Percutaneous arteriovenous fistula creation

Clinical Policy ID: CCP.1469

Recent review date: 9/2025

Next review date: 1/2027

Policy contains: Arteriovenous fistula; Ellipsys; endovascular; everlinQ; hemodialysis; percutaneous; WavelinQ

FirstChoice VIP Care has developed clinical policies to assist with making coverage determinations. FirstChoice VIP Care's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case by case basis, by FirstChoice VIP Care when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. FirstChoice VIP Care's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. FirstChoice VIP Care's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, FirstChoice VIP Care will update its clinical policies as necessary. FirstChoice VIP Care's clinical policies are not guarantees of payment.

Coverage policy

Percutaneous arteriovenous fistula creation for hemodialysis access is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Arteriography.
- Contrast venography.
- Duplex ultrasound.
- Hemodialysis vascular access (arteriovenous graft, central line catheter).
- History and physical examination specific to vascular access selection.
- Nephrology consultation.
- Vein mapping.

Background

According to the National Institute of Diabetes and Digestive and Kidney Diseases (2024), an estimated 808,000 Americans have end stage renal disease, 68% of whom receive dialysis. Among patients on hemodialysis, the surgically-created arteriovenous fistula is the most common vascular access (Jayroe, 2022).

Ideally, referral for initial vascular access placement should occur approximately three to six months in advance of the anticipated need for dialysis to allow for adequate maturation time. Maturation failure, infection, and venous stenosis or thrombosis after maturation continue to complicate hemodialysis access. Additional procedures and prolonged central venous catheter use may be needed, further increasing the risk of bacteremia, inadequate dialysis, and death (Schmidli, 2018). One administrative study of Medicare claims data found that only 54.7% of surgically created fistula were used within four months of placement (Woodside, 2018).

Vascular surgeons generally prefer the vascular anatomy of the non-dominant over dominant upper extremity, as far distally as possible, to preserve proximal sites for future access. The four preferred sites are radiocephalic or radiobasilic transposition in the forearm, and brachiocephalic or brachiobasilic transposition in the upper arm. For optimal placement, duplex ultrasound and vein mapping provide important information on arterial inflow and venous outflow, along with vein diameter and length and proximal vein patency (DeVita, 2020).

To improve arteriovenous creation, maturation, and suitability for dialysis, a minimally invasive endovascular approach has been developed (Jayroe, 2022). Endovascular access minimizes vascular injury at the time of arteriovenous fistula creation and creates a channel between the artery and vein with an angle approaching zero degrees. Endovascular placement can be performed by an interventionalist, which may reduce the delays associated with surgical scheduling. The procedure can be done with regional or local anesthesia without the need for a surgical incision, general anesthesia, or additional interventions.

The U.S. Food and Drug Administration has approved percutaneous catheters for the creation of an arteriovenous fistula for hemodialysis access as Class II devices. The Ellipsys® Vascular Access System (Avenu Medical Inc., San Juan Capistrano, California) applies direct current heat to create an elliptical anastomosis between the proximal radial artery and perforating vein via a retrograde venous access approach (U.S. Food and Drug Administration, 2018). The modified and predicate versions are indicated for patients with a minimum vessel diameter of 2.0 mm and less than 1.5 mm of separation between the artery and vein at the fistula creation. The most recent generation includes a procedural step of balloon dilation immediately following fistula creation. The procedure is carried out under ultrasound guidance. Approval was based on the results of the Ellipsys Vascular Access System Clinical Trial (ClinicalTrials.gov identifier: NCT02363972; Hull, 2018).

Formerly called everlinQ®, the WavelinQ™ Plus EndoAVF System and its predicate WavelinQ™ 4-French EndoAVF version (C.R. Bard, Inc., Tempe, Arizona) employ two magnetized catheters to cannulate both the brachial vein and brachial artery and then advance into the ulnar vein and artery (U.S. Food and Drug Administration, 2019a, 2019b). The device is indicated for the creation of an arteriovenous fistula using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis. Approval was based on performance data from three sources: the EverlinQ Endovascular Access Systems Enhancements Study; ClinicalTrials.gov identifiers NCT03708770 and NCT03708562; and a European Union post-market study.

Findings

Guidelines

No current guidelines have addressed the endovascular approach in vascular access techniques for hemodialysis, including the European Society for Vascular Surgery (Schmidli, 2018).

The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative guideline recommended more prospective research to determine whether endovascular fistula creation can result in a clinically durable and cost effective arteriovenous access compared with traditional surgical arteriovenous access creation and maintenance (Lok, 2020).

Evidence review

We included five systematic reviews and meta-analyses (Bontinis, 2023; Malik, 2021; Shimamura, 2022; Sun, 2022; Yan Wee, 2020). The evidence evaluated the safety and efficacy of endovascular arteriovenous fistula creation and reported on technical success, maturation rates at different follow-up intervals, patency, and procedure-related complications. There was indirect evidence comparing the outcomes of the endovascular approach to the standard surgical approach, but the number of prospective studies representing currently available percutaneous catheters was limited, and studies lacked randomization..

The results suggest endovascular arteriovenous fistula creation is associated with high short-term rates of technical success, maturation, and patency, a low risk of procedure-related complications, and lower associated first-year costs compared with a surgically created arteriovenous fistula. The endovascular approach potentially offers patients with suitable anatomy a less invasive option and leaves open the option of proximal arm placement for secondary arteriovenous access. Nonetheless, given the limited direct comparative analyses with surgical arteriovenous fistula creation and insufficient long-term data, the superiority of an endovascular approach cannot be established at present.

A systematic review/meta-analysis of 18 studies (n = 1,863) compared percutaneous endovascular arteriovenous fistula creation (WavelinQ and Ellipsys) with surgical arteriovenous fistula. No significant differences were observed in primary patency, secondary patency, functional cannulation, and abandonment rates. Patients with percutaneous procedures had a decreased risk of subclavian steal syndrome and wound infection. However, one in three WavelinQ procedures resulted in abandonment (Bontinis, 2023).

Similarly, other systematic reviews and meta-analyses found no significant differences between percutaneous endovascular and surgical techniques with respect to rates of procedural success, maturation, and complications (Malik, 2021; Shimamura, 2022; Sun, 2022; Yan Wee, 2020). Malik (2021) did find significant differences in procedural time, number of interventions needed to maintain patency, and primary patency rate between the two cohorts (all $P < .001$).

Recent results from retrospective analyses suggest both surgical and endovascular access types can provide hemodialysis access, but several factors may influence their relative safety and efficacy. These factors include the technical characteristics of each access type (e.g., Ellipsys versus WaveLinQ or different generations of WaveLinQ), use of drug-coated balloon angioplasty during secondary percutaneous transluminal angioplasty, and choice of outcome measure (e.g., immediate procedural outcomes versus long term functionality) (Hogan, 2024; Shahverdyan, 2024, 2025).

Wasse (2019) highlighted several unanswered questions related to its suitability and durability for dialysis that need to be addressed before widespread use:

- What adjustments to blood pump speed and dialysis time may be required to achieve a prescribed dialysis dose?
- Which secondary interventions will be needed to maintain arteriovenous fistula function long term?
- How would surgical transposition affect arteriovenous fistula function?
- What impact would an endovascular approach have on subsequent arteriovenous access creation?

- What education and training would be required to support widespread use?

In 2024, we updated the references. No policy changes are warranted.

In 2025, we updated the references and reorganized the findings section. No policy changes are warranted.

References

On July 9, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were arteriovenous fistula" (MeSH), "endovascular procedures" (MeSH), "arteriovenous fistula creation," "endoarteriovenous fistula," and "ellipsys." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

9/2020: initial review date and clinical policy effective date: 10/2020

9/2021: policy retired

9/2023: policy re-introduced, references updated.

9/2024: policy references updated.

9/2025: Policy references updated.