# SHP Ellipsys Vascular Access System

AUTH: SHP Medical 318 v4 (AC)

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# Coverage

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See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.

### Application to Products

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Policy is applicable to all products.

## Authorization Requirements

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Pre-certification by the Plan is required.

# **Description of Item or Service**

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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.

#### Exceptions and Limitations

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There is insufficient scientific evidence to support the medical necessity of this service as it is not shown to improve health outcomes upon technology review.

# Clinical Indications for Procedure

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• NA

### **Document History**

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Revised Dates:

2020: January

- · Reviewed Dates:
  - 2023: January
  - 2022: February
  - 2021: February
  - 2020: April
- Effective Date: August 2019

### Coding Information

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- · CPT/HCPCS codes covered if policy criteria is met:
  - None
- · CPT/HCPCS codes considered not medically necessary per this Policy:
  - CPT 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

CPT 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
CPT 37799 - Unlisted procedure, vascular surgery

### References

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References used include but are not limited to the following:

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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Patient selection, education, and cannulation of percutaneous arteriovenous fistulae: An ASDIN White Paper. (2019, Oct 06). Retrieved Dec 20, 2022, from American Society of Diagnostic and Interventional Nephrology: https://cdn.ymaws.com/www.asdin.org/resource/resmgr/positionpaper/ASDIN EndoAVF.pdf

Smeds, M., & Bose, S. (2022, Apr 27). Percutaneous hemodialysis arteriovenous fistula. Retrieved Dec 20, 2022, from UpToDate: https://www.uptodate.com/contents/percutaneous-hemodialysis-arteriovenous-fistula?search=Ellipsys% 20Vascular&source=search\_result&selectedTitle=1~150&usage\_type=default&display\_rank=1#H2676907022

Medical Devices; Cardiovascular Devices; Classification of the Percutaneous Catheter for Creation of an Arteriovenous Fistula for Hemodialysis Access. (2022, Feb 18). Retrieved Dec 20, 2022, from Food and Drug Administration: https://www.federalregister.gov/documents/2022/02/18/2022-03496/medical-devices-cardiovascular-devices-classification-of-the-percutaneous-catheter-for-creation-of

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