



Cohere Medicare Advantage Policy – Catheter-Based Angiogram, Lower Extremity Arteries

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: June 11, 2024

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Guideline Information:

Specialty Area: Cardiovascular Disease

Guideline Name: Cohere Medicare Advantage Policy - Catheter-Based Angiogram, Lower Extremity Arteries

Date of last literature review: 6/11/2024

Document last updated: 6/11/2024

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

Table of Contents

Important Notices	2
Table of Contents	3
Medical Necessity Criteria	4
Service: Catheter-Based Angiogram, Lower Extremity Arteries	4
Benefit Category	4
Recommended Clinical Approach	4
Evaluation of Clinical Benefits and Potential Harms	4
Medical Necessity Criteria	6
Indications	6
Non-Indications	10
Level of Care Criteria	11
Procedure Codes (CPT/HCPCS)	11
Medical Evidence	12
References	14
Clinical Guideline Revision History/Information	15

Medical Necessity Criteria

Service: Catheter-Based Angiogram, Lower Extremity Arteries

Benefit Category

Inpatient Hospital Services
Outpatient Hospital Services

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Recommended Clinical Approach

Catheter-based angiography may be appropriate as the initial advanced imaging modality when the clinician determines that there is a high likelihood that the patient is a candidate for a minimally invasive intervention (e.g., angioplasty, atherectomy, or stent placement).¹

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 catheter-based angiogram procedures for lower extremity arteries. 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 catheter-based angiograms can lead to increased symptoms and complications, especially in patients with significant peripheral artery disease (PAD). The CMS Local Coverage Determination (LCD) for Cardiac Catheterization and Coronary Angiography (L33557) highlights the necessity of timely procedures to avoid adverse outcomes in patients with significant cardiovascular conditions.¹ The ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS

2012 Appropriate Use Criteria for Diagnostic Catheterization also emphasize the importance of timely diagnostic interventions.²

- 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. Conte et al. highlight the importance of appropriate use criteria in managing chronic limb-threatening ischemia to minimize surgical risks.⁵
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Proper use of catheter-based angiogram criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The CMS LCD for Aortography and Peripheral Angiography (L36767) underscores the importance of appropriate diagnostic procedures to prevent unnecessary healthcare utilization.⁴

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to catheter-based angiograms for lower extremity arteries 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. Gerhard-Herman et al. noted the diagnostic accuracy of angiography in managing patients with lower extremity PAD.³
- Enhanced diagnostic accuracy: This is crucial for complex vascular conditions where traditional diagnostic methods may pose additional risks. Angiography offers the advantage of detailed vascular imaging, aiding in decision-making regarding interventions.³
- Reduction in complications and adverse effects: Proper use of catheter-based angiogram criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Conte et al. highlighted the importance of angiography in reducing complications by providing crucial diagnostic information in chronic limb-threatening ischemia management.⁵
- Enhanced overall patient satisfaction: Ensuring that catheter-based angiograms are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. The CMS LCD for Diagnostic Abdominal Aortography and

Renal Angiography (L35092) supports the necessity of appropriate use criteria to minimize healthcare costs and prevent 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, 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

- **Catheter-based angiogram, lower extremity arteries** is considered appropriate if **ANY** of the following is **TRUE**²⁻³:
- ◆ Extra-cardiac angiography (e.g., injection of the abdominal aorta, carotid, iliofemoral, or renal arteries) performed for **ANY** of the following conditions with cardiac catheterization (meeting its own indications):
 - The patient has a specific medical condition that would have been appropriate to require angiography independent of cardiac catheterization (e.g., extra-cardiac angiograms would have been performed at this point in the patient's medical course even if cardiac catheterization had not been performed); **OR**
 - There are reasonably anticipated therapeutic implications for which these angiograms will be used; **OR**
 - The service is specifically requested (and documented in the patient's medical record) by the treating or referring physician; **OR**

- ◆ The patient requires a **diagnostic angiography** when non-invasive tests are inconclusive or not available and **ANY** of the following is **TRUE**^{1,4}:
 - Angiography can be performed during a separate session from an interventional procedure if medically necessary to define anatomy and pathology; **OR**
 - Diagnostic angiography is preceded by non-invasive tests (e.g., duplex ultrasonography, CT angiography, MRA) when these tests are inconclusive or unavailable; **OR**
 - Repeat angiography is medically necessary with new, incapacitating symptoms; **OR**
 - Repeat angiography is medically necessary if the patient is deemed unstable and requires surgical intervention; **OR**
- ◆ The patient is experiencing **chronic limb-threatening ischemia** with **ANY** of the following⁴⁻⁵:
 - Gangrene; **OR**
 - Ischemic rest pain*; **OR**
 - Non-healing wounds; **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 therapy⁴; **AND**
 - Revascularization is being considered; **AND**
 - **ANY** of the following is **TRUE**:
 - MRA, CTA, Doppler testing is abnormal (suggesting greater than 75% stenosis) or has not achieved diagnostic results; **OR**
 - Noninvasive testing is unavailable; **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 angiography³; **OR**
- ◆ The patient requires an **evaluation for dialysis access maintenance** if located in the lower extremity⁶; **OR**
- ◆ The patient requires **ANY** of the following for **diagnostic abdominal aortography, renal angiography, or peripheral angiography**⁷:
 - Abdominal aortography or angiography as indicated by **ANY** of the following:

- 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**
- Stand-alone renal angiography as indicated by **ANY** of the following:
 - Severe or difficult-to-control renal hypertension (e.g., progressive renal insufficiency, resistant hypertension); **OR**
 - Renal neoplasm; **OR**
 - Hematuria of unknown cause; **OR**
 - Abnormal kidney imaging involving radioisotopes; **OR**
 - Renal artery stenosis, aneurysm, trauma, or other intrinsic defects prior to renal arterial intervention; **OR**
- Diagnostic renal angiography or lower extremity angiography performed at the time of an interventional procedure is separately reportable if at least one indication for medical necessity for a stand-alone lower extremity or renal angiography is met with **ANY** 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**

- Stand-alone lower extremity angiography as indicated by a pre-procedure clinical assessment that includes **ALL** of the following:
 - 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 for **ANY** of the following:
 - Blood vessel occlusion, or embolization is needed for **ANY** of the following:
 - Laceration; **OR**
 - Blunt trauma; **OR**
 - Infection; **OR**
 - Intractable bleeding; **OR**
 - Arteriovenous fistula or malformation; **OR**
 - Treatment of malignancy (e.g., hepatic artery embolization); **OR**
 - ◆ Uterine artery embolization for the presence of intractable bleeding after medical therapy (hormone therapy); **OR**
 - ◆ Confirmed uterine fibroids (e.g., endometrial sampling, imaging) and **ALL** of the following:
 - The patient desires a uterine sparing procedure; **AND**
 - Persistent symptoms lasting 3 or more consecutive months despite medical management (e.g., hormonal therapy, NSAIDs) if medically appropriate and not contraindicated; **OR**
 - ◆ Prostatic artery embolism (PAE) for intractable bleeding; **OR**
 - ◆ Geniculate artery embolization (GAE) for intractable knee hemarthrosis; **OR**
 - ◆ Aneurysm; **OR**
 - ◆ The patient has **general diagnostic needs** for **ANY** of the following involving abdominal, pelvic, or lower extremity arterial vasculature⁴:

- Acute or chronic arterial trauma; **OR**
- Certain vasculitis; **OR**
- Tumor.

*Ischemic rest pain is 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 (TcPO₂) less than 30 mm Hg, and flat or minimally pulsatile pulse volume recording (PVR) waveforms (equivalent to Wifl ischemia grade 3).^{1a}

Non-Indications

- **Catheter-based angiogram, lower extremity arteries** is not considered appropriate if **ANY** of the following is **TRUE**⁴:
- ◆ The patient is unwilling to undergo interventional therapy if angiography discovers disease; **OR**
 - ◆ The procedure risk is high due to concurrent medical problems (e.g., severe hypertension, uncorrectable coagulopathy, significant sensitivity to iodinated contrast material); **OR**
 - ◆ Routine non-selective renal arteriography without prior non-invasive studies; **OR**
 - ◆ For use in conditions like renal insufficiency, congestive heart failure, or certain connective tissue disorders.

NOTE: Catheter-based angiogram, lower extremities may not be considered appropriate if **ANY** of the following is **TRUE**^{2,8}:

- ◆ Severe allergy to contrast media; **OR**
- ◆ Severe renal insufficiency; **OR**
- ◆ The patient uses metformin; **OR**
- ◆ There was prior vascular surgery at the proposed access site (e.g., femoral access at the site of a prior femoral reconstruction); **OR**
- ◆ There is a known or suspected arterial aneurysm or significant vascular anomaly (e.g., AV fistula) at the proposed access site.

Level of Care Criteria

Inpatient and Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
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

Medical Evidence

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. This was a Class I (Strong) recommendation with Level of Evidence as Expert Opinion. 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 in the invasive scenario. The committee concluded that invasive and noninvasive angiography is not recommended in asymptomatic peripheral arterial disease (Class of Recommendation: Harm; Level of Evidence B-R (Randomized)).³

Woo and colleagues (2022) published the Society of Vascular Surgery 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.⁹

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. They make a strong recommendation for revascularization to all average-risk patients with advanced limb-threatening conditions and significant perfusion deficits. There was a weak recommendation for revascularization in average-risk patients with intermediate limb threat (based on a scoring tool such as Wlfi).

It is stated that a more in-depth study is required regarding the relationship between regional ischemia and patterns of infrapopliteal and pedal disease.¹⁵

References

1. Centers for Medicare and Medicaid Services (CMS). Local coverage determination: Cardiac catheterization and coronary angiography (L33557). Revision Effective Date October 1, 2019. Accessed May 22, 2024. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
2. Patel MR, Bailey SR, Bonow RO, et al. ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 Appropriate Use Criteria for Diagnostic Catheterization. *J Am Coll Cardiol*. 2012;59(22):1995–2027. doi: 10.1016/j.jacc.2012.03.003.
3. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC guideline on the management of patients With lower extremity peripheral artery disease. *J Am Coll Cardiol*. 2017;69 (11). <http://dx.doi.org/10.1016/j.jacc.2016.11.007>.
4. Centers for Medicare and Medicaid Services (CMS). Local coverage determination: Aortography and peripheral angiography (L36767). Revision Effective Date October 1, 2019. Accessed May 27, 2024. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
5. Conte MS, Bradbury AW, Kolh P, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. *J Vasc Surg*. 2019;69(6):3S–125S.e40. doi: 10.1016/j.jvs.2019.02.016.
6. Centers for Medicare and Medicaid Services (CMS). Local coverage determination: Dialysis access maintenance (L34062). Revision Effective Date February 1, 2024. Accessed May 27, 2024. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
7. Centers for Medicare and Medicaid Services (CMS). Local coverage determination: Diagnostic abdominal aortography and renal angiography (L35092). Revision Effective Date November 7, 2019. Accessed May 27, 2024. <https://www.cms.gov/medicare-coverage-database/search.aspx>.
8. Wang C, Asch D, Callahan MJ, et al. ACR manual on contrast media. Published 2023. Accessed May 26, 2024. https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf.
9. Woo K, Syracuse JJ, Klingbell K, et al. Society for Vascular Surgery appropriate use criteria for management of intermittent claudication. *J Vasc Surg*. 2022; 76(1): 3–22 e21. doi: 10.1016/j.jvs.2022.04.012. PMID: 35470016.

Clinical Guideline Revision History/Information

Original Date: May 31, 2024		
Review History		
Version 2	6/11/2024	422.101 Disclaimer Added