, Nagabandi A, Kapoor D. Stentablation with rotational atherectomy for the management of underexpanded and undilatable coronary stents. Cardiovasc Revasc Med 2019;20:1203-1208.
14. Albiero R, Silber S, Di Mario C, et al. Cutting balloon versus conventional balloon angioplasty for the treatment of in-stent restenosis: results of the restenosis cutting balloon evaluation trial (RESCUT). J Am Coll Cardiol. 2004;43:943–949.
15. Kufner S, Joner M, Schneider S, et al. Neointimal modification with scoring balloon and efficacy of drug-coated balloon therapy in patients with restenosis in drug-eluting coronary stents: a randomized controlled trial. JACC Cardiovasc Interv. 2017;10:1332–1340.
16. Ali ZA, Nef H, Escaned J, et al. Safety and effectiveness of coronary intra-vascular lithotripsy for treatment of severely calcified coronary stenoses: the Disrupt CAD II study. *Circ Cardiovasc Interv*. 2019;12:e008434.
17. Kereiakes DJ, Di Mario C, Riley RF, et al. Intravascular lithotripsy for treatment of calcified coronary lesions: patient-level pooled analysis of the dis-rupt CAD studies. *JACC Cardiovasc Interv*. 2021;14:1337–1348.
18. Badr S, Ben-Dor I, Dvir D, Barbash IM, Kitabata H, Minha S, Pendyala LK, Loh JP, Torguson R, Pichard AD, Waksman R. The state of the excimer

laser for coronary intervention in the drug-eluting stent era. Cardiovasc Revasc Med. 2013 Mar-Apr;14(2):93-8.
19. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Percutaneous coronary intervention (L33623). Revision Effective Date November 7, 2019. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33623. Accessed June 3, 2024.
20. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Percutaneous coronary interventions (L34761). Revision Effective Date December 28, 2023. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34761&ver=32&bc=0. Accessed June 3, 2024.
21. Mehanna E, Abbott JD, Bezerra HG. Optimizing percutaneous coronary intervention in calcified lesions: insights from optical coherence tomography of atherectomy. Circ Cardiovasc Interv. 2018;11:e006813.
22. Fujino A, Mintz GS, Matsumura M, et al. A new optical coherence tomography-based calcium scoring system to predict stent underexpansion. Eurointervention 2018;13:e2182-e2189.

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