Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 10/1/2024
Policy Number: ccp.1469.07	**Effective Date:** 10/2020 **Revision Date:** September 1, 2024
Policy Name: Percutaneous arteriovenous fistula creation	

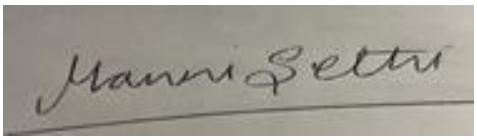
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☒ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Keystone First
Family of Health Plans

Percutaneous arteriovenous fistula creation

Clinical Policy ID: CCP.1469.07

Recent review date: 9/2024

Next review date: 1/2026

Policy contains: Arteriovenous fistula; ellipsys; endovascular; everlinQ; hemodialysis; percutaneous; wavelinQ

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First'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 by Keystone First, on a case by case basis, 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. Keystone First'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. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First'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.

Note: For Medicare Advantage and for Pennsylvania Medical Assistance, percutaneous arteriovenous fistula creation for hemodialysis access may be requested as a program exception and may be reviewed on a case by case basis.

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 (2023), an estimated 808,000 Americans have end stage renal disease, 69% of whom receive dialysis. Among patients on hemodialysis, the surgically-created arteriovenous fistula is the most common vascular access (Jayroe, 2020).

Ideally, referral for initial vascular access placement should occur approximately 3 - 6 months in advance of the anticipated need for dialysis (Schmidli, 2018). The average maturation time of a new autogenous access is two to four months, and additional procedures may be needed to promote maturation or place a new vascular access. Until this process is completed, hemodialysis usually occurs through a central venous catheter, which is associated with bacteremia, inadequate dialysis, and higher mortality.

Optimal vascular access should allow cannulation using two needles and deliver a minimum blood flow of at least 500 mL/min to be usable for hemodialysis, be resistant to infection and thrombosis, and have minimum adverse events (Schmidli, 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 (DeVita, 2020). 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.

However, maturation failure weeks to months after arteriovenous fistula creation, infection, and venous stenosis or thrombosis after maturation continue to complicate hemodialysis access (DeVita, 2020). The surgical procedure itself can cause vascular injury and contribute to maturation failure. 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). Additional procedures and prolonged central venous catheter use are often needed for hemodialysis access.

To improve arteriovenous creation, maturation, and suitability for dialysis, a minimally invasive endovascular approach has been developed (Jayroe, 2020). 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 0 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.

In 2018, the U.S. Food and Drug Administration approved two Class II endovascular systems under the de novo regulatory pathway for arteriovenous fistula creation, using 6-French catheters and either heat or radiofrequency energy for patients who have chronic kidney disease requiring dialysis (procode PQK; 21 CFR 870.1252):

- 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, 2018a). The device is 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 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).
- The everlinQ® endoAVF system (TVA Medical, Becton, Dickinson, and Company, Franklin Lakes, New Jersey) employs 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, 2018b). Once the catheters are aligned in position, the magnets pull the ulnar artery and vein together as radiofrequency energy is applied to create a side-to-side anastomosis. The brachial vein is then coil-embolized to direct

flow toward the superficial veins. The device is indicated for patients with minimum artery and vein diameters of 2.0 mm and less than 2.0 mm separation between the artery and vein at the fistula creation site. Approval was based on the results of the Novel Endovascular Access Trial (ClinicalTrials.gov identifier: NCT02036671) and a global analysis of data from four prospective clinical studies.

In 2019, the U.S. Food and Drug Administration issued 510(k) approval to the WavelinQ™ 4-French endoAVF version (TVA Medical, Becton, Dickinson, and Company, Franklin Lakes, New Jersey). Its lower profile allows more options for fistula location with additional venous wrist access points (ulnar vein or radial vein), which, in turn, increases surgical flexibility and reduces the risk of scarring or arm disfigurement. 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). Both endoAVF systems use angiography guidance limited to the antecubital fossa and forearm at the start of the procedure (U.S. Food and Drug Administration, 2019).

Findings

We included five systematic reviews and meta-analyses (Bontinis, 2023; Malik, 2021; Shimamura, 2022; Sun, 2022; Yan Wee, 2020). No current guidelines have addressed the endovascular approach in vascular access techniques for hemodialysis, including the European Society for Vascular Surgery (Schmidli, 2018). 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.

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 steal syndrome and wound infection. However, one in three WavelinQ procedures resulted in abandonment (Bontinis, 2023).

A systematic review/meta-analysis of 19 studies (n = 1,929) included 14 case series and five cohort studies. In three cohort studies, no significant differences between percutaneous endovascular and surgical techniques were found in procedural success, maturation rates, and complications. Authors state the endovascular approach is “potentially effective and safe” but randomized studies are lacking (Sun, 2022).

A systematic review/meta-analysis of seven studies (n = 860) documented percutaneous endovascular arteriovenous fistula creation was not significantly different from surgical techniques for technical success and adverse events, and had lower costs. Meta-analysis was not possible for procedure time, complications, and patient satisfaction due to insufficient data. Authors conclude evidence to support the endovascular approach over conventional surgery is limited, and randomized trials are needed (Shimamura, 2022).

A systematic review/meta-analysis of four studies (n = 527) also compared percutaneous endovascular (WavelinQ and Ellipsys) with surgical fistula creation. No significant differences were found between the two groups for procedural success, complications, follow-up time, failure rate, and time for two-needle cannulation. Significant differences occurred for procedural time, number of interventions needed to maintain patency, and primary patency rate (all $P < .001$) Authors note the number of studies was limited, lacked heterogeneity and randomization, and only one of four was prospective (Malik, 2021).

Yan Wee (2020) pooled the results of four studies examining the everlinQ system and three studies examining the Ellipsys system (using the older 6-French system in two studies and the newer 4-French system in one study). Results were reported on a total of 300 participants as effect size (95% confidence interval). The overall technical success rate, defined as angiographic evidence of brisk flow within the fistula and absence of leakage of blood outside the fistula, was 97.50% (94.98% to 99.31%, *P* = .487). The 90-day maturation rate, defined as brachial artery flow rate ≥ 500 mL/min and the vein diameter > 4 mm, was 89.27% (84.00% to 93.66%, *P* = .283). The 6-month patency and 12-month patency rates were 91.99% (87.98% to 95.35%, *P* = .780) and 85.71% (79.90% to 90.71%, *P* = not significant), respectively. The overall procedure-related complication rate was 5.46% (0.310% to 14.42%, *P* = .000).

A cost-effectiveness analysis compared one study (n = 33) of WavelinQ patients with surgical patients. WavelinQ patients had lower cost and better quality of life (Rognoni, 2021).

In a national sampling using Medicare claims data, 45,087 new arteriovenous fistulas were placed in 39,820 prevalent hemodialysis patients in the United States in 2013 (Woodside, 2018). Older age, female sex, Black race, certain comorbid conditions (e.g., cardiovascular disease, peripheral artery disease, diabetes, needing assistance, or institutionalized status), dialysis vintage longer than one year, and catheter or arteriovenous graft use at end-stage renal disease incidence were associated with lower successful fistula maturation rates. In contrast, hypertension and prior arteriovenous fistula placement at end-stage renal disease incidence were associated with higher rates of successful fistula maturation.

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. 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 found a low quality narrative review article that explored the emerging technology of percutaneous creation of autogenous hemodialysis fistulae, focusing on two devices, WavelinQ and Ellipsys, and compares their methods, outcomes, and potential advantages over surgically created hemodialysis fistulae. While highlighting the possible benefits of percutaneous fistulae creation, such as improved technical success, reduced costs, and higher patient acceptance, the authors emphasize the need for more rigorous research to validate these advantages, particularly in terms of long-term durability and patient outcomes (Rajan, 2022). No policy changes warranted.

References

On August 7, 2023, 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 technique” (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.

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.

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.

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.

Jayroe H, Foley K. Arteriovenous fistula. *StatPearls*. Treasure Island (FL): StatPearls Publishing. Copyright © 2020, StatPearls Publishing LLC.; 2020.

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.

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 May, 2023.

Rajan DK, Ahmed O. Percutaneous Hemodialysis Fistula Creation. *J Vasc Interv Radiol*. 2022;33(9):1135-1142. Doi:10.1016/j.jvir.2022.06.012.

Rognoni C, Tozzi M, Tarricone R. Endovascular versus surgical creation of arteriovenous fistula in hemodialysis patients: Cost effectiveness and budget impact analyses. *J Vasc Access*. 2021;22(1):48-57. Doi: 10.1177/1129729820921021.

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.

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. February 6, 2019.

U.S. Food and Drug Administration. De novo classification request for Ellipsys® vascular access system. Dated January 10, 2017. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170004.pdf. Decision date June 22, 2018. (a)

U.S. Food and Drug Administration. De novo classification request for Everlinq® endoAVF system. Dated February 3, 2016. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160006.pdf. Decision date June 22, 2018. (b)

Wasse H. Place of percutaneous fistula devices in contemporary management of vascular access. *Clin J Am Soc Nephrol.* 2019;14(6):938-940. Doi: 10.2215/cjn.00980119.

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.