



Evolut Clinical Guideline 7264 for Renal and Mesenteric Angiography and Intervention

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

Indications for determining medical necessity for renal angiography and those required interventions after angiography.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ⁽¹⁻⁵⁾

Special Notes

- Intervention on renal and mesenteric arteries is only considered medically necessary when there is documentation of clinical pathology associated with a significant risk of morbidity or mortality if left untreated.
 - The type of intervention (ie, open surgical or endovascular) is provider-dependent and will not be the basis for authorization.
- There are alternatives to renal and mesenteric artery intervention for the indications described below. Accordingly, there must be documentation of a shared decision-making process for renal and mesenteric artery intervention that includes a discussion of all

alternatives to the procedure, benefits and risks of the procedure and alternatives, and the possibility of recurrent clinical issues and need for further treatment following the procedure.

INDICATIONS FOR RENAL ANGIOGRAPHY

Renal Artery Stenosis

Note: 2013 ACCF/AHA ⁽⁶⁾ and 2024 ESC ⁽⁷⁾ recommend noninvasive DUS (duplex ultrasonography) as the first-line imaging, followed by CTA (eGFR is ≥ 60 mL/min) and/or MRA (eGFR is ≥ 30 mL/min) to establish the diagnosis of renal artery stenosis (RAS). When the clinical index of suspicion is high and the results of noninvasive studies are inconclusive, 2013 ACC/AHA recommends catheter angiography, while 2017 ESC ⁽⁸⁾ recommends DSA (digital subtraction angiography).

- Hypertension:
 - Uncontrolled arterial hypertension ($> 140/90$ mm Hg) ⁽⁹⁾ despite being on maximal tolerated guideline-directed medical therapy (≥ 3 antihypertensive medications), defined as resistant hypertension ^(6,7)
 - Accelerated (defined as sudden and persistent worsening of controlled hypertension) and malignant hypertension (defined as hypertension with evidence of acute end-organ damage) ⁽⁶⁾
 - Onset of hypertension at < 30 years old ^(6,7)
 - Onset of severe hypertension at > 55 years old, with evidence of CKD (chronic kidney disease) and cardiac failure ^(6,7)
- Renal Dysfunction
 - New azotemia or worsening renal function after administration of an ACE inhibitor or ARB agent ^(6,7)
 - Unexplained atrophic kidney (7 to 8 cm) or size discrepancy greater than 1.5 cm between kidneys ^(6,7)
 - Unexplained renal dysfunction, including individuals starting renal replacement therapy (dialysis or renal transplantation) ^(6,7)
- Sudden and unexplained pulmonary edema, especially in azotemic patients ^(6,7)
- Multivessel coronary artery disease with no evidence of PAD at the time of arteriography ⁽⁶⁾
- Unexplained congestive heart failure or refractory angina ⁽⁶⁾

Fibromuscular Dysplasia ⁽¹⁰⁾

Note: CTA is the first-line imaging for suspected FMD for accurate differentiation of FMD from atherosclerotic renal artery stenosis. Contrast-enhanced magnetic resonance angiography (MRA) is the next option if CTA is contraindicated. When the results of CTA or MRA confirm the

diagnosis of FMD, or when a clinical index of suspicion is high despite negative findings on CTA or MRA, catheter angiography should be considered for angioplasty and gradient obliteration assessment. Translesional pressure gradient measurement is also recommended for assessment of hemodynamic significance of stenosis, particularly in multifocal FMD, as well as post-angioplasty in both focal and multifocal FMD. ^(10,11)

- Onset of hypertension less than 30 years of age, especially women
- Accelerated, malignant, or grade 3 (> 180/110 mm Hg) hypertension
- Drug-resistant hypertension despite being on maximally tolerated GDMT (blood pressure target not achieved despite 3 drug-therapy at optimal doses including a diuretic)
- Unilateral small kidney without a causative urological abnormality
- Abdominal bruit in the absence of atherosclerotic disease or risk factors for atherosclerosis
- Suspected renal artery dissection or infarction
- Presence of FMD in at least one other vascular territory

INDICATIONS FOR RENAL ARTERY INTERVENTION

- Cardiac Disturbance Syndromes
 - Hemodynamically significant renal artery stenosis (RAS) and recurrent, unexplained congestive heart failure or sudden, unexplained pulmonary edema ⁽⁶⁾
 - Hemodynamically significant RAS and unstable angina ⁽⁶⁾
 - Flash pulmonary edema or acute coronary syndrome with hypertension and moderate RAS with resting translesional mean gradient of ≥ 10 mm Hg and/or severe RAS. **(AUC Score 9)** ⁽⁹⁾
 - Recurrent congestive heart failure with unilateral moderate RAS with resting translesional mean gradient of ≥ 10 mm Hg **(AUC Score 5)** ⁽⁹⁾
- Hypertension
 - Hemodynamically significant RAS and accelerated/resistant/malignant hypertension, or hypertension with an unexplained unilateral small kidney, or hypertension with intolerance to medication ⁽⁶⁾
 - Fibromuscular Dysplasia with early onset of accelerated/malignant/resistant hypertension ⁽¹¹⁾
 - Resistant hypertension (uncontrolled arterial hypertension despite being on maximal (≥ 3) tolerated medical therapy including diuretic) with evidence of bilateral or solitary severe RAS **(AUC Score 7)** ⁽⁹⁾
 - Resistant hypertension with evidence of unilateral severe RAS **(AUC Score 6)** ⁽⁹⁾
 - Resistant hypertension severe unilateral RAS and high-risk lesion or complex anatomy **(AUC Score 4)** ⁽⁹⁾

- Nonproteinuric hypertension with unilateral renal artery disease ⁽¹¹⁾
- Kidney Dysfunction
 - Progressive chronic kidney disease (CKD) with bilateral (>70%) RAS or a RAS in a solitary kidney ^(6,7)
 - Chronic renal insufficiency with unilateral RAS (>70%) ^(6,7)
 - CKD Stage 4 with bilateral moderate RAS and resting mean translesion gradient of \geq 10mm Hg with kidney size > 7 cm in pole-pole length (**AUC Score 8**) ⁽⁹⁾
 - CKD Stage 4 and global renal ischemia (unilateral severe RAS with solitary kidney or bilateral severe RAS) without other explanation (**AUC Score 7**) ⁽⁹⁾
 - CKD class II with bilateral severe RAS (**AUC Score 5**) ⁽⁹⁾
 - CKD class III, stable for one year, with bilateral severe RAS (**AUC Score 5**) ⁽⁹⁾
- Hypertension and/or signs of renal dysfunction due to RAS caused by fibromuscular dysplasia ⁽⁷⁾
- Evidence of progressive renal artery occlusion ⁽¹¹⁾
- Identifiable activation of renin-angiotensin system with hyperreninemia or with unilateral renal artery stenosis, lateralization of renal vein renin ⁽¹¹⁾
- Angiotensin-dependent glomerular filtration rate ⁽¹¹⁾
- Renal artery dissection; renal artery aneurysm and renal artery atherosclerosis greater than 50% in a transplanted kidney
- Special Populations ⁽¹¹⁾:
 - Transplant renal artery stenosis with or without calcineurin inhibitors
 - Episodic, circulatory congestion with bilateral atherosclerotic renovascular disease
 - Progressive loss of glomerular filtration rate with occlusive atherosclerotic renovascular disease and no other kidney disease (ischemic nephropathy)
 - Aortic disease with renovascular protection as part of endovascular repair
 - Left-ventricular assist device
 - Radiation-induced renovascular disease with clinical syndromes
 - Other diseases: e.g., Takayasu arteritis, extrinsic vascular compression
 - Pediatric patients with mid aortic syndrome or fibromuscular variants

Note: Atherosclerotic renovascular disease with **hemodynamically insignificant stenosis** do **not** benefit from vascular intervention when treated with optimal guideline-directed medical therapy (GDMT). Symptomatic Fibromuscular dysplasia (FMD)-related renovascular disease is warranted for consideration for renal balloon angioplasty procedure, followed by stenting in dissection management or balloon angioplasty failure. ^(8,11)

LIMITATIONS FOR RENAL ARTERY INTERVENTION ⁽⁹⁾

- Resistant hypertension and unilateral moderate RAS with a mean translesional gradient of < 10 mm Hg
- Progressive CKD stage 3 to stage 4 over six months with solitary or unilateral, severe RAS, with kidney size < 7 cm in pole-to-pole length
- Resistant hypertension with unilateral chronic total occlusion of the renal artery
- Blood Pressure (BP) \geq 150/100 mm Hg on two medications (one diuretic) with severe unilateral RAS
- BP \geq 150/100 mm Hg on one hypertensive agent with severe unilateral RAS
- Solitary or bilateral severe RAS with controlled BP and normal renal function
- CKD class II with unilateral severe RAS
- Bilateral or unilateral severe RAS with controlled BC and normal renal function
- Bilateral severe RAS with chronic end stage renal disease on hemodialysis > 3 months

INDICATIONS FOR MESENTERIC ARTERY INTERVENTION

NOTE: The superior mesenteric artery (SMA) should be the primary target vessel for intervention unless the individual's SMA is not suitable for intervention or a technical result was unacceptable.⁽¹²⁾ Stenting the inferior mesenteric artery (IMA) can only be considered medically necessary if stenting the SMA and celiac artery (CA) cannot be accomplished and IMA intervention is the only alternative to open surgery.

Chronic Mesenteric Ischemia (CMI) ^(13,14)

When alternative nonvascular gastrointestinal etiologies have been reasonably excluded, and any **ONE** of the following symptoms are present:

- Postprandial abdominal pain
- Unintentional weight loss
- Food fear or avoidance
- Diarrhea

AND any **ONE** of the following duplex ultrasound stenosis screening criteria are met, **ONLY** if confirmed by computed tomography angiography (CTA), magnetic resonance angiography (MRA), or catheter angiography ⁽¹⁵⁾:

- \geq 70% stenosis (fasting peak systolic velocity (PSV) \geq 400 cm/s) or occlusion of the SMA in the presence of atherosclerotic involvement
- \geq 70% stenosis of the CA (fasting PSV \geq 320 cm/s) due to Median Arcuate Ligament Syndrome (MALS)

- $\geq 50\%$ stenosis of both the SMA (fasting PSV ≥ 295 cm/s) and CA (fasting PSV ≥ 240 cm/s)

NOTE: Critical stenosis in all three mesenteric arteries may constitute an indication for intervention in select asymptomatic patients after intensive counseling about the risks of invasive treatment compared to continued observation.

Visceral Artery Aneurysm or Pseudoaneurysm ⁽¹⁶⁾

- CA aneurysm > 2 cm in diameter
- Hepatic artery aneurysm > 2 cm in diameter or growth > 0.5 cm/year
- Jejunal and ileal artery aneurysm > 2 cm in diameter
- Splenic artery aneurysm ≥ 3 cm in diameter (all sizes in women of childbearing age)
- Superior mesenteric, gastric, gastroepiploic, colic, pancreaticoduodenal, or gastroduodenal artery aneurysm
- Symptomatic aneurysm
- Pseudoaneurysm

Hemorrhage or High-risk Bleeding ⁽¹⁷⁾

- Active bleeding or high-risk vascular lesions involving splanchnic arteries (eg, pseudoaneurysm-related gastrointestinal bleeding, post-pancreatitis hemorrhage, post-operative or traumatic arterial injury)

Median Arcuate Ligament Syndrome (MALS) ⁽¹⁸⁾

When **ALL** the following criteria are met:

- Duplex imaging with velocity profiles as per chronic mesenteric ischemia (CMI) and decrease in velocities with inspiration
- Classic symptoms consistent with CMI (eg, postprandial abdominal pain, unintentional weight loss, food fear or avoidance, diarrhea)
- CTA demonstrating CA compression with respiratory variation
- Failure of conservative management
- Multidisciplinary evaluation documented

NOTE: Endovascular stenting alone will only be authorized if the patient remains symptomatic after surgical decompression of the median arcuate ligament

INDICATIONS FOR REPEAT MESENTERIC ARTERY INTERVENTION ⁽¹⁴⁾

When **ALL** the following criteria are met:

- Recurrent ischemic symptoms
- Imaging demonstrating $\geq 70\%$ restenosis or occlusion
- Documented symptomatic improvement following prior intervention

LIMITATIONS FOR MESENTERIC ARTERY INTERVENTION ^(13,14)

Intervention is not considered medically necessary for:

- Prophylactic or preventive stenting
- Incidental imaging findings without ischemic symptoms
- Asymptomatic or surveillance-only mesenteric artery stenosis
- Single-vessel stenosis without ischemic symptoms

CODING AND STANDARDS

Codes

Angiography: 36251, 36252, 75726

Intervention: 37236, 37237, 37246, 37247

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Renal angiography is X-ray study of blood vessels to the kidney. X-rays are taken while contrast dye is injected into a catheter (a tiny tube) that has been placed into the blood vessels of the kidneys to detect any signs of blockage, narrowing, or other abnormalities affecting the blood supply to the kidneys.

Renal Artery Angioplasty is an endovascular procedure to widen narrowed or obstructed renal arteries typically to treat arterial atherosclerosis. An empty, collapsed balloon, known as a balloon catheter, is passed over a wire into the narrowed locations and then inflated to a fixed size. The balloon forces expansion of the stenosis (narrowing) within the vessel and the surrounding muscular wall, opening up the blood vessel for improved flow, and the balloon is then deflated and withdrawn. A stent may or may not be inserted at the time of ballooning to ensure the vessel remains open.

Renovascular hypertension is one of many clinical syndromes of renovascular disease, derived most often from atherosclerosis, followed by FMD. Other less common causes include renal artery aneurysm, dissection, extravascular compression, infarction, mid aortic coarctation, partial or complete renal artery coverage by stent grafts, allograft inflow obstruction, and anatomic variants. ⁽¹¹⁾

Definitions

- Hemodynamically significant RAS is defined as either ⁽⁹⁾:
 - Angiographic stenosis severity between 50-70% stenosis with resting or hyperemic mean pressure gradient ≥ 10 mm Hg
 - Angiographic stenosis severity between 50-70% stenosis with resting or hyperemic systolic pressure gradient ≥ 20 mm Hg
 - Angiographic stenosis severity between 50-70% stenosis with Renal Pd/Pa ≤ 0.8
 - Angiographic stenosis severity with $\geq 70\%$ stenosis.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

Acronyms/Abbreviations

ACE: Angiotensin-converting enzyme

ARB: Angiotensin II receptor blockers

BP: Blood pressure

CA: Celiac artery
CKD: Chronic kidney disease
CTA: Computed tomography angiography
CMI: Chronic mesenteric ischemia
DUS: Duplex ultrasonography
DSA: Digital subtraction angiography
eGFR: Estimated glomerular filtration rate
FMD: Fibromuscular dysplasia
GDMT: Guideline-directed medical therapy
IMA: Inferior mesenteric artery
MALS: Median Arcuate Ligament Syndrome
MRA: Magnetic resonance angiography
PAD: Peripheral artery disease
PSV: Peak systolic velocity
RAS: Renal Artery Stenosis
SMA: Superior mesenteric artery

SUMMARY OF EVIDENCE

Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations) ⁽⁶⁾

Study Design: The guidelines are based on a compilation of recommendations from the 2005 and 2011 ACCF/AHA guidelines. The document does not present new evidence but repackages existing recommendations to provide a complete set of guidelines in a single resource.

Target Population: The guidelines target individuals at risk for or diagnosed with renal artery stenosis (RAS), including those with hypertension, chronic kidney disease, and other related conditions.

Key Factors: Diagnostic studies are recommended for patients with early-onset hypertension, severe hypertension, accelerated or malignant hypertension, new or worsening renal function after ACE inhibitor or ARB therapy, unexplained atrophic kidney, or sudden unexplained pulmonary edema. Revascularization may be considered for asymptomatic bilateral or solitary viable kidney with significant RAS and is reasonable for patients with significant RAS and hypertension, progressive chronic kidney disease, recurrent unexplained congestive heart failure, or unstable angina. Renal stent placement is indicated for ostial atherosclerotic RAS lesions, and balloon angioplasty with bailout stent placement is recommended for fibromuscular dysplasia lesions. Vascular surgical reconstruction is indicated for patients with fibromuscular dysplastic RAS with clinical indications for intervention, atherosclerotic RAS with clinical indications for intervention, and atherosclerotic RAS in combination with pararenal aortic reconstructions.

These guidelines provide a comprehensive approach to the diagnosis and treatment of renal artery stenosis, aiming to improve patient outcomes through evidence-based recommendations.

2024 ESC Guidelines for the management of peripheral arterial and aortic diseases ⁽⁷⁾

Study Design: The guidelines are developed by the task force on the management of peripheral arterial and aortic diseases of the European Society of Cardiology (ESC). The document is endorsed by several reputable organizations, including the European Association for Cardio-Thoracic Surgery (EACTS), the European Reference Network on Rare Multisystemic Vascular Diseases (VASCERN), and the European Society of Vascular Medicine (ESVM). The guidelines are based on a critical review and evaluation of published literature, including clinical trials and meta-analyses.

Target Population: The target population for these guidelines includes patients with peripheral arterial and aortic diseases, specifically those with renal artery disease. The guidelines address both atherosclerotic and non-atherosclerotic causes of renal artery stenosis (RAS), as well as special populations such as patients with fibromuscular dysplasia.

Key Factors: Duplex Ultrasound (DUS) is recommended as the first-line imaging modality for patients with suspicion of RAS. It provides high sensitivity and specificity for detecting significant stenosis. Catheter Angiography is considered the gold standard for diagnosing RAS, allowing for additional hemodynamic measurements.

Treatment Strategy: Revascularization should be considered in patients with atherosclerotic unilateral RAS (>70%) with high-risk features and signs of kidney viability, bilateral RAS, or RAS in a solitary kidney. It is also recommended for patients with hypertension and/or signs of renal dysfunction due to RAS caused by fibromuscular dysplasia.

SCAI appropriate use criteria for peripheral arterial interventions: An update ⁽⁹⁾

Study Design: The document discusses various studies, including prospective multicenter registries and randomized controlled trials (RCTs). One notable RCT mentioned is the CORAL (Cardiovascular Outcomes in Renal Atherosclerotic Lesions) trial, which compared medical therapy alone to medical therapy combined with renal stenting.

Target Population: The studies primarily focus on patients with renal artery stenosis (RAS) and hypertension. The CORAL trial, for example, included patients with newly diagnosed renal artery stenosis and hypertension.

Key Factors: The document highlights improvements in systolic and diastolic blood pressure, renal function stabilization, and cardiac destabilization syndromes (heart failure and angina exacerbations) as benefits of renal artery stenting. The CORAL trial had limitations such as enrolling patients with moderate hypertension receiving only two antihypertensive medications and not requiring maximally tolerated doses. Hemodynamically severe renal artery stenosis is defined by specific pressure gradients and fractional flow reserve measurements. Meta-analyses show that fewer antihypertensive medications are required to achieve desired blood pressure reduction following renal artery revascularization.

ANALYSIS OF EVIDENCE

Analysis ^(6,7,9):

In summary, while all three articles agree on the importance of accurate diagnosis and medical management for RAS, they differ in their conclusions regarding the impact of revascularization on cardiovascular events and the preferred methods for revascularization. This analysis highlights the evolving understanding and approaches to managing renal artery disease.

Shared Conclusions:

- Importance of Accurate Diagnosis: All three articles emphasize the need for accurate diagnosis of RAS using non-invasive methods like DUS, CTA, and MRA, with catheter angiography reserved for inconclusive cases.
- Medical Management: They all highlight the role of medical management, particularly antihypertensive therapy, as a first-line treatment for RAS.
- Criteria for Revascularization: The articles agree on the criteria for revascularization, focusing on patients with bilateral RAS, RAS in a solitary kidney, and those with high-risk features.

Differing Conclusions

- Impact of Revascularization on Cardiovascular Events: Anderson 2013 and Mazzolai 2024 discuss the benefits of revascularization in improving blood pressure and renal function, while Klein 2017 notes that revascularization has not shown a significant impact on major adverse cardiovascular events.
- Preferred Revascularization Methods: Anderson 2013 and Mazzolai 2024 recommend renal stent placement and balloon angioplasty, with Mazzolai 2024 also suggesting open surgical revascularization for complex cases. Klein 2017 emphasizes the importance of GDMT before considering revascularization.

POLICY HISTORY

Date	Summary
March 2026	<ul style="list-style-type: none"> ● Guideline renamed from Renal Angiography and Intervention to Renal and Mesenteric Angiography and Intervention ● Added Special Notes section on documentation of clinical pathology and shared decision-making process ● Added sections on indications for mesenteric intervention, repeat mesenteric intervention, and associated limitations
July 2025	<ul style="list-style-type: none"> ● Added a Summary of Evidence and Analysis of Evidence
May 2025	<ul style="list-style-type: none"> ● This guideline replaces Evolent Clinical Guideline 7324 for

Date	Summary
	Renal Angiography <ul style="list-style-type: none"> • This guideline replaces Evolent Clinical Guideline 7325 for Renal Artery Intervention

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity

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