

## Ellipsys Vascular Access System, Medical 319

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<u>Effective Date</u>	8/2019
<u>Next Review Date</u>	1/2025
<u>Coverage Policy</u>	Medical 319
<u>Version</u>	5

**Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details\*.**

### Purpose:

This policy addresses the medical necessity of Ellipsys Vascular Access System.

### Description & Definitions:

The Ellipsys vascular access system uses a minimally invasive device to join the artery and vein together to create an Arteriovenous Fistula (AVF) guided by ultrasound and thermal energy.

### Criteria:

Ellipsys Vascular Access System is considered **not medically necessary** for any indication.

### Coding:

Medically necessary with criteria:

Coding	Description
	None

Considered Not Medically Necessary:

Coding	Description
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 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
37799	Unlisted procedure, vascular surgery

U.S. Food and Drug Administration (FDA) - approved only products only.

## Document History:

### Revised Dates:

- 2020: January

### Reviewed Dates:

- 2024: January
- 2023: January
- 2022: February
- 2021: February
- 2020: April

### Effective Date:

- August 2019

## References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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National Coverage Determination (NCD) Percutaneous Transluminal Angioplasty (PTA) 20.7. (2013, Jan). Retrieved Jan 2024, from CMS - NCD: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=201&ncdver=10&bc=0>

Percutaneous arteriovenous fistula creation. (2023). Retrieved Jan 2024, from HAYES: <https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Percutaneous%2520arteriovenous%2520fistula%2520creation%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522typ>

Procedure Fee Files & CPT Codes. (2023). Retrieved Jan 2024, from Department of Medical Assistance Services: <https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/> & <https://www.dmas.virginia.gov/for-providers/cardinal-care-transition/>

Technical aspects of percutaneous endovascular arteriovenous fistula creation with the Ellipsys® Vascular Access System. (2023, Jan 17). Retrieved Jan 2024, from Langenbeck's Archives of Surgery: NIH: [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9931805/pdf/423\\_2023\\_Article\\_2812.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9931805/pdf/423_2023_Article_2812.pdf)

The Ellipsys® Vascular Access System. (2024). Retrieved Jan 2024, from AVENU MEDICAL: <https://avenumedical.com/ellipsys/>

KDOQI Clinical Practice Guideline for Vascular Access (2020, Apr). Retrieved Jan 2024, from American Journal of Kidney Diseases <https://www.ajkd.org/action/showPdf?pii=S0272-6386%2819%2931137-0>

### Special Notes: \*

This medical policy expresses Sentara Health Plan's determination of medical necessity of services, and they are based upon a review of currently available clinical information. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

### Keywords:

SHP Ellipsys Vascular Access System, SHP Medical 318, hemodialysis, arteriovenous fistula, end-stage renal disease, EndoAVF, Endovascular creation of arteriovenous fistula, Percutaneous Arteriovenous Fistula (pAVF) for Hemodialysis, Ellipsys Vascular Access System (Ellipsys System), Crossing Needle, EndoAVF, Percutaneous Arteriovenous Fistula (pAVF) for Hemodialysis, endo-AV fistulas, WavelinQ System