

# **Evolut Clinical Guideline 7300 for Hemodialysis Access Maintenance**

<b><u>Guideline Number:</u></b> <b><u>Evolut CG 7300</u></b>	<b><u>Applicable Codes</u></b>	
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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 hemodialysis maintenance using angiography, endovascular, or open surgical procedures.**

### **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)**

### **General Considerations**

- **For this Policy, the specific endovascular (e.g. angioplasty or stent) or surgical methods (e.g. interposition graft, transposition, or Distal Revascularization and Interval Ligation DRIL procedure) that may be utilized should not be considered when determining whether a procedure can be approved or denied**
- **Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided.**

## **INDICATIONS FOR DIAGNOSTIC FISTULOGRAM (6,7)**

**Includes any of the following:**

- **ANY change in physical examination of the dialysis access or limb such as:**
  - **Decreased or absent thrill or bruit**
  - **Increased pulsatility**
  - **Ipsilateral limb swelling**
  - **Development of new superficial collateral venous channels consistent with venous outflow stenosis or obstruction**
  - **Distal steal syndrome**
  - **Ischemic monomelic neuropathy**
  - **Aneurysm(s) or pseudoaneurysm(s)**
  - **Clinical evidence of high flow e.g. high output cardiac failure**
- **ANY abnormality encountered during dialysis such as:**
  - **Arteriovenous access (AV) access thrombosis**
  - **Aspiration of clots**
  - **Persistent or new difficulty in cannulation**
  - **Elevated venous pressures recorded during hemodialysis (static and dynamic pressures) or measured within the vascular access during a diagnostic study (static pressures)**
  - **Increased bleeding from the needle puncture sites, usually for 3 consecutive dialysis sessions**
  - **Evidence of decreased flow (Qa)**
    - **Inadequate dialysis**
    - **Low Kt/V on a constant dialysis prescription without prolongation of dialysis duration**
- **ANY abnormality encountered by duplex ultrasound such as:**
  - **Increased pulsatility**
  - **Decreased flow volume**
  - **Fistula size <3 mm**
  - **Severe tortuosity**
  - **Aneurysm and pseudoaneurysm**
  - **Depth of the arteriovenous fistula (AVF) or graft (AVG) that would make cannulation difficult**

## **INDICATIONS FOR THERAPEUTIC INTERVENTION ON THE AV ACCESS CIRCUIT <sup>(6)</sup>**

- **ANY of the following**
  - **Autogenous fistulae that have failed to mature after 4 to 6 weeks as expected**
  - **Symptomatic or complicated aneurysm(s) or pseudoaneurysm(s) (see Limitations)**
  - **AV access infection**
  - **High flow complications**
  - **Erosion of the skin overlying the AV access**
  - **Severe tortuosity or depth of the AV access that would make cannulation difficult**
  - **ANY finding(s) during an indicated diagnostic fistulogram confirming reason(s) for decreased dialysis function, steal, or other access related complication(s), including:**
    - **Thrombosis**
    - **Anastomotic stenosis**
      - **At the arterial anastomosis of an AVF or AVG**
      - **At the venous anastomosis of an AVG**
    - **Proximal Inflow arterial stenosis unrelated to the arterial anastomosis**
    - **Venous outflow stenosis or obstruction distal to the AVF or AVG**
    - **Intraluminal high-grade stenosis**
    - **Aberrant veins draining flow away from the main AVF**
- **Covered intraluminal stents can be utilized to manage AV access aneurysms or pseudoaneurysms but should be reserved for patient contraindications to surgery, lack of a surgical option, or as a temporizing measure for patients with active bleeding**
- **Symptoms or conditions warranting intervention on aneurysms include any of the following:**
  - **Pain**
  - **Access flow dysfunction**
  - **Thrombus**
  - **Limited cannulation sites**
  - **High output congestive heart failure**
  - **Unacceptable cosmetic disfigurement**
  - **Rapid enlargement**

**NOTE: Aneurysm size alone is likely not an indication for treatment in the absence of symptoms of threatened skin.**

## **Limitations (6)**

- **A diagnostic fistulogram should not be performed without new clinical findings. Routine fistulogram for “surveillance” is not appropriate**
- **Preemptive endovascular intervention to improve patency of an AVF or AVG with stenosis, not associated with clinical indicators, is not appropriate**

## **CODING AND STANDARDS**

### **Codes**

**36831, 36832, 36833, 36901, 36902, 36903, 36904, 36905, 36906, 36907, 36908, 36909, 37607**

### **Applicable Lines of Business**

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

## **BACKGROUND**

### **Definitions (6)**

- **Interventions on Arteriovenous (AV) dialysis graft/fistula are intended to restore and/or maintain functional patency of the AV access circuit. However, occasionally interventions may be necessary to move, alter, add to or close the access circuit. Access related procedures encompass endovascular percutaneous or open surgical procedures. They are utilized to treat thrombotic or non-thrombotic flow-related complications or dysfunction, infection, aneurysm, or pseudoaneurysm. In most, but not all cases, a diagnostic fistulogram is performed first. If identified during the fistulogram, culprit lesion(s) should be concurrently treated by an endovascular procedure if appropriate, or soon thereafter by open or hybrid procedures. Open surgical procedures are usually reserved for recurrent stenotic lesions, aneurysms and pseudoaneurysms, AV access infections, steal,**

ischemic monomelic neuropathy, or difficult access due vein size, tortuosity, or depth.

- Dialysis access circuit is the continuing from the heart and the arterial inflow through the AV access to the venous outflow back to the heart. For coding purposes, the hemodialysis circuit is comprised of a peripheral segment and a central segment. The peripheral segment begins at the arterial anastomosis and extends to the central segment. In the upper extremity the peripheral segment extends up to and includes the axillary vein and entire cephalic vein including the cephalic arch. In the lower extremity, the peripheral segment extends up to and includes the common femoral vein. In the upper extremity, the central segment includes the subclavian and innominate veins through the superior vena cava. In the lower extremity the central segment includes the external iliac and common iliac veins through the inferior vena cava
- Arteriovenous access allows for dialysis and includes arteriovenous fistula (AV fistula) or arteriovenous graft (AV graft)
- Diagnostic Fistulogram is the diagnostic angiography of the entire AV access circuit from the arterial anastomosis through the central vena cava is performed to identify the area or areas of narrowing or occlusion that are creating flow problems for, or related to, the AV access. It is performed through the AV access or via a remote artery
- Endovascular fistula (endoAVF) is an autologous fistula created by endovascular techniques
- Endovascular interventions are procedures performed percutaneously utilizing angioplasty, stents, thrombectomy, or thrombolysis. Thrombolysis involves the use of pharmaceuticals that are infused or injected directly into the thrombosed access and which dissolve clot. Mechanical thrombectomy devices may also be utilized to percutaneously remove clots. Thrombectomy can also be performed surgically
- Open surgical therapy utilizes direct open access to the conduit and contiguous vessels. Residual vascular stenosis or obstructive lesions are removed and corrected using standard vascular surgical techniques. Angiography is adjunctively employed, when appropriate and medically necessary, to assess the functional integrity of afferent and efferent vessels remote from the surgical field.
- Vessel superficialization or Transposition is a procedure where the vessel used for dialysis needs to be moved closer to the surface or away from the neural structures for it to be safely punctured for dialysis
- DRIL procedure is a surgical procedure to treat steal and involve distal revascularization and interval ligation of an AV fistula or graft
- Kt/V is a number used to quantify hemodialysis treatment (where K = dialyzer clearance of urea, t = dialysis time, and V = volume of distribution of urea approximately equal to the patient's total body water)
- Failure to mature an AV fistula that cannot be used successfully for dialysis despite at least 4 weeks of observation since creation, or 6 months despite

endovascular or surgical attempts to allow successful cannulation and dialysis

- Pseudoaneurysm implies a hole through the vessel or graft with accumulation of flowing blood outside of that vessel but contained by the surrounding tissues.
- Aneurysm implies dilatation of all 3 layers of a fistula, vein or artery beyond what would be normally expected following creation of a fistula. Aneurysms can develop anywhere along the course of the AV access circuit including the inflow artery, but typically occur in the outflow vein. By definition, aneurysms do not occur in grafts, but a ballooning of a collagen biologic graft should still be considered an aneurysm
- Steal occurs when creation of an AV access results in distal ischemic complications usually related to decreased distal blood flow. Clinically it presents as a cool extremity with few symptoms, progressing to intermittent symptoms during dialysis, limb claudication, ischemic rest pain and tissue loss. Left untreated Steal can result in limb deformity or amputation.
- Ischemic monomelic neuropathy is a poorly understood syndrome that occurs soon after creation of an AV access usually at the elbow. It is diagnosed by acute onset of severe forearm pain, numbness and paresthesia usually without hemodynamic evidence of ischemia and requires immediate ligation of the AV access

## 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. <sup>(2)</sup>

- 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

AV: Arteriovenous

AVF: Arteriovenous fistula

AVG: Arteriovenous graft

endoAVF: Endovascular arteriovenous fistula

Qa: Intra-access blood flow

## SUMMARY OF EVIDENCE

KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update <sup>(6)</sup>

**Study Design:** The guideline update was conducted by the National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative (KDOQI). The update involved a comprehensive review of the literature, including more than 4,600 articles, of which 286 were included in the evidence tables used to develop the 26 guideline sections. The evidence review was independently conducted using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach.

**Target Population:** The guidelines are intended for multidisciplinary practitioners who care for chronic kidney disease (CKD) patients and their vascular access. This includes nephrologists, surgeons, interventional radiologists, nurses, and other healthcare professionals involved in the management of hemodialysis vascular access.

**Key Factors:**

**End-Stage Kidney Disease (ESKD) Life-Plan:** The guidelines introduce the concept of an individualized ESKD Life-Plan, which maps out a comprehensive strategy for dialysis modalities and vascular access for the lifetime of the patient.

**Vascular Access Choice:** The guidelines provide recommendations on the choice of vascular access, including arteriovenous fistulas (AVFs), arteriovenous grafts (AVGs), and central venous catheters (CVCs), based on patient circumstances and preferences.

**Vascular Access Types and Locations:** The guidelines discuss the indications for use, types, and locations of vascular access, emphasizing a patient-centered approach.

**Preoperative and Postoperative Care:** The guidelines include recommendations for preoperative vessel mapping, postoperative evaluation, and interventions to enhance AVF maturation and prevent complications.

**Complications and Management:** The guidelines address the prevention, monitoring, and treatment of complications related to vascular access, including infections, thrombosis, and stenosis.

**ACR Appropriateness Criteria® Dialysis Fistula Malfunction <sup>(7)</sup>**

**Study Design:** The study is a rigorous evaluation of dialysis access dysfunction, focusing on arteriovenous access dysfunction, which includes thrombotic flow-related complications, nonthrombotic flow-related complications, and infectious complications. The American College of Radiology Appropriateness Criteria are evidence-based guidelines for specific clinical conditions reviewed annually by a multidisciplinary expert panel. The guideline development and revision process supports the systematic analysis of medical literature from peer-reviewed journals, using established methodology principles such as Grading of Recommendations Assessment, Development, and Evaluation (GRADE) and the RAND/UCLA Appropriateness Method User Manual.

**Target Population:** The target population includes patients with end-stage renal disease who require dialysis. The study emphasizes the importance of creating and maintaining dialysis access to reduce morbidity, mortality, and treatment costs for these patients. The quality of dialysis is directly dependent on the integrity and reliability of access to the patient's vascular system.

**Key Factors:**

**Dialysis Access Dysfunction:** The study categorizes dialysis access dysfunction into three distinct classes: thrombotic flow-related complications, nonthrombotic flow-related complications, and infectious complications. It discusses the restoration of arteriovenous access dysfunction through diagnostic imaging, clinical consultation, percutaneous interventional procedures, surgical management, or a combination of these methods.

**Appropriateness Criteria:** The American College of Radiology Appropriateness Criteria documents are updated regularly and provide guidelines for determining appropriate imaging examinations for diagnosis and treatment of specified medical conditions. These criteria guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment.

**Monitoring and Surveillance:** The study highlights the importance of monitoring and surveillance to preempt adverse outcomes and identify lesions within the vascular access before they provoke complications. It suggests the performance of physical examinations, noninvasive and invasive device-based methods, and diagnostic imaging such as Doppler ultrasound or diagnostic fistulography upon detection or suspicion of an access abnormality.

## **ANALYSIS OF EVIDENCE**

**Shared Conclusions** <sup>(6,7)</sup>:

**Importance of Diagnostic Imaging:** Both articles highlight the critical role of diagnostic imaging in evaluating and managing dialysis access dysfunction.

**Endovascular Interventions:** Both emphasize the use of PTA and stent placements as primary treatments for stenosis.

**Patient-Centered Approach:** Both stress the importance of considering individual patient circumstances and preferences in managing dialysis access.

## **POLICY HISTORY**

<u>Date</u>	<u>Summary</u>
<u>June 2025</u>	<ul style="list-style-type: none"> <li>• <u>Added new bullet-point to the General Statement section</u></li> <li>• <u>Added a Summary of Evidence and Analysis of Evidence</u></li> </ul>
<u>January 2025</u>	<ul style="list-style-type: none"> <li>• <u>This guideline replaces UM CARDIO 1339 for Hemodialysis Access Maintenance</u></li> <li>• <u>Clinical indications were updated per societal guidance</u></li> </ul>

## **LEGAL AND COMPLIANCE**

### **Guideline Approval**

#### **Committee**

**Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee**

#### **Disclaimer**

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

**Evolut 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 Evolut Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.**

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