



# **Cohere Medicare Advantage Policy – Catheter-Based Angiogram**

*Clinical Policy for Medical Necessity Review*

**Version:** 3

**Revision Date:** June 26, 2025

# Important Notices

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## Policy Information:

**Specialty Area:** Cardiovascular Disease

**Policy Name:** Cohere Medicare Advantage Policy – Catheter-Based Angiogram

**Type:** ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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# Medical Necessity Criteria

## **Service: Catheter-Based Angiogram**

### **Related CMS Documents**

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.<sup>1-8</sup>

- [Local Coverage Determination \(LCD\). Dialysis access maintenance \(L34062\)](#)<sup>1</sup>
  - [Billing and Coding: Dialysis access maintenance \(A56460\)](#)<sup>2</sup>
- [Local Coverage Determination \(LCD\). Thoracic aortography and carotid, vertebral, and subclavian angiography \(L35035\)](#)<sup>3</sup>
  - [Billing and Coding: Thoracic aortography and carotid, vertebral, and subclavian angiography \(A56631\)](#)<sup>4</sup>
- [Local Coverage Determination \(LCD\). Diagnostic abdominal aortography and renal angiography \(L35092\)](#)<sup>5</sup>
  - [Billing and Coding: Diagnostic Abdominal aortography and renal angiography \(A56682\)](#)<sup>6</sup>
- [Local Coverage Determination \(LCD\). Aortography and peripheral angiography \(L36767\)](#)<sup>7</sup>
  - [Billing and Coding: Aortography and peripheral angiography \(A57056\)](#)<sup>8</sup>

### **Description**

Catheter-based angiography of non-cardiac arteries is a procedure in which a catheter is inserted into blood vessels to assess vascular structures and identify blockages. The provider can then evaluate the suitability of vessels for interventions such as angioplasty, atherectomy, stent placement, or creation and maintenance of vascular access for dialysis. After a needle or catheter is inserted, contrast dye is injected, and images are generated to facilitate clinical decision-making.<sup>9</sup>

## Medical Necessity Criteria

### Indications

**Catheter-based angiogram** is considered appropriate if **ANY** of the following is **TRUE**:

- The patient is experiencing chronic limb-threatening ischemia (CTLI) with **ANY** of the following<sup>9,10</sup>:
  - Gangrene; **OR**
  - Ischemic rest pain; **OR**
  - Non-healing wounds; **OR**
- The patient is experiencing symptomatic (effort-related) peripheral artery disease (PAD) including **ALL** of the following<sup>11</sup>:
  - Intermittent claudication characterized by exertional muscle pain which is relieved by rest; **AND**
  - Physical exam findings indicating reduced blood flow (e.g., decreased or absent pulses); **AND**
  - Ankle-brachial index (ABI) greater than or equal to 0.90 or toe-brachial index (TBI) greater than or equal to 0.70; **OR**
- Lower extremity (LE) (popliteal, femoral) aneurysm<sup>11</sup>; **OR**
- Pre-procedure (e.g., TAVR) that requires arterial access and the patient has confirmed or suspected arterial blockage or other arterial disease<sup>11</sup>; **OR**
- The patient is experiencing non-limb-threatening peripheral artery disease (PAD) with lifestyle-limiting symptoms and **ALL** of the following:
  - The patient has failed optimal medical therapy<sup>9,10,12</sup>; **AND**
  - **ALL** of the following:
    - Revascularization is being considered; **AND**
    - **ANY** of the following is **TRUE**:
      - MRA, CTA, or Doppler testing is abnormal (suggesting greater than 75% stenosis) or has not achieved diagnostic results; **OR**
      - An invasive angiogram has been considered an appropriate initial test; **OR**
      - Noninvasive studies for anatomic assessment (e.g., CTA and/or MRA) are perceived to be a greater risk to the patient than invasive angiography; **OR**
- The patient requires an evaluation for dialysis access maintenance of an arteriovenous (AV) fistula, including **ANY** of the following<sup>1</sup>:
  - Compromised flow with threatened occlusion; **OR**

- Recent thrombosis of AV dialysis access; **OR**
- Management of structural abnormalities such as pseudoaneurysms/aneurysms; **OR**
- Clinical findings including **ANY** of the following:
  - Venous outflow impediment clinical findings including **ANY** of the following:
    - Elevated venous pressure in the AV dialysis access; **OR**
    - Elevated venous/arterial ratio (static venous pressure ratio above 40%); **OR**
    - Prolonged bleeding following needle removal; **OR**
    - Inefficient dialysis; **OR**
    - Recirculation percentage greater than 10–15%; **OR**
    - Development of pseudoaneurysm(s); **OR**
    - Swelling of the extremity, face, or neck; **OR**
    - Development of large superficial collateral venous channels; **OR**
    - Loss of "machine-like" bruit (i.e., short sharp bruit); **OR**
    - Abnormal physical findings, specifically pulsatile graft/fistula or loss of thrill; **OR**
  - Arterial inflow impediment clinical findings including **ANY** of the following:
    - Low pressure in graft even when outflow is manually occluded; **OR**
    - Ischemic changes of the extremity (steal syndrome); **OR**
    - Diminished intra-access flow; **OR**
- The patient requires percutaneous transluminal angioplasty (PTA) and **ALL** of the following:
  - Documentation supporting the presence of residual, hemodynamically significant stenosis, generally greater than 50% of the vessel diameter; **AND**
  - Clear documentation of the site and extent of any hemodynamically significant stenosis; **OR**
- The patient requires venous PTA to treat stenoses anywhere from the arterial inflow through the vena cava (most commonly at the level of the venous anastomosis for synthetic graft accesses); **OR**
- The procedure is an abdominal aortography or abdominal angiography as indicated by **ANY** of the following<sup>5,7</sup>:
  - Acute traumatic abdominal injury; **OR**
  - Aneurysm and other primary vascular abnormalities; **OR**

- Occlusive disease, including evaluation for acute or chronic intestinal ischemia; **OR**
- Acute GI hemorrhage; **OR**
- Congenital anomaly; **OR**
- Prior to arterial interventional procedures or open surgical procedures; **OR**
- The procedure is a stand-alone renal angiography as indicated by **ANY** of the following:
  - Severe or difficult-to-control renal hypertension (e.g., progressive renal insufficiency, hypertension not controlled by 3 medications)<sup>5</sup>; **OR**
  - Renal neoplasm<sup>5</sup>; **OR**
  - Hematuria of unknown cause<sup>5</sup>; **OR**
  - Abnormal kidney imaging involving radioisotopes<sup>5</sup>; **OR**
  - Renal artery stenosis, aneurysm, trauma, or other intrinsic defects prior to renal arterial intervention<sup>5</sup>; **OR**
  - Renovascular occlusive disease (e.g., renal artery stenosis, severe or difficult to control renal hypertension, hypertension not controlled by 3 medications, or progressive renal insufficiency)<sup>7</sup>; **OR**
  - Renal aneurysm<sup>7</sup>; **OR**
  - Renovascular trauma<sup>7</sup>; **OR**
  - Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis<sup>7</sup>; **OR**
  - Renal neoplasm<sup>7</sup>; **OR**
  - Hematuria of unknown cause<sup>7</sup>; **OR**
  - Pre- and postoperative evaluations for renal transplantation<sup>7</sup>; **OR**
  - Other intrinsic defects prior to interventional procedures on the renal arteries<sup>7</sup>; **OR**
  - Abnormal kidney imaging involving radioisotopes<sup>7</sup>; **OR**
  - Prior to interventional procedures on the renal arteries<sup>7</sup>; **OR**
- The procedure is a non-selective renal angiography performed at the time of cardiac catheterization and **ALL** of the following<sup>7</sup>:
  - The clinical index of suspicion for atherosclerotic renal artery stenosis (RAS) is high as indicated by **ANY** of the following:
    - Onset of severe hypertension before age 30 or severe hypertension after age 55; **OR**
    - Exacerbation of previously well-controlled hypertension; **OR**

- Resistant hypertension (i.e., failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic); **OR**
- Malignant hypertension (hypertension with coexistent evidence of acute end-organ damage; i.e., acute renal failure, acutely decompensated congestive heart failure, new visual or neurological disturbance, and/or advanced [grade III to IV] retinopathy); **OR**
- New azotemia or worsening renal function after the administration of an ACE inhibitor or an angiotensin receptor-blocking agent; **OR**
- Unexplained atrophic kidney (7 to 8 cm) or a discrepancy in size between the two kidneys of greater than 1.5 cm. The atrophy should be otherwise unexplained by, for example, a prior history of chronic pyelonephritis, reflux nephropathy, or trauma; **OR**
- Sudden, unexplained pulmonary edema (especially in azotemic patients); **OR**
- Unexplained renal failure, including patients starting renal replacement therapy (dialysis or renal transplantation); **AND**
- There are reasonable anticipated therapeutic implications for which the results of this angiogram will be used; **AND**
- The results of noninvasive imaging studies cannot be obtained or are inconclusive; **OR**
- The procedure is a renal angiography or lower extremity angiography performed at the time of an interventional procedure and **ALL** of the following<sup>57</sup>:
  - At least one indication for medical necessity for a stand-alone lower extremity or renal angiography is met; **AND**
  - **ANY** of the following:
    - **ALL** of the following:
      - No prior catheter-based angiographic study is available; **AND**
      - A full diagnostic study is performed; **AND**
      - The decision to intervene is based on the diagnostic study; **OR**
    - A prior study is available with **ANY** of the following:
      - The patient's condition with respect to the clinical indication has changed since the prior study; **OR**
      - There is inadequate visualization of the anatomy or pathology; **OR**
      - There is a clinical change during the interventional procedure that requires new evaluation outside the target area of intervention; **OR**



- The procedure is a stand-alone lower extremity angiography as indicated by a pre-procedure clinical assessment that includes documentation of **ALL** of the following<sup>5,7</sup>:
  - An invasive intervention is planned; **AND**
  - A prior non-invasive study was completed and indicates further study is needed by angiography for the planned intervention; **AND**
  - The patient has **ANY** of the following conditions
    - Arterial embolism; **OR**
    - Acute or chronic ischemia<sup>5,7</sup>; **OR**
    - Peripheral vascular disease (including claudication)<sup>5,7</sup>; **OR**
    - Aneurysm<sup>5,7</sup>; **OR**
- The procedure is a thoracic aortography or carotid, vertebral, or angiography and **ANY** of the following<sup>3,7</sup>:
  - Documented symptoms of ischemic cerebral disease; **OR**
  - Documented results from previous noninvasive test(s) indicating severely stenotic carotid disease or severely ulcerated carotid disease; **OR**
  - Medical history consistent with known or suspected trauma, tumor, or other intracranial anomalies; **OR**
  - Medical history consistent with upper extremity claudication, acute or chronic arterial trauma, thoracic outlet obstruction disease, certain vasculitis, and subclavian steal; **OR**
  - Surgical or percutaneous correction of the occlusive disease must be beneficial to the candidate's clinical status.

## Non-Indications

**Catheter-based angiogram** is not considered appropriate if **ANY** of the following is **TRUE**:

- The procedure is an evaluation for dialysis access maintenance of an arteriovenous (AV) fistula, and **ANY** of the following<sup>1</sup>:
  - In the absence of clinical findings suggesting the need to re-establish appropriate flow in a dialysis fistula, it is seldom reasonable and necessary to perform diagnostic angiography or sonographic confirmatory studies as part of the decision to treat; **OR**
  - Percutaneous interventions to treat total occlusion of graft due to thrombus of more than one year in duration; **OR**
  - Angioplasty of vessels not documented to be stenosed significantly by angiography or ultrasound; **OR**

- Dilation of the graft anastomotic site will be considered either arterial or venous, but not both; **OR**
- Revision procedures that are not for repair and/or maintenance of an existing fistula, but are performed as part of a planned staged procedure to create a new fistula; **OR**
- The procedure is a catheter-based renal angiography for renal artery stenosis (RAS) and there is no prior non-invasive renal artery study that is either inconclusive or unavailable, except in patients with fibromuscular dysplasia or renal artery aneurysms where there may be branch involvement<sup>7</sup>; **OR**
- The procedure is a routine non-selective renal arteriography performed at the time of cardiac catheterization in the absence of accepted clinical indications that support medical necessity<sup>7</sup>; **OR**
- The procedure is a repeat angiography and **ANY** of the following<sup>3,5,7</sup>:
  - Appropriate non-invasive tests have not been performed; **OR**
  - There has been no trial of or change in medical management unless the patient is deemed unstable and in need of some type of surgical intervention; **OR**
- The procedure is a second diagnostic angiogram (fluoroscopic or computer tomographic) in the absence of documentation to support the medical necessity of repeating the study.<sup>3</sup>

**Catheter-based angiography** may not be considered appropriate if **ANY** of the following is true:

- The procedure is a diagnostic aortography/angiography and **ANY** of the following<sup>3,5,7</sup>:
  - Uncorrectable coagulopathy or thrombocytopenia; **OR**
  - Clinically significant sensitivity to iodinated contrast material; **OR**
  - Renal insufficiency based on the estimated glomerular filtration rate (eGFR).

## **Definitions**

- **Ischemic Rest Pain:** Typically described as affecting the forefoot and is often made worse with recumbency while being relieved by dependency. It should be present for greater than 2 weeks and be associated with one or more abnormal hemodynamic parameters. These parameters include an ankle-brachial index (ABI) less than 0.4 (using higher of the dorsalis pedis [DP] and posterior tibial [PT] arteries), absolute highest AP less than 50

mm Hg, absolute TP less than 30 mm Hg, transcutaneous partial pressure of oxygen (TcPO<sub>2</sub>) less than 30 mm Hg, and flat or minimally pulsatile pulse volume recording (PVR) waveforms (equivalent to Wiffl ischemia grade 3).<sup>5</sup>

### **Level of Care Criteria**

Inpatient and Outpatient

### **Procedure Codes (CPT/HCPCS)**

<b>CPT/HCPCS Code</b>	<b>Code Description</b>
36245	Insertion of catheter into first order abdominal branch of artery, within a vascular family
36246	Insertion of catheter into initial second order abdominal branch of artery, within a vascular family
36247	Insertion of catheter into initial third order abdominal branch of artery, within a vascular family
37252	Radiologic supervision and interpretation with the IVUS procedure and are used for procedures involving both arteries and/or veins. Reported once per procedure for the first vessel studied with IVUS.
37253	Radiologic supervision and interpretation with the IVUS procedure and are used for procedures involving both arteries and/or veins. Each initial vessel.
75710	Angiography, extremity, unilateral, radiological
75716	Angiography, extremity, bilateral, radiological

**Disclaimer:** S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

## **Evaluation of Clinical Harms and Benefits**

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for catheter-based angiogram may include:

- Adverse effects from delayed or denied treatment, such as increased symptoms, complications, and adverse outcomes, especially in undiagnosed or incorrectly diagnosed patients. The 2024 European Society of Cardiology guidelines note that peripheral arterial and aortic diseases (PAAD) are highly prevalent and increase mortality and morbidity from cardiovascular disease.<sup>11</sup> Moreover, PAAD is often underdiagnosed and undertreated, while early diagnosis improves outcomes.
- Risks from inappropriate procedures include exposure to ionizing radiation and iodinated contrast. The 2024 American College of Cardiology guidelines note that patients undergoing invasive angiography risk contrast nephropathy, adverse outcomes related to radiation exposure, procedural discomfort, and access site complications, including bleeding events.<sup>10</sup>

The clinical benefits of using these criteria for catheter-based angiogram may include:

- Improved patient selection, resulting in better long-term outcomes. Catheter-based non-cardiac angiogram is recommended for patients expected to undergo revascularization procedures. Moreover, catheter-based angiogram is also recommended when noninvasive imaging has not been definitive.<sup>10,11</sup>

- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

# Medical Evidence

Allen et al. (2022) compared outcomes (restenosis) in 150 patients with severe lifestyle-limiting claudication or critical limb ischemia undergoing femoropopliteal revascularization who received catheter-based angiography alone or in combination with intravascular ultrasound (IVUS). Blockage recurrence (restenosis) rates were higher 12 months after revascularization in patients who received angiography alone compared to patients who received angiography and IVUS; restenosis was seen in 72.4% and 55.4% of patients treated with angiography alone and angiography with IVUS, respectively. The authors suggested that IVUS may provide more accurate artery diameter and lesion length measurements, leading to selection of more appropriately sized devices, including drug-coated balloons.<sup>13</sup>

In the 2024 American College of Cardiology/American Heart Association joint committee on clinical practice guideline for the management of lower extremity peripheral artery disease, Gornik et al. recommended catheter angiography after initial non-invasive diagnostic testing when further definition of vascular structure is required, for example in planning revascularization or when peripheral arterial disease (PAD) is suspected and the ankle-brachial index (ABI) test is inconclusive. They note that catheter angiography carries several risks, including exposure to potentially carcinogenic radiation and contrast agents, as well as catheter-specific risks including arterial injury and bleeding. They recommend restriction of this procedure to patients with severe PAD and when revascularization is being considered. Specific recommendations for catheter-based angiography include for patients with functionally limiting claudication who are not responsive to disease management and who are being considered for revascularization, in order to assess anatomy and disease severity and to plan revascularization, and in patients with chronic limb-threatening ischemia. Catheter angiography is not recommended for PAD patients when revascularization is not being considered.<sup>10</sup> The European Society of Cardiology 2024 guidelines for the management of peripheral arterial and aortic diseases similarly recommend restriction of catheter-based angiography to chronic limb-threatening ischemia patients and only PAD patients undergoing revascularization.<sup>11</sup>

Gerhard-Herman et al. (2017) developed the 2016 AHA/ACC guideline for the management of patients with lower extremity peripheral artery disease. Invasive angiography is recommended in a patient with critical limb ischemia in whom revascularization is considered. The use of noninvasive imaging can create a delay in crucial treatment for the patient. A Class IIa (Moderate Strength of Recommendation) Level of Evidence Expert Opinion rating was given to invasive angiography in patients with lifestyle-limiting claudication with an inadequate response to guideline-directed medical treatment (GDMT) when revascularization is considered. The risk of invasive angiography can be less than in noninvasive studies, particularly in advanced chronic kidney disease, as the contrast dose is lower.<sup>12</sup>

Woo et al. (2022) published the Society of Vascular Surgery's appropriate use criteria for the management of intermittent claudication. 2280 unique intermittent claudication treatment scenarios were rated. Invasive treatment recommendations were made for patients who have completed exercise therapy, are nonsmokers, and are on optimal medical therapy with severe lifestyle limitations. The group stated unclear benefits and possible harms related to invasive intervention in the infrapopliteal segment for intermittent claudication.<sup>14</sup>

Conte et al. (2019) developed global vascular guidelines for the management of chronic limb-threatening ischemia. The group proposed a new anatomic scheme for threatened limbs, the Global Limb Anatomic Staging System (GLASS). This integrated, limb-based approach is based on a set of clinical assumptions and simplified approaches to stratification. The group concluded that there is a strong recommendation for revascularization to all average-risk patients with advanced limb-threatening conditions and significant perfusion deficits.<sup>9</sup>

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# Clinical Guideline Revision History/Information

Original Date: May 31, 2024		
Review History		
Version 2	06/11/2024	422.101 Disclaimer Added
Version 2.1	03/18/2025	Updated policy per CMS revisions for 2/6/2025 Updated Effective date Updated Links and Bookmarks
Version 3	06/26/2025	Annual Review.  Changed title of policy (from "Catheter-Based Angiogram, Lower Extremity Arteries" to "Catheter-Based Angiogram")  Revised indications and non-indications to better align with LCDs.  Added note detailing ischemic rest pain.  Updated references, Evaluation of Clinical Harms and Benefits, and Medical Evidence sections.