2021 Ellipsys™ System Coding Guide

Ambulatory Surgery Center

Ellipsys™ Vascular Access System for Percutaneous Creation of Arterio-Venous Fistulas.

Medtronic does not represent or guarantee that this information is complete, accurate, or applicable to any particular patient or third-party payer. The final decision of billing for any service must be made by the health care provider. Healthcare providers should consult with their own advisors regarding coding, coverage, and payment.

<table>
<thead>
<tr>
<th>HCPCS/ CPT® Code</th>
<th>Description</th>
<th>Status Indicator</th>
<th>Payment</th>
<th>Professional (Facility) Fees</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ellipsys™ System endoAVF procedure coding</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G2170</td>
<td>Percutaneous arteriovenous fistula creation (avf), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed</td>
<td>G2</td>
<td>$7,056</td>
<td>Carrier Priced(^5)</td>
</tr>
<tr>
<td><strong>Common pre-procedure codes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>93985</td>
<td>Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study</td>
<td>P2</td>
<td>$116</td>
<td></td>
</tr>
<tr>
<td>93986</td>
<td>Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study</td>
<td>P2</td>
<td>$55</td>
<td></td>
</tr>
<tr>
<td><strong>Common AV fistula maintenance codes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>93990</td>
<td>Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>36901</td>
<td>Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit</td>
<td>P2</td>
<td>$545</td>
<td>$171</td>
</tr>
<tr>
<td>36902</td>
<td>Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit... with transluminal balloon angioplasty, peripheral dialysis segment</td>
<td>G2</td>
<td>$2,156</td>
<td>$243</td>
</tr>
<tr>
<td>36903</td>
<td>Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit... with transcatheter placement of intravascular stent(s), peripheral dialysis segment</td>
<td>J8</td>
<td>$6,447</td>
<td>$320</td>
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<tr>
<td>36904</td>
<td>Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit</td>
<td>G2</td>
<td>$2,156</td>
<td>$373</td>
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<tr>
<td>36905</td>
<td>Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit... with transluminal balloon angioplasty, peripheral dialysis segment</td>
<td>G2</td>
<td>$4,263</td>
<td>$450</td>
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<tr>
<td>36906</td>
<td>Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit... with transcatheter placement of intravascular stent(s), peripheral dialysis segment</td>
<td>J8</td>
<td>$10,661</td>
<td>$518</td>
</tr>
<tr>
<td>+36907</td>
<td>Transluminal balloon angioplasty, central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the angioplasty</td>
<td>N</td>
<td>Packaged</td>
<td>$149</td>
</tr>
<tr>
<td>+36908</td>
<td>Transcatheter placement of intravascular stent(s), central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the stenting, and all angioplasty in the central dialysis segment</td>
<td>N</td>
<td>Packaged</td>
<td>$210</td>
</tr>
<tr>
<td>+36909</td>
<td>Dialysis circuit permanent vascular embolization or occlusion</td>
<td>N</td>
<td>Packaged</td>
<td>$204</td>
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<tr>
<td>37607</td>
<td>Ligation or banding of angioaccess arteriovenous fistula</td>
<td>A2</td>
<td>$1,365</td>
<td>$382</td>
</tr>
</tbody>
</table>

1. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index?redirect=/ASCPayment/
2. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Index
3. Office Based Labs may use HCPCS code G2170 to report the endoAVF procedure performed with the Ellipsys Vascular Access System. Physician reimbursement for these codes is under the jurisdiction of Medicare Administrative Contractors. CMS does not establish Physician payments for HCPCS codes including G codes which have a payment status indicator "C". Physician reimbursement for these codes is under the jurisdiction of Medicare Administrative Contractors.

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Non-Medicare payers may have different rules and guidelines for coding and reimbursement for the procedures discussed in this document. Commercial, or private payers may not update their systems at the same cadence that new codes are introduced. For appropriate code selection, it is recommended that you contact your local payer prior to submitting your claim.

Code C9754 was appropriate until G2170 was implemented on July 1, 2020, if your payer does not recognize code G2170 you should contact them to determine which code they recommend is submitted for these services.

Status indicators:
- **ASC**: Carrier Priced.
- **A2**: Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight.
- **G2**: Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.
- **N**: Packaged. Payment packaged into the primary procedure payment.
- **P2**: Office-based surgical procedure added to ASC list in CY 2008 or later with MFPS non-facility PE RVUs; payment based on OPPS relative payment weight.

### Indications
The Ellipsys™ System is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0mm and less than 1.5mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis.

### Contraindications
The Ellipsys™ System is contraindicated for use in patients with target vessels that are < 2mm in diameter. The Ellipsys™ System is contraindicated for use in patients who have a distance between the target artery and vein > 1.5mm.

### Warnings
The Ellipsys™ System has only been studied for the creation of an AV fistula using the proximal radial artery and the adjacent perforating vein. It has not been studied in subjects who are candidates for surgical fistula creation at other locations, including sites distal to this location.

- The Ellipsys™ System is not intended to treat patients with significant vascular disease or calcification in the target vessels.
- The Ellipsys™ System has only been studied in subjects who had a patent palmar arch and no evidence of ulnar artery insufficiency.
- Use only with the Ellipsys™ Power Controller, Model No. AMI-1001.
- The Ellipsys™ Catheter has been designed to be used with the 6F Terumo Glidesheath Slender. If using a different sheath, verify the catheter can be advanced through the sheath without resistance prior to use.
- Use ultrasound imaging to ensure proper placement of the catheter tip in the artery before retracting the sheath, since once the distal tip of the catheter has been advanced into the artery, it cannot be easily removed without creation of the anastomosis. If the distal tip is advanced into the artery at an improper location, complete the procedure and remove the catheter as indicated in the Directions For Use.
- It is recommended that a follow-up evaluation of the patient is performed using appropriate clinical standards of care for surgical fistulae to determine if any clinically significant flow develops that require further clinical action.
  - For single use only. Do not reuse. Do not re-sterilize. Do not reprocess. Reuse, re-sterilization and/or reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.
  - Do not use if the unit package, sterile barrier or product has been damaged or soiled.
  - Do not use after the labeled “use by” (expiration) date.

### Precautions
- This product is sterilized by ethylene oxide gas.
- Additional products are expected to be required to increase and direct blood flow to the AVF target outflow vein and to maintain patency of the AVF. Care should be taken to proactively plan for any fistula maturation procedures when using the device.
- In the Ellipsys™ study (summarized below), 99% of subjects required balloon dilatation (PTA) to increase flow to the optimal access vessel and 62% of subjects required embolization coil placement in competing veins to direct blood flow to the optimal access vessel. Prior to the procedure, care should be taken to assess the optimal access vessel for maturation, the additional procedures that may be required to successfully achieve maturation, and appropriate patient follow-up. Please refer to the “Arteriovenous Fistula (AVF) Maturation” section of the labeling below for guidance about fistula flow, embolization coil placement, and other procedures to assist fistula maturation and maintenance.
- The Ellipsys™ System is intended to only be used by physicians trained in ultrasound guided percutaneous endovascular interventional techniques using appropriate clinical standards of care for fistula maintenance and maturation including balloon dilatation and coil embolization.
- Precautions to prevent or reduce acute or longer term clotting potential should be considered. Physician experience and discretion will determine the appropriate anticoagulant/antiplatelet therapy for each patient using appropriate clinical standards of care.

### Potential Complications/Adverse Events
Potential complications which may be associated with the creation or maturation of an arteriovenous fistula include, but may not be limited to the following:
- Total occlusion, partial occlusion or stenosis of the anastomosis or adjacent outflow vein
- Stenosis of the central AVF outflow requiring treatment per the treatment center’s standard of care
- Failure to achieve fistula maturation
- Incomplete vessel ligation when using embolization coil to direct flow
- Steal Syndrome
- Hematoma
- Infection or other complications
- Need for vessel superficialization or other maturation assistance procedures.

For questions regarding coding, coverage and payment

Contact the Ellipsys™ Reimbursement Hotline at 888-ENDOAVF (363-6283)

For email communication: ellipsys@emersonconsultants.com

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Reimbursement Information

www.medtronic.com/cvreimbursement

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