Percutaneous Arteriovenous Fistula Creation

Clinical Policy ID: CCP.1469

Recent review date: 8/2026

Next review date: 12/2027

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

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas'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 AmeriHealth Caritas 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. AmeriHealth Caritas'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.'s AmeriHealth Caritas's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritaswill update its clinical policies as necessary.AmeriHealth Caritas's clinical policies are not guarantees of payment.

Coverage policy

Percutaneous arteriovenous fistula creation for hemodialysis access is clinically proven and, therefore, may be medically necessary when all of the following criteria are met (Society of Interventional Radiology [Dolmatch, 2025]):

- One of the following U.S. Food and Drug Administration-approved devices is used:
  - Ellipsys Vascular Access System (Medtronic, Minneapolis, Minnesota)
  - WavelinQ Plus EndoAVF System (Becton, Dickinson and Company, Franklin Lakes, New Jersey)
- All of the following medical necessity criteria are met:
  - Procedure is performed by a physician who has completed procedure-specific training.
  - Member is diagnosed with end stage renal disease.
  - Member is not a candidate for a distal surgical arteriovenous fistula.

- Member is ≥ 18 years of age.
- Pre-procedure ultrasound vascular mapping confirms suitable vascular anatomy (both criteria are met):
  - Minimum vessel diameter ≥ 2.0 mm
  - Separation between the artery and vein at the fistula creation site < 2.0 mm (for WavelinQ) or < 1.5 mm (for Ellipsys)

Limitations

Percutaneous arteriovenous fistula creation is investigational/not clinically proven and, therefore, not medically necessary when the above medical necessity criteria are not met or there is presence of any of the following (Hull, 2018):

- Documented or suspected central venous stenosis including upper extremity arterial stenosis on ipsilateral side (> 20 mm/Hg systolic blood pressure difference between arms)
- Prior vascular surgery at or proximal (central) to the arteriovenous fistula target site
- Diagnosed hypercoagulable state
- Presence of any of the following on the ipsilateral side of the proposed arteriovenous fistula site:
  - Prior axillary dissection or mastectomy
  - Evidence of vascular disease at the radial artery/adjacent vein site
  - History of steal syndrome from a previous hemodialysis vascular access that required intervention or abandonment

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
- Vessel 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 fistulas 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 fistula creation, maturation, and suitability for dialysis, a minimally invasive percutaneous approach has been developed (Jayroe, 2022). Percutaneous 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. Percutaneous 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 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 of Ellipsys 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 (Hull, 2018). Ellipsys was withdrawn from the U.S. market in 2025 but is slated to return in 2026 (Endovascular Today, 2026).

Formerly called everlinQ, the WavelinQ Plus EndoAVF System and its predicate WavelinQ 4-French EndoAVF version 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 the EverlinQ Endovascular Access Systems Enhancements (EASE) and EASE-2 studies and a European Union post-market study (Berland, 2022).

Findings

Percutaneous and surgical vascular access approaches can provide reliable long-term functional access for hemodialysis, but there are differences in reintervention rates, maturation time, and management of complications. Both percutaneous and surgical arteriovenous fistulas demonstrate high technical success, significantly higher maturation rates for Ellipsys and surgical arteriovenous fistulas, higher primary patency rates for surgical arteriovenous fistulas, lower secondary patency rates for WavelinQ, and similar reintervention numbers. These findings underscore the importance of personalized vascular access planning. Guidelines reflect growing clinical interest in percutaneous options and the need to evaluate effectiveness relative to the current standard of care. The percutaneous approach offers patients with suitable anatomy a less invasive option and leaves open the option of proximal arm placement for secondary arteriovenous access.

Guidelines

The National Kidney Foundation's 2019 Kidney Disease Outcomes Quality Initiative guideline mentioned percutaneous fistula techniques as novel, under investigation, and which may play a role in the future. The guideline emphasizes the importance of devising a patient’s Life-Plan for vascular access needs that considers careful planning for both the initial access and the types of access or kidney replacement modalities that may follow. General considerations to facilitate arteriovenous access maturation are: the need for detailed vascular mapping before arteriovenous access creation; selection of access that best preserves future access options; and consideration of patient anatomy, expected dialysis duration, comorbidity burden, and life expectancy. The guideline recommended more prospective research to compare the durability and cost effectiveness of novel arteriovenous access methods compared with traditional surgical arteriovenous access (Lok, 2020).

The National Kidney Foundation (2021) acknowledged the potential for percutaneous arteriovenous fistula options to solve some of the problems associated with surgical approaches arising from incisions, vessel dissection and translocation, and the sutured anastomosis. While observational outcomes at one year were positive, long-term data were needed.

The Society of Interventional Radiology developed consensus guidance for the creation and maturation of the percutaneous arteriovenous fistula for hemodialysis access. The guidance emphasizes standardized mapping, expectation setting, troubleshooting algorithms for non-maturation, and dialysis-unit cannulation training to support consistent implementation. The optimal candidate will have thin arms, noncalcified arteries of the arm with normal arterial Doppler examination findings (if using Ellipsys), a patent palmar arch, suitable venous anatomy, and patent thoracic central veins. A minimum artery and vein diameter is typically 2 mm, depending on the device. Even with these features, when a patient can undergo surgical options such as a surgical Brescia-Cimino arteriovenous fistula or snuff-box arteriovenous fistula at the wrist, surgery may be considered before percutaneous arteriovenous fistula creation. If the forearm veins cannot be used for a surgical arteriovenous fistula, then percutaneous arteriovenous fistula becomes a more attractive option. Prior or current thoracic central venous devices (pacemakers or catheters) and all prior arteriovenous access surgeries that may cause venous obstruction should be documented. Additional procedures may be required to create a functional fistula (Dolmatch, 2025).

Evidence review

The evidence from secondary analyses evaluated the safety and efficacy of percutaneous 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 percutaneous approaches 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 percutaneous arteriovenous fistula creation is associated with high short-term rates of technical success exceeding 95%, maturation, and patency, while achieving a successful cannulation rate of approximately 80%. There is a low risk of procedure-related complications but higher associated first-year costs compared with a surgically-created arteriovenous fistula. Limited direct comparisons with surgical arteriovenous fistula creation suggest comparable durability up to five years. The percutaneous approach potentially offers patients with suitable anatomy a less invasive option and leaves open the option of proximal arm placement for secondary arteriovenous access. There is insufficient evidence to establish the superiority of one percutaneous approach over another.

A systematic review and meta-analysis of 20 single-arm studies and eight comparative studies examined the clinical outcomes of percutaneous arteriovenous fistula and surgical arteriovenous fistula for hemodialysis access. For percutaneous arteriovenous fistula, the pooled technical success rate and maturation rate were 97% and 77%, respectively. Primary patency rates were 64% at six months and 77% at 12 months. The overall complication rate was 9%. There was moderate to high heterogeneity across several outcomes. There were no statistically significant differences between Ellipsys and WavelinQ outcomes. Compared to the surgical approach, there were no statistically significant differences in maturation rate or primary patency, but the percutaneous arteriovenous fistula was associated with higher reintervention rates and lower complication rates (Ameen, 2026).

A cost-effectiveness analysis comparing percutaneous and surgical arteriovenous fistula creation in the United States found percutaneous arteriovenous fistula was not cost effective compared with the surgical approach when modeling five-year outcomes. The main drivers were the four times higher up-front cost and a relatively low additional increase in quality of life for the percutaneous approach (Mulaney-Topkar, 2024). Slow adoption

due to financial and logistical problems for providers, dialysis patients, and dialysis centers may be important contributors (Dolmatch, 2025).

A systematic review/meta-analysis of 18 studies (n = 1,863) compared percutaneous 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 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).

Long-term outcomes

Several factors may influence relative safety and efficacy over time. 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).

Long-term data from the original pivotal study of Ellipsys suggested clinical efficacy, durability, and functional patency with no serious complications. Of the 107 intention-to-treat participants with end stage renal disease, 85 provided follow-up data with a median follow-up duration of 50 months (range, 12 to 60 months). Through five years, 92% achieved sustained fistula use, 91.8% achieved functional patency, and 82% achieved cumulative patency. Twenty-seven (32%) participants had complications, the most common being dysfunction (21.2%), thrombosis (5.9%), swelling (4.7%), and cannulation injury (12.9%). Treatments were predominantly balloon angioplasty, thrombectomy, and stent graft placement (Hull, 2022).

Another retrospective analysis compared the long-term outcomes of different vascular access methods performed in a single vascular access center from September 2017 to September 2023. The mean follow-up was 654 days (interquartile range 164, 1,049 days; range 0 to 2,061 days). A total of 217 percutaneous arteriovenous fistulas (61 WavelinQ, 156 Ellipsys) and 158 surgical Gracz-type arteriovenous fistulas were created. Gracz fistulas were typically created if percutaneous creation was deemed unsuitable or failed. There was a statistically significant difference in sex distribution, with a majority of males undergoing percutaneous procedures (P = .006), likely due to vessel size requirements. Long-term durability was similar for surgical arteriovenous fistulas and Ellipsys, while WavelinQ showed higher access abandonment. Re-intervention rates were comparable across groups (0.60 to 0.69 interventions per patient-year). Hemodialysis access-induced distal ischemia occurred more frequently in the surgical group (nine events = 5.7%) compared with none in WavelinQ and one in Ellipsys (0.6%) (P = .008). The rate of juxta-anastomotic stenosis was significantly higher among the percutaneous groups (51% and 54%) than the surgical group (30%; $P <$ .001) (Shahverdyan, 2025).

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.

In 2026, we updated the references and changed the medical necessity criteria to medically necessary based on new guideline recommendations from the Society of Interventional Radiology.

References

On July 16, 2026, 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,” “endovascular arteriovenous 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.

Ameen NK, Albadawi AI, Alghamdi SK, et al. Endovascular arteriovenous fistula: Outcomes and comparison with surgical arteriovenous fistula: An updated systematic review and meta-analysis. *J Vasc Access*. 2026:11297298261424630. Doi: 10.1177/11297298261424630.

Berland T, Clement J, Inston N, Kreienberg P, Ouriel K. Percutaneous arteriovenous fistula creation with the 4F WavelinQ EndoAVF system. *J Vasc Surg*. 2022;75(3):1038-1046.e3. Doi: 10.1016/j.jvs.2021.09.025.

Bontinis A, Bontinis V, Koutsoumpelis A, et al. A systematic review aggregated data and individual participant data meta-analysis of percutaneous endovascular arteriovenous fistula. *J Vasc Surg*. 2023;77(4):1252-1261.e3. Doi: 10.1016/j.jvs.2022.10.039.

ClinicalTrials.gov. everlinQ Endovascular Access System Enhancements (EASE) Study. ClinicalTrials.gov ID NCT03708770. https://clinicaltrials.gov/study/NCT03708770?term=NCT03708770&viewType=Card&rank=1. Last update posted December 11, 2025.

ClinicalTrials.gov. everlinQ Endovascular Access Systems Enhancements (EASE-2) Study. ClinicalTrials.gov ID NCT03708562. https://clinicaltrials.gov/study/NCT03708562?term=NCT03708562&viewType=Card&rank=1. Last update posted December 11, 2025.

DeVita MV, Khine SK, Shivarov H. Novel approaches to arteriovenous access creation, maturation, suitability, and durability for dialysis. *Kidney Int Rep.* 2020;5(6):769-778. Doi: 10.1016/j.ekir.2020.02.1024.

Dolmatch BL, Gunn AJ, Arslan B, et al. A Society of Interventional Radiology practice guidance document on percutaneous arteriovenous fistulae for dialysis access. *J Vasc Interv Radiol*. 2025;36(12):1945-1957.e2. Doi: 10.1016/j.jvir.2025.08.019.

Endovascular Today. Ellipsys vascular access system to return to market. https://evtoday.com/news/ellipsys-vascular-access-system-to-return-to-market. Dated April 2, 2026.

Hogan D, Otoya D, Lavingia K, Amendola M. What is the MAUDE database telling us about 510(k) authorization? Evaluation of two generations of endovascular arteriovenous fistula devices. *Ann Vasc Surg*. 2024;106:394-399. Doi: 10.1016/j.avsg.2024.03.029.

Hull JE, Jennings WC, Cooper RI, et al. The pivotal multicenter trial of ultrasound-guided percutaneous arteriovenous fistula creation for hemodialysis access. *J Vasc Interv Radiol.* 2018;29(2):149-158.e145. Doi: 10.1016/j.jvir.2017.10.015.

Hull JE, Jennings WC, Cooper RI, Narayan R, Mawla N, Decker MD. Long-term results from the pivotal multicenter trial of ultrasound-guided percutaneous arteriovenous fistula creation for hemodialysis access. *J Vasc Interv Radiol*. 2022;33(10):1143-1150. Doi: 10.1016/j.jvir.2022.05.016.

Jayroe H, Foley K. Arteriovenous fistula. *StatPearls [internet]*. Treasure Island (FL): StatPearls Publishing. 2026 Jan-. https://www.ncbi.nlm.nih.gov/books/NBK559213/. Updated November 21, 2022.

Lok CE, Huber TS, Lee T, et al. KDOQI clinical practice guideline for vascular access: 2019 update. *Am J Kidney Dis*. 2020;75(4 Suppl 2):S1-S164. Doi: 10.1053/j.ajkd.2019.12.001.

Malik MH, Mohammed M, Kallmes DF, Misra S. Endovascular versus surgical arteriovenous fistulas: A systematic review and meta-analysis. *Kidney Med*. 2021;4(3):100406. Doi: 10.1016/j.xkme.2021.100406.

Mulaney-Topkar B, Ho VT, Sgroi MD, Garcia-Toca M, George EL. Cost-effectiveness analysis of endovascular vs surgical arteriovenous fistula creation in the United States. *J Vasc Surg*. 2024;79(2):366-381.e1. Doi: 10.1016/j.jvs.2023.11.009.

National Institute of Diabetes and Digestive and Kidney Diseases. Kidney disease statistics for the United States. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease#:~:text=Nearly%20808%2C000%20people%20in%20the,to%20develop%20ESKD%20than%20women. Last reviewed September 2024.

National Kidney Foundation. The endovascular arteriovenous fistula. A clinical update. https://www.kidney.org/sites/default/files/approved_bd-19074_nkf_bd_bulletin_v1.0_8-25-21.pdf. Published 2021.

Schmidli J, Widmer MK, Basile C, et al. Editor's choice – Vascular access: 2018 clinical practice guidelines of the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc Surg*. 2018;55(6):757-818. Doi: 10.1016/j.ejvs.2018.02.001.

Shahverdyan R, Lessne ML, Mehta TI. Comparison of outcomes of drug-coated balloons versus plain balloons in secondary interventions on percutaneous arteriovenous fistulae. *J Vasc Interv Radiol*. 2024;35(8):1176-1186.e1. Doi: 10.1016/j.jvir.2024.04.014.

Shahverdyan R, Mehta TI, Inston N, Konner K, Vartanian S. Long term results of a comparative study of percutaneous and surgically created proximal forearm arteriovenous fistulae. *Eur J Vasc Endovasc Surg*. 2025;69(5):757-765. Doi: 10.1016/j.ejvs.2025.01.020.

Shimamura S, Kuniyoshi Y, Ueta H, Miyauchi T, Yamazaki H, Tsujimoto Y. A comparison between the efficacy and safety of endovascular arteriovenous fistula creation and surgical fistula creation: A systematic review and meta-analysis. *Cureus*. 2022;14(5):e25091. Doi: 10.7759/cureus.25091.

Sun J-B, Liu C-C, Shen X, Chen Q, Xu C-L, Cui T-L. Percutaneous endovascular arteriovenous fistula: A systematic review and meta-analysis. *Front Cardiovasc Med*. 2022;9:978285. Doi: 10.3389/fcvm.2022.978285.

U.S. Food and Drug Administration. 510(k) submission letter K182796. Trade/Device Name: WavelinQ 4F EndoAVF System. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182796.pdf. Decision date February 6, 2019. (a)

U.S. Food and Drug Administration. 510(k) submission letter K192239. Trade/Device Name: WavelinQ Plus EndoAVF System. https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192239.pdf. Decision date October 17, 2019. (b)

U.S. Food and Drug Administration. De novo classification request for Ellipsys vascular access system. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN170004. Decision date June 22, 2018.

Woodside KJ, Bell S, Mukhopadhyay P, et al. Arteriovenous fistula maturation in prevalent hemodialysis patients in the United States: A national study. *Am J Kidney Dis.* 2018;71(6):793-801. Doi: 10.1053/j.ajkd.2017.11.020.

Yan Wee IJ, Yap HY, Tang TY, Chong TT. A systematic review, meta-analysis, and meta-regression of the efficacy and safety of endovascular arteriovenous fistula creation. *J Vasc Surg.* 2020;71(1):309-317.e305. Doi: 10.1016/j.jvs.2019.07.057.

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.

9/2026: Policy references updated. Coverage modified.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1469. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
36836	Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation [using thermal energy and ultrasound guidance]
36837	Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation [using magnetic-guided arterial and venous catheters and radiofrequency energy].
37799	Unlisted procedure, vascular surgery