Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 5/1/25**
(See policy history boxes for previous effective dates)

Title: Percutaneous Arteriovenous Fistula (pAVF)

Description/Background

Individuals with chronic kidney disease (CKD) have impaired ability to filter urea and other metabolic waste products from the blood, leading to illness and if untreated, death. This condition is called “chronic” because the damage to the kidneys happens slowly over a long period of time and is not reversable.[1] Advanced chronic kidney disease is called end stage renal disease (ESRD). Individuals with ESRD often require dialysis two or three times per week to prevent death from complete renal failure.

The two most common forms of dialysis are peritoneal dialysis and hemodialysis. In the former, toxic waste products are flushed from the body by instilling and removing dialysis fluid from the peritoneal cavity via dialysis catheter. In the latter, waste products are filtered directly from the bloodstream using a hemodialysis machine. Vascular access to the bloodstream can be achieved by accessing a vein with high blood flow produced by creation of an arteriovenous fistula (AVF), which is a direct communication between a peripheral artery and vein, usually in the upper extremity. Arterial flow directly into the vein causes the recipient veins to enlarge, i.e., for the AVF to “mature,” until it is big enough and has enough flow to be used for inserting intravenous tubing that connects to the dialysis machine. Surgery is the traditional method of creating an AVF.

New percutaneous methods for creating AVFs using radiographic imaging and thermal technologies in individuals whose vascular anatomy is suitable have been developed as an alternative to surgery in selected situations. Percutaneous hemodialysis AV fistula systems create a connection between the ulnar or radial artery in the distal forearm and an adjacent vein if it is large enough and close enough. Once the connection between artery and vein is created, blood flows directly from the arterial system into the venous system just as it would had the connection been made surgically. Once mature, the arterialized vein can be accessed for hemodialysis. See Table 1.

Ellipsys® Vascular Access System

The Ellipsys® Vascular Access System (Medtronic, Minneapolis, MN) is a percutaneous catheter system intended to create an AVF for hemodialysis access in individuals with ESRD. The system is indicated for use in individuals with a minimum vessel diameter of 2 mm and less than 1.5 mm of separation between the artery and vein at the fistula creation site. The anastomosis is created between the proximal radial artery and adjacent vein using direct current thermal heating. Using 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 source 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. [2,3]

WavelinQ™ Endovascular Arteriovenous Fistula (EndoAVF) System

The WavelinQ™ EndoAVF System (Becton, Dickinson and Company [BD], Franklin Lakes, NJ) (originally marketed at EverlinQ) is a minimally invasive electrosurgical tool intended to create AVFs for individuals with minimum artery and vein diameters of 2 mm at the fistula creation site with catheters that are each inserted into an artery (brachial) and a vein (brachial, ulnar or radial) in the arm through a small puncture or incision. Using fluoroscopy, the catheters are both advanced to the appropriate location for endovascular AVF creation. The magnets in the catheters allow them to be precisely aligned while pulling the two adjacent vessels closer together. The venous catheter, which contains the electrode, delivers a burst of radiofrequency energy to create a connection between the artery and the vein. [4,5]

Table 1. Comparison of the Two Percutaneous Arteriovenous Fistula Devices [6]

	WavelinQ™ EndoAVF System	**Ellipsys® Vascular Access System**
Device Components	Two 4Fr, magnetic, hydrophilic coated catheters (venous catheter with radiofrequency electrode and arterial catheter with backstop for receiving the electrode), ESU-1 electrosurgical unit, and electrosurgical pencil	Access needle, 6Fr over-the-wire tissue fusion and cutting catheter, and a power controller
Mechanism of Fistula Creation	Radiofrequency energy	Thermal resistance energy and pressure
Access Sites	Arterial and venous: brachial artery/vein, ulnar artery/vein, or radial artery/vein	Venous: cephalic, median cubital, median basilic, or brachial vein
Site of Fistula Creation	Proximal ulnar artery and ulnar vein or proximal radial artery and radial vein	Proximal radial artery and deep communicating vein
Contrast Required?	Yes, fluoroscopic imaging used to confirm alignment and for confirmation fistulogram	No, ultrasound guidance only

Additional Procedures at Time of Fistula Creation	Brachial vein coil embolization or AMPLATZER™ plug (Abbott Laboratories, Chicago, Illinois)	Immediate balloon angioplasty of the anastomosis with a 5x20mm balloon

EndoAVF: endovascular arteriovenous fistula; Fr: French; ESU: electrosurgical unit; mm: millimeters.

Regulatory Status

The U.S. Food and Drug Administration (FDA) granted 510k(k) marketing clearance for the Ellipsys® System (K191114) in August 2019 based on its substantial equivalence to a previous device model, which initially received 510(k) clearance in October 2018 (K181725). The FDA first cleared Ellipsys® through the De Novo pathway in January 2017 (DEN170004). [3,6]

The WavelinQ™ Plus EndoAVF System was granted 510(k0 marketing clearance by the FDA in October 2019 (K192239) and the WavelinQ™ 4F EndoAVF System in February 2019 (K182796). Prior to the 510(k) clearance, the FDA granted De Novo clearance to the EverlinQ EndoAVF System in June 2018 (DEN160006). [5,8]

Medical Policy Statement

The use of an endovascular percutaneous device for the creation of an arteriovenous fistula (pAVF) for hemodialysis (HD) access is considered **established** when criteria are met.

Inclusionary and Exclusionary Guidelines

Note: Percutaneous arteriovenous fistula (pAVF) placement should be performed by a physician who has completed procedure-specific training with insertion of FDA approved systems.

Inclusions and Exclusions:

WavelinQ Inclusionary Criteria
All of the following must be met:

- Individuals with ESRD
- Life expectancy greater than one year
- Individuals who are not candidates for a distal surgical AVF
- Adult (age ≥ 18 years old)
- Procedural access vessels ≥ 2 mm in diameter
- Perforator vein ≥ 2 mm in diameter
- Ulnar artery and paired ulnar vein OR radial artery and paired radial vein ≥ 2 mm in diameter at the fistula creation site
- Less than 2.0 mm separation between the artery and vein at the fistula creation site

WavelinQ Exclusions:

- When above criteria are not met
- Known central venous stenosis or central vein narrowing > 50% based on imaging on the same side as the planned endoAVF creation
- Upper extremity venous occlusion(s) and/or vessel abnormality(ies) on the same side as the planned endoAVF creation that precludes endoAVF creation.
- New York Heart Association class III or IV heart failure despite optimal therapy
- Hypercoagulable state

Ellipsys Inclusionary Criteria

All of the following must be met:

- Individuals with ESRD
- Life expectancy greater than one year
- Individuals who are not candidates for a distal surgical AVF
- Adult (age ≥ 18 years old)
- Proximal radial artery and adjacent perforating vein with a minimum vessel diameter of 2.0 mm
- Distance between the artery and vein at the fistula creation site <1.5 mm

Ellipsys Exclusions:

- When above criteria are not met
- Known central venous stenosis or central vein narrowing > 50% based on imaging on the same side as the planned endoAVF creation
- Upper extremity venous occlusion(s) and/or vessel abnormality(ies) on the same side as the planned endoAVF creation that precludes endoAVF creation.
- Hypercoagulable state
- New York Heart Association class III or IV heart failure despite optimal therapy

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CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

36836 36837

Other codes (investigational, not medically necessary, etc.):

NA

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

In a systematic review of literature, Choinski et al. compared the available studies for the Elipsys® Vascular Access System and the WavelinQ™ EndoAVF System.[6] They found that in all trials with percutaneous arteriovenous fistulas (pAVSs), individuals were only considered for the procedure if they were not candidates for a surgically created distal radiocephalic AVF at the wrist. Individuals were typically CKD IF/CKD V (chronic kidney disease), planning for future dialysis, or already in end-stage renal disease ESRD), receiving dialysis via a tunneled venous catheter. Individuals with a previously failed surgical AVF were eligible for pAVF creation. Both devices had a high technical success rate in pAVF creation ranging from 94-100% for WavelinQ™ and 88%-100^ for the Ellipsys®. Patency had been more extensively studied for the Ellipsys® pAVF than for the WavelinQ™ and appear to have a higher patency. Analysis for two-year patency has only been conducted for the Ellipsys® pAVF, displaying a cumulative patency of 92.7%. Both endovascular and open secondary interventions were required for the maturation and maintenance of pAVFs, with balloon angioplasty used most frequently for the Ellipsys® pAVF. The authors noted the creation of a pAVF does not prohibit future conversion to a surgical AVF when the creation of a distal, wrist radiocephalic fistula is not possible. They also noted none of the trials reviewed had direct comparison of pAVF to surgical AVF outcomes, and given that, the evidence does not support pAVF as a first-line approach in comparison to surgical AVF. Surgical AVFs, if selected properly, have high maturation rates, with a distal radiocephalic maturation rate up to 75-85%. Current trials offer the pAVF as a possible alternative to surgical AVF when the creation of a distal, wrist radiocephalic fistula is not possible.

Ellipsys® Vascular System Access

Hull et al.(2018) reported on a pivotal trial to evaluate the safety and efficacy of arteriovenous fistula (AVF) created with a thermal resistance anastomosis device.[9] A prospective singe-arm trial at 5 sites enrolled 107 individuals between February 2015 and June 2016. Individuals underwent ultrasound (US)-guided anastomosis creation between the proximal radial artery and perforating vein with the Ellipsys® Vascular Access System (Avenu Medical, Inc, San Juan Capistrano, California-now Medtronic) followed by separate maturation procedures in an office-based laboratory. Primary endpoints were brachial artery flow volume ≥ 500ml/min and target vein diameter ≥ 4 mm in > 49% of individuals and absence of device-related complications at 90 days. AVFs with fused anastomoses were created in 95% (102/107) of individuals. Maturation procedures included anastomotic balloon dilation in 72% (77/107), brachial vein embolization in 32% (34/107), cubital vein ligation in 31% (33/107), and surgical transposition in 26% (28/107) of individuals. Primary flow and diameter endpoints were achieved in 86.0% (92/107) of individuals, exceeding performance goal of 49% (P <.0001). No major adverse events were attributed to the device. “Cumulative patency was 91.6%, 89.3%, and 86.7% at 90 days, 180 days, and 360 days. Target dialysis veins were cephalic, basilic, and brachial veins in 74% (73/99), 24% (24/99), and 2% (2/99) of individuals, Two-needle dialysis was achieved in 88% (71/81) of individuals on hemodialysis at a mean 114.3 days ± 66.2. Functional patency was 98.4%, 98.4% and 92.3% at 90 days, 180 days and 360 days. The authors note the primary safety and efficacy endpoint goals in this trial were met.

Thermal Resistance Anastomosis Devices (TRAD) fistulas were created with ultrasound guidance in the office-based laboratory with good clinical outcomes and minimal complications

meeting and safety and efficacy thresholds of the US pivotal trial. The TRAD fistulas demonstrated AVF characteristics similar to surgically created fistulas at the favored proximal radial artery site using a minimally invasive approach performed in the office-based laboratory. Hull (2020) Studies support 63%-65% of patients requiring hemodialysis to be eligible candidates for the Ellipsys® procedure.[10,11] Percutaneous fistulas were created in most patients at a multidisciplinary office-based laboratory. The fistula was created with a high level of technical and clinical success, rapidly achieving the critical milestones of fistula placement, 2-needle cannulation, functional fistula, and catheter removal. The clinical characteristics of the maturing and functional single-vessel outflow percutaneous fistula were defined for the US population.

Mallios et at (2019)[12] Summarized a single-center comprehensive database of all consecutive predialysis and end-stage renal disease patients who had a pAVF creation with the Ellipsys® device was reviewed retrospectively. Study end points included technical success, maturation, functional patency, and required interventions. 234 patients (mean age, 64 years; 148 male [63%]) who had a pAVF created. Technical success was achieved in 232 individuals (99%), and average duration of the procedure was 15 minutes (7-35 minutes). Average follow-up was 252 days (range, 83-696 days). The 1-year primary, primary assisted, and secondary patency rates were 54%, 85%, and 96%, respectively. Average pAVF flow was 923 mL/min (range, 425-1440 mL/min). There were no significant adverse events related to the procedure. Only three patients (1%) required a later conversion of the pAVF anastomosis to a surgical fistula. Twenty-four (10%) patients required superficialization of deep outflow veins because of difficult cannulation. Average maturation time was 4 weeks (range, 1-12 weeks). Fourteen patients (6%) had early (<2 weeks after creation) cannulation of the pAVF. The Ellipsys® pAVF device allows the rapid and safe creation of a reliable autogenous access. Rates of technical success, patency, and maturation were excellent. For patients unsuited for a distal radiocephalic arteriovenous fistula, it should be considered the next preferred access option.

Hebibi et al. (2019) looked at records of 34 individuals who had a pAVF created using the Ellipsys® system.[13] "Technical success was achieved in 33 individuals (97%). Twenty-eight out of 34 (82%) individuals had successful two needle cannulation within 10 days to 6 weeks after pAVF creation. The mean dialysis adequacy (Kt/v) was 1.6 and the average recirculation was 10%. Fifteen individuals (44%) needed no further access intervention. Twelve individuals (35%) required an additional procedure to assist maturation of the pAVF in order to facilitate puncture. The average blood flow measured at the brachial artery, before the first cannulation, was 850 ml/min. From causes unrelated to the procedure, four individuals died during the follow up study. Two individuals required revision to a surgical AVF. None of the pAVFs developed aneurysmal degeneration steal syndrome, or high access flow related issues." Limitations include the retrospective single arm observational nature of the study, the relatively small number of individuals and short follow-up. The Ellipsys® pAVF offers a safe and functional vascular access for hemodialysis. Advantages included prompt access maturation, avoidance of high flow AVFs, and a simple nonsurgical procedure with high patient satisfaction. Functional outcomes are equivalent and likely better than surgical fistulas. There appears to be less aneurysmal degeneration and need for future re-intervention. Objective dialysis parameters indicate excellent quality of hemodialysis for the patient.

In 2020, Beathard et al.[14] published results of a retrospective analysis of data generated by five vascular access programs in the United States. An endovascular arteriovenous fistula was created in 105 individuals using either local or regional anesthesia and conscious sedation.

Patient data were obtained from each program's electronic health record system. Data collection was truncated at 2 years post-procedure and used to calculate cumulative patency. Post-access creation patient satisfaction was assessed. "A physiologically mature arteriovenous fistula (blood flow ≥500 mL/min and a target vein internal diameter ≥4 mm) was obtained in 98%. A clinically functional arteriovenous fistula (supporting two-needle dialysis according to the individual's dialysis prescription) was demonstrated in 95%. Access failure resulting in the loss of access occurred in eight cases during the study period. The cumulative patency rate at 6, 12, 18, and 24 months was 97%, 93.9%, 93.9%, and 92.7%, respectively. The post-procedure patient evaluation emphasized a high level of patient satisfaction". The proximal radial artery arteriovenous fistula created using an endovascular approach for the anastomosis is associated with excellent 2-year cumulative patency and is associated with a high level of patient satisfaction.

WavelinQ™ Endovascular Arteriovenous Fistula (EndoAVF) System

Lok et al. in 2017 published the results of a prospective, single-arm, multicenter study (Novel Endovascular Access Trial [NEAT]) evaluating catheter-based endovascular technology and radiofrequency energy to create an endovascular AVF (endo AVF).[15] Hemodialysis arteriovenous fistulas (AVFs) are suboptimally used primarily due to problems with maturation, early thrombosis, and patient nonacceptance. An endovascular approach to fistula creation without open surgery offers another hemodialysis vascular access option. Using catheter-based endovascular technology and radiofrequency energy, an anastomosis was created between target vessels, resulting in an endovascular AVF (endoAVF). 80 patients were enrolled (20 roll-in and 60 participants in the full analysis set, the latter are reported). EndoAVFs were created in 98% of participants, 8% had a serious procedure-related adverse event (2% device related). 87% were physiologically suitable for dialysis (eg, mean brachial artery flow, 918mL/min; endoAVF vein diameter, 5.2mm [cephalic vein]). EndoAVF functional usability was 64% in participants who received dialysis. 12-month primary and cumulative patencies were 69% and 84% respectively. The study was limited due to the unique anatomy and vessels used to create endoAVFs, this was a single-arm study without a surgical comparator. The authors summarized an endoAVF can be reliably created using a radiofrequency magnetic catheter-based system, without open surgery and with minimal complications. The endoAVF can be successfully used for hemodialysis and demonstrated high 12-month cumulative patencies. It may be a viable alternative option for achieving AVFs for hemodialysis patient in need of vascular access.

Berland et al. published results of pooled data from three prospective, multicenter, single-arm trials conducted outside of the United States in 2021.[16] "The use of the 4F WavelinQ™ system in three studies, EASE (32 individuals), EASE-2 (24 individuals), and the European Union (EU) post-market clinical follow-up study (64 individuals) was aggregated and analyzed. Individuals were followed with duplex ultrasound at discharge and follow-up visits at 1, 3, 6 months. Primary, assisted primary, and secondary patency rates were evaluated as Kaplan-Meier estimates and standard errors. Time to maturity and time to successful cannulation were defined as the mean 6 standard deviation days from the procedure in individuals enrolled on dialysis. "Procedural success was achieved in 116 individuals (96.7%). Primary, assisted-primary, and secondary 6-month patency rates were 71.9% ± 4.5%, 80.7% ± 4.1%, and 87.8% ± 3.3%, respectively. Time to maturity averaged 41 ± 17 days. Time to successful cannulation averaged 68 ± 51 days. Device related serious adverse events were reported in 3 of 120 individuals (2.5%) and procedure-related serious adverse events were reported in 3 of 120 individuals (5.8%). Arterial or venous access complications were not reported in any of the

individuals. Access circuit reinterventions were performed in 23 individuals (19.2%), split between those performed for EndoAVF maturation (13/120 [10.8%]) and maintenance (11/120 [9.2%]).” Percutaneous creation of native dialysis fistula with the 4F WavelinQ™ EndoAVF System is safe and effective, with favorable durability and a low rate of serious complications and reinterventions through 6-month follow-up. “Use of the 4F device allows for percutaneous fistula creation between the radial artery and radial vein or the ulnar artery and ulnar vein”.

An analysis by Kitrou et al. 2022 assess the safety and efficacy of pAVF creation with the WavelinQ™ 4-F EnodAVF System.[17] "From February 2018 to June 2020, 30 pAVFs were created in 30 consecutive individuals (men, age, 55.3 ± 13.6). Of the 30 individuals, 21 (70%) were already on hemodialysis using a central venous catheter. The primary outcome measures were technical success, complications, and cannulation rate. The secondary outcome measures included the number of secondary procedures needed for cannulation, maintenance time to cannulation, and pAVF survival”. “Technical success was 100%. The adverse event rate was 6.7% (2/30), including a pseudoaneurysm of the brachial artery that developed immediately after sheath removal and an aneurysm of the anastomosis 17 days mean follow-up was 547 days ± 315.7 (rang, 14-,071 days). The cannulation rate as 86% (26/30). The mean time to cannulation was 61.3 days ± 32.5 range (range, 15-135 days). The mean follow-up after cannulation, with 2 of them successfully declotted. Sixteen interventions were needed to achieve cannulation after the index procedure in 15 individuals (overall, 0.53 procedures/patient). Seven maintenance endovascular interventions (following cannulation) were performed during the follow-up period in 6 individuals (overall, 0.27 procedures/patient, 0.17 procedures/patient-years). For the pAVFs that were cannulated, patency was 96% at 1 year, and 82% at 2 and 3 years, according to the Kaplan-Meier survival analysis”. “This initial experience suggests that pAVF creation is safe and can be successfully performed with high maturation and long-term patency rates”.

Systematic review and meta-analysis[18]: Methods: We searched the Medline, Embase, Cochrane Library, and ClinicalTrials.gov databases for studies on endovascular or endovascular versus surgery for the creation of AVF. Two reviewers independently selected studies and extracted data. A systematic review and meta-analysis were performed by Review Manager 5.4 software (Revman, The Cochrane Collaboration, Oxford, United Kingdom) and Stata 15.0 (Stata Corp, College Station, TX, United States).

Results: A total of 14 case series and 5 cohort studies, with 1,929 patients, were included in this study. The technique success was 98.00% for endoAVF (95% CI, 0.97–0.99; I^2 = 16.25%). There was no statistically significant difference in 3 cohort studies between endovascular and surgical AVF for procedural success (OR = 0.69; 95% CI, 0.04–11.98; P = 0.80; I^2 = 53%). The maturation rates of endoAVF were 87.00% (95% CI, 0.79–0.93; I^2 = 83.96%), and no significant difference was observed in 3 cohort studies between the 2 groups (OR = 0.73; 95% CI, 0.20–2.63; P = 0.63; I^2 = 88%). Procedure-related complications for endoAVF was 7% (95% CI, 0.04–0.17; I^2 = 78.31%), and it did not show significant difference in 4 cohort studies between the 2 groups (OR = 1.85; 95% CI, 0.37–9.16; P = 0.45; I^2 = 59%).

Conclusion: The endovascular creation of AVF is potentially effective and safe. These important data may provide evidence to support clinicians and patients in making decisions with endovascular AVF.

Summary of Evidence

The evidence reviewed for percutaneous arteriovenous fistula creation using the Ellipsys® Vascular Access System or the WaveLinQ™ Endovascular Arteriovenous Fistula (EndoAVF)

System includes a pivotal trial as well as retrospective reviews of literature. The evidence supports the Ellipsys® system and WavelinQ provide substantial clinical benefits by virtue of high rates of clinically functioning, mature fistulas, reduced time to two-needle cannulation and fewer secondary interventions and missed dialysis treatments. .

Ongoing and Unpublished Clinical Trials

Some currently ongoing or unpublished clinical trials that might influence this policy are listed in Table 2.

Table 2. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04634916	Post-market Surveillance Study of the BD® WavelinQ™ EndoAVF System (CONNECT-AV)	280	September 2024
Completed			
NCT04484220	Ellipsys® Vascular Access System Post Market Surveillance (PS) Study	134	August 2023
NCT03454113	Ellipsys® Vascular Access System Registry	100	July 2020

NCT: national clinical trial.

Government Regulations

National:

There is no national coverage determination on this topic.

Local:

There is no local coverage determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

1. National Institute of Diabetes and Diabetes and Digestive and Kidney Diseases. Available at What Is Chronic Kidney Disease? | NIDDK (nih.gov) (accessed 1/3/25)
2. Medtronic. Ellipsys® Vascular Access System Brochure. Available at <http://www.medtronic.com> (Accessed 1/3/25).
3. ECRI Institute. Ellipsys® Vascular System Access (Avenu Medical, Inc.) for Creating Hemodialysis Arteriovenous Fistulas. Plymouth Meeting (PA): ECRI Institute; August 2021. Clinical Evidence Assessment.
4. Becton, Dickinson and Company (BD). WavelinQ™ EndoAVF Screening and Procedure Frequently Asked Questions. Available at <http://www.wavelinq.bd.com> (Accessed 1/3/25).
5. ECRI Institute. WavelinQ™ EndoAVF System (BD) for Creating Hemodialysis Arteriovenous Fistulas. Plymouth Meeting (PA): ECRI Institute; April 2022. Clinical Evidence Assessment.
6. Choinski KN, Sundick SA, Roa, AG, et al. The Current Role of the Percutaneous Arteriovenous Fistula for Hemodialysis Access. Surg Technol Int. 2020 Nov 28; 37:217-224. PMID 32681730
7. FDA. Ellipsys® Vascular Access System 510(k) Premarket Notification. U.S. Food and Drug Administration. 2019. Available at <http://www.fda.gov> (Accessed 1/3/25).
8. FDA.WavelinQ™ EndoAVF System. 510(k) Premarket Notification. U.S. Food and Drug Administration. 2019. Available at <http://www.fda.gov> (Accessed 1/3/25).
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13. Hebibi H, Achiche J, Franco G, et al. Clinical Hemodialysis with Percutaneous Arteriovenous Fistulas Created with the Ellipsys® Vascular Access System. Hemodial Int. 2019 Apr; 23(2):167-172. PMID 30821894
14. Beathard GA, Litchfield T, Jennings WC. Two-year Cumulative Patency of Endovascular Arteriovenous Fistula. J Vasc Access. 2020 May; 21(3): 350-356. PMID 31566061
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16. Berland T, Clement J, Inston N, et al. Percutaneous Arteriovenous Fistula Creation with the 4F WavelinQ™ EndoAVF System.J Vasc Surg. 2022 Mar; 73(3):1038-1046. PMID 34601046

17. Kitrou PM, Balta L, Papachristou E, et al. Percutaneous Arteriovenous Fistula Creation with the WavelinQ™ 4-French EndoAVF System: A Single-Center Retrospective Analysis of 30 Individuals. J Vasc Interv Radiol. 2022 Jan; 33(1):33-40. PMID 34610421

18. Ji-Bio Sun, Chun-chung Liu, Xi Shen, Qin Chen, et al. Percutaneous endovascular arteriovenous fistula: A systematic review and meta-analysis. Frontiers in Cardiovascular Medicine. 2022 Sept 06; Systematic Review. https://doi.org/10.3389/fcvm.2022.978285 Accessed 1/3/25

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 1/3/25, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/23	2/21/23		Joint policy established (jf). New medical document. The use of an endovascular percutaneous device (e.g., Ellipsys® System; WavelinQ™ System) for the creation of an arteriovenous fistula (AVF) for hemodialysis access is considered experimental, investigational and/or unproven. Vendor Managed: NA
5/1/24	2/20/24		Maintenance Review (jf) Vendor Managed (NA) Added codes 36836 and 36837 as EST/payable status change E/I to EST Edits to MPS, Rationale, inclusions and exclusions Added ref: 10, 11,19,20
5/1/25	2/18/25		Maintenance Review (jf) Vendor Managed (NA)

Next Review Date: 1st Qtr, 2026

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: PERCUTANEOUS ARTERIOVENOUS FISTULA (pAVF)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.