

Intravascular Ultrasound (Coronary and Non-Coronary)

ACG: A-0717 (AC)

[Link to Codes](#)

MCG Health
Ambulatory Care
30th Edition

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Clinical Indications

- Intravascular ultrasound (coronary and non-coronary) may be indicated for **1 or more** of the following(1)(2)(3)(4):
 - Cardiac transplant, as indicated by **1 or more** of the following(18)(19)(20)(21):
 - Cardiac allograft vasculopathy surveillance needed
 - Cardiac allograft vasculopathy, suspected, and need for detection of rapidly progressive disease
 - Exclusion of donor coronary artery disease needed
 - Prognostic information needed
 - Coronary artery disease, and need for assessment of angiographically indeterminate left main disease or angiographically intermediate non-left main stenoses (50% to 70% stenosis)(25)(26)(27)[N](#)
 - Coronary artery dissection, spontaneous(30)(31)(32)(33)[N](#)
 - Coronary artery stent implantation(6)(7)(36)(37)[N](#)

- Coronary artery stent restenosis, and need for determination of its mechanism(9)(44)(45)(46)N
- Coronary artery stent thrombosis, and need for determination of its mechanism(45)N
- Iliac vein compression syndrome (eg, May-Thurner syndrome),[A] suspected, as indicated by **ALL** of the following(51)(54)(55):N
 - Clinical symptoms of iliac vein compression syndrome, as indicated by **1 or more** of the following(59):
 - Chronic unilateral lower extremity swelling, pain, varicosities, or venous ulcers(60)
 - Recurrent unilateral lower extremity DVT
 - Unilateral iliofemoral vein thrombosis
 - Imaging needed due to **1 or more** of the following(61):
 - Doppler ultrasonography nondiagnostic
 - Patient being considered for intravascular intervention (eg, stent placement)
- Left main coronary artery stent implantation(7)(9)(62)(63)N
- Left renal vein compression, suspected, as indicated by **ALL** of the following(57)(65)(66):N
 - Patient has clinical symptoms of left renal vein compression, as indicated by **1 or more** of the following(53):
 - Hematuria
 - Left flank pain or abdominal pain
 - Left-sided varicocele
 - Doppler ultrasonography nondiagnostic

Evidence Summary

Background

Intravascular ultrasound utilizes a miniaturized ultrasound probe attached to the distal end of a catheter in order to directly image a vessel wall.(3)(5)(6)(7) **(EG 2)** A computer translates reflections of sound waves into images that characterize endovascular plaque (including fibrosis, calcium, and necrotic core).(8) **(EG 2)** Intravascular ultrasound can assess plaque volume within the arterial wall as well as the degree of stenosis of the artery lumen.(3)(6)(7)(9) **(EG 2)** Because no common technical standards exist, intravascular ultrasound catheters from different manufacturers are not interchangeable.(10)(11) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 58 published peer reviewed articles, 7 specialty society or other evidence-based guidelines, and 1 book section.

For cardiac transplant, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Review articles note that intravascular ultrasound is reasonable to perform for the assessment of allograft vasculopathy, for the exclusion of donor coronary artery disease, and to provide prognostic information in cardiac transplant patients at 4 to 6 weeks and at 1 year after the procedure.(22)(23) **(EG 2)** Intravascular ultrasound is superior to angiography for early detection of diffuse immune-mediated cardiac allograft vasculopathy.(20)(23) **(EG 2)** A prospective study of 31 adult patients who had undergone cardiac transplant found that the use of intravascular ultrasound doubled the detection rate for cardiac allograft vasculopathy as compared with coronary angiography.(24) **(EG 2)** A review article notes that advances in intravascular ultrasound technology have allowed for detection of subangiographic cardiac allograft vasculopathy.(21) **(EG 2)**

For coronary artery disease, and need for assessment of angiographically indeterminate left main disease or angiographically intermediate non-left main stenoses (50% to 70% stenosis), evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A specialty society guideline states that it may be reasonable to use intravascular ultrasound to assess angiographically indeterminate left main disease or angiographically intermediate non-left main stenoses (50% to 70% stenosis).(1) **(EG 2)** A specialty society report notes that

intravascular ultrasound can help detect unstable coronary atherosclerotic plaques.(28) **(EG 2)** A prospective observational study of 581 patients undergoing coronary angiography found that detection of high-risk coronary plaques by intravascular ultrasound in a nonculprit coronary artery was independently predictive of major adverse cardiac events within 1 year, particularly acute coronary syndrome and death.(8) **(EG 2)** A retrospective observational study of 225 patients with 233 coronary ostial lesions (47% of which were aorto-ostial lesions) found that the use of intravascular ultrasound, as compared with no use of intravascular ultrasound, was associated with significantly lower rates of the composite of cardiovascular death, myocardial infarction, or target lesion revascularization after a mean follow-up of 4.2 years.(29) **(EG 2)**

For spontaneous coronary artery dissection, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Review articles note that intravascular ultrasound is helpful for determining the presence of a false lumen or intramural hematoma in patients with acute spontaneous coronary artery dissection identified on angiography.(30)(31)(34) **(EG 2)** Another review article notes that intracoronary imaging with intravascular ultrasound can aid in the diagnosis of spontaneous coronary artery dissection and can clearly demonstrate the true and the false lumen as well as the presence of intramural hematoma.(35) **(EG 2)**

For coronary artery stent implantation, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A systematic review and meta-analysis of 16 trials including 7814 patients undergoing cardiac catheterization and angiography compared intravascular imaging-guided (9 trials exclusively used intravascular ultrasound, 4 exclusively used optical coherence tomography, and 3 used both) or angiography-guided percutaneous coronary intervention (PCI) and found, at a weighted mean follow-up of 28.8 months, that intravascular imaging-guided PCI was associated with lower rates of major adverse cardiac events, cardiac death, stent thrombosis, and target-lesion revascularization compared with angiography-guided PCI.(38) **(EG 1)** A follow-up study of one of the trials included in the meta-analysis (1183 patients initially randomized to intravascular ultrasound-guided or angiography-guided drug-eluting stent placement) found, at 5 years post procedure, that intravascular ultrasound was associated with lower rates of cardiac death, target lesion-related myocardial infarction, and target vessel revascularization compared with angiography.(39) **(EG 1)** An observational study of 6855 patients with complex coronary artery lesions found, at 1 year post procedure, that intervention guided by intravascular ultrasound was associated with a lower rate of major adverse cardiac events (composite of all-cause mortality, myocardial infarction, and target vessel revascularization) compared with intervention guided by angiography alone.(40) **(EG 2)** A specialty society guideline recommends intravenous ultrasound for procedural guidance during coronary artery stent implantation for patients with acute coronary syndrome and complex coronary lesions.(41) **(EG 2)** An international specialty society guideline and review articles note that intravascular ultrasound is especially useful for planning PCI strategies in high-risk patients, such as those with bifurcation lesions, calcified lesions, and left main coronary artery stenosis, as well as during coronary stent placement to assess stent sizing, expansion, and apposition.(7)(27)(42)(43) **(EG 2)**

For coronary artery stent restenosis, and need for determination of its mechanism, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** National specialty society guidelines state that it is reasonable to use intravascular ultrasound to determine the cause of stent restenosis, including stent underexpansion or malapposition.(1)(44) **(EG 2)** Neointimal hyperplasia can be reliably seen and measured on intravascular ultrasound, and characterization of the restenosis as focal or diffuse may help to guide treatment strategy.(47)(48) **(EG 2)** An observational study of 1522 patients undergoing percutaneous coronary intervention for in-stent restenosis found, at 1-year follow-up, that intravascular ultrasound guidance was associated with lower rates of major adverse cardiac events (composite of all-cause mortality, Q-wave myocardial infarction, and target vessel revascularization) compared with intervention with angiography guidance alone.(49) **(EG 2)** Review articles note that intravascular ultrasound can readily detect coronary stent underexpansion or edge problems in addition to the presence of neointimal hyperplasia, which may obstruct the stent itself.(45)(48) **(EG 2)** An international specialty society guideline recommends the use of intravascular ultrasound to identify and correct underlying mechanical factors in cases of stent failure, including restenosis and stent thrombosis.(50) **(EG 2)**

For coronary artery stent thrombosis, and need for determination of its mechanism, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A national specialty society guideline states that it may be reasonable to use intravascular ultrasound to determine the mechanism of stent thrombosis.(1)(22) **(EG 2)**

For iliac vein compression syndrome (eg, May-Thurner syndrome), evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A specialty society guideline and review articles note that intravascular ultrasound

is helpful for evaluating suspected iliac vein compression when lower extremity venous duplex (Doppler) imaging is not diagnostic, and to help guide stent placement in symptomatic patients.(51)(54)(55)(56)(57)(58) **(EG 2)**

For left main coronary artery stent implantation, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A meta-analysis of 14 studies with 18,944 patients evaluating the use of intravascular ultrasound guidance for left main coronary artery percutaneous intervention found, at a mean follow-up of 3 years, that intravascular ultrasound-guided intervention was associated with lower rates of all-cause mortality, cardiovascular mortality, need for left main coronary artery revascularization, and myocardial infarction compared with left main coronary artery percutaneous intervention guided by angiography alone.(64) **(EG 1)** National specialty society guidelines state that intravascular ultrasound is recommended for guidance of left main coronary artery stenting.(1)(27)(41) **(EG 2)**

For left renal vein compression between the superior mesenteric artery and the aorta (nutcracker syndrome), evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A review article notes that diagnosis of left renal vein compression in nutcracker syndrome is often possible by clinical examination and noninvasive imaging; however, intravascular ultrasound is useful when noninvasive imaging is unrevealing or nondiagnostic. Intravascular ultrasound and phlebography are the 2 diagnostic procedures that still remain the gold standard for the diagnosis of nutcracker syndrome, and intravascular ultrasound has been shown to have a higher specificity of 90% compared with 62% for phlebography.(65) **(EG 2)**

Inconclusive or Non-Supportive Evidence

For carotid artery stent implantation, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A prospective randomized controlled trial of 60 patients with carotid artery stenosis at high surgical risk who underwent carotid artery stenting found that adding intravascular ultrasound to routine preprocedural MR angiography or CT angiography led to a different choice of stent in only 5% of patients and was useful after stent deployment in another 5% of patients. It was hypothesized that intravascular ultrasound may be useful when treating challenging plaques or to help guide stent choice; however, larger studies are needed to confirm these results.(12) **(EG 1)** A prospective cohort study of 119 consecutive patients with symptomatic or asymptomatic severe carotid artery stenosis undergoing carotid stenting assessed the safety and feasibility of intravascular ultrasound before and after stent implantation. The authors found no significant association between intravascular ultrasound findings and acute and 30-day adverse events and concluded that the use of intravascular ultrasound for prediction of clinical events associated with stenting remains uncertain; larger studies with long-term follow-up are needed.(13) **(EG 2)**

For peripheral venous and arterial interventions, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review evaluating intravascular ultrasound use in lower extremity peripheral arterial interventions (29 studies) or iliofemoral venous interventions (19 studies) found that intravascular ultrasound improved clinical outcomes compared with other imaging modalities; the authors noted, however, that further conclusions were limited by the heterogeneity of clinical outcomes and the retrospective nature of most included studies.(14) **(EG 1)** A randomized controlled trial of 150 patients undergoing femoropopliteal endovascular interventions compared intravascular ultrasound with angiographic guidance and found that intravascular ultrasound-guided interventions were associated with fewer cases of binary restenosis (evaluated by duplex ultrasound) at 12 months, but no change in target vessel revascularization rates, compared with angiography-guided interventions. The authors note that future prospective studies with larger sample sizes and longer follow-up are needed to evaluate whether intravascular ultrasound is clinically beneficial and cost-effective.(15) **(EG 1)** An expert consensus appropriate-use document notes that although intravascular ultrasound may be appropriate for most arterial and venous lower extremity interventions, future studies are needed to understand its long-term effectiveness for clinical outcomes such as major adverse limb events and target lesion revascularization rates.(16) **(EG 2)** An expert consensus document endorsed by several specialty societies states that intravascular ultrasound is appropriate to plan or guide many peripheral vascular procedures but notes that this recommendation is based on only moderate-quality evidence and recommends further randomized controlled trials to assess long-term outcomes and the cost-effectiveness of the technology.(17) **(EG 2)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(67); 42 CFR 422.101(68)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(69); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(70); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(71)

Medicare Coverage Determinations: Medicare Coverage Database(72)

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Footnotes

[A] Although the most common iliac vein compression syndrome is left common iliac vein compression by the right common iliac artery (May-Thurner syndrome), right common or external iliac vein compression can also occur.(51)(52)(53) [A in Context Link 1]

Codes

CPT®: 37252, 37253, 92978, 92979

HCPCS: C1753, C7516, C7518, C7521, C7523, C7525, C7527, C7532

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Last Update: 1/25/2026 12:54:08 AM
Build Number: 30.0.2026012500524.025256