



Evolut Clinical Guideline 7319 for Percutaneous Iliocaval Interventions

<u>Guideline Number:</u> Evolut CG 7319	<u>Applicable Codes</u>	
<i>"Evolut" refers to Evolut Health LLC and Evolut Specialty Services, Inc.</i> <i>© 2019 - 2026 Evolut. All rights Reserved.</i>		
<u>Original Date:</u> September 2019	<u>Last Revised Date:</u> July 2025	<u>Implementation Date:</u> January 2026

TABLE OF CONTENTS

STATEMENT 2
 GENERAL INFORMATION 2
 PURPOSE 2
 CLINICAL REASONING 2

INDICATIONS 2
 LIMITATIONS 3
 CONTRAINDICATIONS 3

CODING AND STANDARDS 3
 CODES 4
 APPLICABLE LINES OF BUSINESS 4

BACKGROUND 4
 DEFINITIONS 4
 AUC SCORE 4
 ACRONYMS/ABBREVIATIONS 5

SUMMARY OF EVIDENCE 5

ANALYSIS OF EVIDENCE 6

POLICY HISTORY 7

LEGAL AND COMPLIANCE 7
 GUIDELINE APPROVAL 7
 Committee 7
 DISCLAIMER 7

REFERENCES 9

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 Percutaneous Iliocaval Intervention.

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)

INDICATIONS

- **Acute ilio caval thrombophlebitis:**
 - **Can be treated by lytic therapy, mechanical thrombectomy, a combination of both, surgical thrombectomy or bypass. If an underlying lesion is encountered, it may be stented. Angioplasty alone is not sufficient (6)**
- **When both of the following criteria are met:**

- Patients have undergone at least 3 months of conservative treatment (including pain management, compression stockings and wound care if ulceration is present) ⁽⁷⁾
- Results from a diagnostic venogram and intravascular ultrasound performed in the anterior-posterior (AP) and multiplanar positions, with at least one in the left lateral decubitus, demonstrate either of the following ⁽⁸⁾:
 - Iliocaval compression related to external compression from malignancy, bone spurs, arterial grafts, or other causes of external compression not due to arterial compression syndromes
 - A fixed (Non-dynamic; see Definitions) iliofemoral venous stenosis/occlusion with a $\geq 50\%$ area or $\geq 61\%$ diameter reduction ⁽⁷⁻⁹⁾

Limitations ⁽⁷⁻⁹⁾

- Incidentally identified venous stenosis of the iliac veins or inferior vena cava on imaging performed for other reasons
- Prophylactic stent placement for non-thrombotic iliac vein (NILV) in asymptomatic patients to prevent possible future venous thromboembolism events
- Dynamic lesions, where the severity of stenosis varies with factors that include hydration, respiration, position, Valsalva maneuvers, phasicity, or variation in intra-abdominal pressure
- NILV in a patient with mild symptoms or findings e.g. CEAP 1-2 or C3 where swelling is limited to the calf and is controlled with stockings
- NILV in the presence of bilateral leg swelling in patients with other reasons for edema
- NILV in patients 80 years or older with recent onset of bilateral leg swelling
- NILV in non-ambulatory individuals
- Post thrombotic iliac vein lesions for C3 disease in non-ambulatory individuals

Contraindications ^(7,8)

- Active Infection: Presence of systemic or local infections at the planned intervention site
- Severe Comorbidities: Conditions that significantly increase procedural risk or limit life expectancy
- Uncorrected Coagulopathy: Bleeding disorders that cannot be managed appropriately

CODING AND STANDARDS

Codes

37238, 37239

Applicable Lines of Business

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

BACKGROUND

Definitions

- Chronic iliofemoral venous obstruction is a medical condition related to chronic narrowing or occlusion of the iliac or common femoral veins usually as a result of a prior deep vein thrombophlebitis but also non-thrombotic iliac vein lesions
- Non-thrombotic iliac vein lesions are related to external compression of the iliac veins usually by iliac arteries
- May Thurner or Crockett syndrome involves left iliac vein stenosis as a result of the left iliac vein being crossed by the right iliac artery
- A fixed Non-Dynamic iliac vein stenosis/occlusion is a stenosis which does not vary dependent on the patient’s position, state of hydration, breathing, or changes in intra-abdominal pressure. It is usually a result of a post thrombotic event but can also be due to an NILV. It is generally considered safer to stent a fixed non-dynamic lesion since stent migration is less likely and it is more likely that the lesion will be responsible for symptoms.

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. ⁽³⁾

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

Acronyms/Abbreviations

AUC: Appropriate use criteria

CEAP: Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)

NILV: Non thrombotic iliac vein lesion/s

SUMMARY OF EVIDENCE

ACR Appropriateness Criteria® Radiologic Management of Iliofemoral Venous Thrombosis ⁽⁶⁾

Study Design: This document is an appropriate use criteria guideline from the American College of Radiology (ACR) on the radiologic management of iliofemoral venous thrombosis. It includes evidence-based guidelines reviewed annually by a multidisciplinary expert panel.

Target Population: Patients with iliofemoral venous thrombosis, including those with mild to severe symptoms, pregnant patients, and those with underlying conditions such as May-Thurner syndrome.

Key Factors: Prevent morbidity from venous occlusive disease and mortality from pulmonary embolism. Anticoagulation remains the standard of care, with catheter-based interventions or surgery in select circumstances. Various scenarios are addressed, including acute iliofemoral DVT with mild symptoms, moderate to severe symptoms, femoropopliteal DVT, and limb-threatening ischemia. Based on recent prospective trials, the guidelines provide recommendations for anticoagulation, catheter-directed thrombolysis, graded compression stocking therapy, and surgical thrombectomy. Includes results from trials such as the CaVenT and ATTRACT trials, which evaluated the effectiveness of catheter-directed thrombolysis.

European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs ⁽⁷⁾

Study Design: This document is a clinical practice guideline from the European Society for Vascular Surgery (ESVS) on the management of chronic venous disease (CVD) of the lower limbs. It includes a comprehensive review of the literature, methodology for producing guidelines, and recommendations based on evidence.

Target Population: The guidelines are intended for vascular and general surgeons, vascular physicians, interventional radiologists, phlebologists, dermatologists, and emergency medicine physicians treating patients with CVD of the lower limbs.

Key Factors: To update the existing ESVS guidelines on the management of CVD, focusing on the lower limbs. Cover diagnosis, conservative management, interventions for superficial venous incompetence, and management of venous ulceration. Symptoms and signs of CVD, acute complications, and scoring systems. Clinical examination, duplex ultrasound, cross-sectional imaging, and endovenous imaging. Conservative methods, compression therapy, pharmacological treatment, and interventional strategies.

Society of Interventional Radiology Position Statement on the Management of Chronic Iliofemoral Venous Obstruction with Endovascular Placement of Metallic Stents ⁽⁸⁾

Study Design: This document is a position statement from the Society of Interventional Radiology (SIR) on the management of chronic iliofemoral venous obstruction with endovascular placement of metallic stents. It includes recommendations based on a comprehensive literature review and expert consensus.

Target Population: Patients with chronic iliofemoral venous obstruction, including those with postthrombotic syndrome (PTS) and nonthrombotic iliac vein lesions (NIVLs).

Key Factors: To provide updated recommendations on the use of endovascular stent placement for chronic iliofemoral venous obstruction. Emphasize careful patient selection, optimization of conservative therapy, appropriate stent sizing, and quality procedural technique. Based on 41 studies, including randomized trials, systematic reviews, prospective single-arm studies, and retrospective studies. Discusses primary and secondary stent patency rates, improvements in venous disease severity, and quality of life measures. Addresses complications such as stent migration, thrombosis, and bleeding. Includes considerations for pregnant women and children.

ANALYSIS OF EVIDENCE

Analysis ⁽⁶⁻⁸⁾:

The evidence from these articles collectively supports the use of percutaneous ilio caval interventions, particularly stenting, as an effective treatment for chronic venous disease. The shared conclusions reinforce the importance of stenting in improving patient outcomes, while the differing conclusions highlight the nuances in patient management, particularly regarding antithrombotic therapy, the management of NIVLs, and the need for long-term follow-up.

In summary, these articles provide a comprehensive overview of the current best practices and considerations for percutaneous ilio caval interventions, emphasizing the need for individualized patient care and the use of advanced imaging techniques to guide treatment decisions.

Shared Conclusions

- All three articles agree on the effectiveness of stenting for managing chronic ilio caval venous obstruction. They highlight that stenting can significantly improve venous outflow, reduce symptoms, and enhance the quality of life for patients with chronic venous disease.
- The articles emphasize the importance of careful patient selection. They suggest that stenting should be considered for patients with significant symptoms and documented venous obstruction, ensuring that the benefits outweigh the risks.
- The use of advanced imaging techniques, such as intravascular ultrasound (IVUS) and venography, is recommended to accurately diagnose and guide the treatment of ilio caval venous obstruction.

POLICY HISTORY

<u>Date</u>	<u>Summary</u>
<u>July 2025</u>	<ul style="list-style-type: none"> ● <u>Added a Summary of Evidence and Analysis of Evidence</u>
<u>May 2025</u>	<ul style="list-style-type: none"> ● <u>No substantial clinical content changes</u> ● <u>Added in general information statement regarding guideline criteria development by reputable sources, standard of care, and best practices</u> ● <u>Applicable Line of Business adjusted – Medicare checked</u> ● <u>Updated references</u>
<u>January 2025</u>	<ul style="list-style-type: none"> ● <u>This guideline replaces UM CARDIO 1368 for Percutaneous Iliocaval Interventions</u> ● <u>Clinical indications were updated per societal guidance</u>

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical



advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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.

REFERENCES

1. Bonow RO, Douglas PS, Buxton AE, et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *J Am Coll Cardiol.* 2011;58(14):1517-1538. doi:10.1016/j.jacc.2011.07.007
2. Fitch Kathryn, Bernstein SJ, Aguilar MD, et al. *The RAND/UCLA Appropriateness Method User's Manual.* RAND.; 2001. Accessed October 8, 2024. https://www.rand.org/pubs/monograph_reports/MR1269.html
3. Hendel RC, Lindsay BD, Allen JM, et al. ACC Appropriate Use Criteria Methodology: 2018 Update. *J Am Coll Cardiol.* 2018;71(8):935-948. doi:10.1016/j.jacc.2018.01.007
4. Hendel RC, Patel MR, Allen JM, et al. Appropriate Use of Cardiovascular Technology: 2013 ACCF appropriate use criteria methodology update. *J Am Coll Cardiol.* 2013;61(12):1305-1317. doi:10.1016/j.jacc.2013.01.025
5. Patel MR, Spertus JA, Brindis RG, et al. ACCF Proposed Method for Evaluating the Appropriateness of Cardiovascular Imaging. *J Am Coll Cardiol.* 2005;46(8):1606-1613. doi:10.1016/j.jacc.2005.08.030
6. Farsad K, Kapoor BS, Fidelman N, et al. ACR Appropriateness Criteria® Radiologic Management of Iliofemoral Venous Thrombosis. *Journal of the American College of Radiology.* 2020;17(5):S255-S264. doi:10.1016/j.jacr.2020.01.035
7. De Maeseneer MG, Kakkos SK, Aherne T, et al. Editor's Choice – European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs. *European Journal of Vascular and Endovascular Surgery.* 2022;63(2):184-267. doi:10.1016/j.ejvs.2021.12.024
8. Vedantham S, Weinberg I, Desai KR, et al. Society of Interventional Radiology Position Statement on the Management of Chronic Iliofemoral Venous Obstruction with Endovascular Placement of Metallic Stents. *Journal of Vascular and Interventional Radiology.* 2023;34(10):1643-1657. doi:10.1016/j.jvir.2023.06.013
9. Desai KR, Sabri SS, Elias S, et al. Consensus Statement on the Management of Nonthrombotic Iliac Vein Lesions From the VIVA Foundation, the American Venous Forum, and the American Vein and Lymphatic Society. *Circ Cardiovasc Interv.* 2024;17(8):e014160. doi:10.1161/CIRCINTERVENTIONS.124.014160

-