Subject: Percutaneous Arteriovenous Fistula (pAVF) for Hemodialysis

Medical Policy #: 55.0

Original Effective Date: May 24, 2023

Status: Reviewed

Last Annual Review Date: 05-22-2024

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Technology Description

Radiofrequency endoarteriovenous fistula:

WavelinQ device — The WavelinQ EndoAVF system is a **two-catheter** system consisting of a magnetic 4 Fr venous and 4 Fr arterial catheter and a **radiofrequency** generator. The arterial catheter contains orienting magnets and a ceramic backstop, while the venous catheter contains orienting magnets and the cutting electrode. Both catheters have rotational indicator windows that help guide the catheters into the correct orientation. The end goal of this device is to use radiofrequency energy to create a fistula between an artery and vein in the proximal forearm, most commonly the ulnar artery and the ulnar vein.

Thermal energy AV fistula:

Ellipsys Vascular Access System -enables physicians to percutaneously access the proximal radial artery in the forearm to create an AV fistula. Under high frequency ultrasound guidance, the system uses an outer access cannula, guidewire and vessel capture construct that creates a connection of the vein to the artery using an intravascular approach. A low power **thermal energy** is used to cut the walls of the vessels and fuse the tissue, creating an anastomosis without leaving any foreign material (including sutures) in the resulting AV fistula. **The Ellipsis Vascular Access System is an ultrasound-based technique that uses thermal energy to create the AV fistula.

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

PREOPERATIVE EVALUATION

Upper extremity vascular evaluation is necessary to determine if the patient is a candidate for creation of a distal surgical AV fistula (eg, radial-cephalic fistula at the wrist), and if not, whether they meet the anatomic criteria for creation of a more proximal antecubital fistula. Such "vascular mapping" allows determination of artery and vein sizes and suitability for both percutaneous and surgical fistulas.

Note: It must be ensured the patient is not a candidate for a distal surgical AV fistula before a more proximal antecubital fistula (percutaneous or surgical) is created. This approach preserves more options if the initial access fails and serves to augment proximal venous flow and facilitate future options.

Preoperative imaging also confirms adequate triphasic flow to the hand through the artery that will not be used for the AV fistula, as well as an intact palmar arch using either arterial duplex or Doppler waveforms.

For Medicare, Commercial and Medicaid.

Percutaneous Arteriovenous Fistula (pAVF) is covered in patients who meet one of the following:

- Patient with clinical risk for high output failure, such as history of heart failure, pulmonary HTN, or chronic profound anemia.
- Patient at risk for Subclavian Steal Syndrome, such as diabetics with calcification of distal arteries.
- Patient at risk for venous stenosis leading to clotting, such as hypercoagulable states AND history of DVT/PE.
- Vascular anatomy is conducive to either the usage of Ellipsys and WavelinQ devices.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Codes
36836	Percutaneous arteriovenous fistula creation, upper extremity, **single** access of both the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when

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	performed, including all vascular access, imaging guidance and radiologic supervision and interpretation
36837	Percutaneous arteriovenous fistula creation, upper extremity, **separate** access **sites** of the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation.

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee (PHCQC): Gray Clarke MD
Medical Director: Ana Maria Rael MD
Date Approved: May 22, 2024
Reviewed by: Satyaki Banjeree MD, Nephrologist, May 2024.

References

1. CMS, National Government Services, Inc (out of region) (RETIRED), LCD - (L38573) Percutaneous Arteriovenous Fistula (pAVF) for Hemodialysis, LCA, Percutaneous Arteriovenous Fistula (pAVF) for Hemodialysis (A58037) Retired Date:05/05/2022. [Cited 05/22/2024]
2. Hayes, Ellipsys Vascular Access System (Avenu Medical) in Patients with End-Stage Renal Disease, Evolving Evidence Review Aug 4, 2021, Annual Review: Feb 2, 2023. [Cited 05/22/2024]
3. Hayes, WavelinQ (formerly EverlinQ) EndoAVF System, Evolving Evidence Review: Jul 23, 2021, Annual review: 03-28-2023. [Cited 05/22/2024]
4. Up-To-Date, Percutaneous Hemodialysis Arteriovenous Fistula, Literature review current through: Apr 2024. | This topic last updated: Mar 12, 2024. [Cited 05/23/2024]
5. Humana, Code Compendium (Miscellaneous), Effective Date: 01/25/2024 Revision Date: 01/25/2024 Review Date: 01/25/2024 Policy Number: HUM-0562-018 Line of Business: Commercial. [Cited 0523/2024]

Publication History

05-24-2023 Original effective date. Reviewed by TAC on April 04, 2023. Reviewed by PHP Medical Policy Committee on 04/21/2023. EndoAVF (percutaneous AVF) using Ellipsys and WavelinQ devices are considered medically necessary for Medicare, Medicaid and Commercial, but only for those patients who are not a candidate for a distal surgical AV fistula. Both codes 36836 and 36837 will require PA for ALOB.

05-22-2024 Annual review. Reviewed by PHP Medical Policy Committee on 06/12/2024. No change, keep status quo.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such. For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

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When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.