

Ellipsys Vascular Access System, Medical 318

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<u>Coverage Policy</u>	Medical 318
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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

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:

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- 2020: January

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

Effective Date:

- August 2019

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2024). Retrieved Jan 2024, from MCG 27th Edition: <https://careweb.careguidelines.com/ed27/index.html>

Code of Federal Regulations Title 21 CFR Sec. 870.1252 Percutaneous catheter for creation of an arteriovenous fistula for hemodialysis access. (2023, Oct 17). Retrieved Jan 2024, from FDA: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=870.1252>

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

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 express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. 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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

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

