
Percutaenous Creation of Arterio- Venous Fistulas: 2021 Proposed APC Assignment for G2170

Advisory Panel on Hospital Outpatient Payment

August 31, 2020

Presentation on behalf of Avenu Medical, Inc.

Presenters

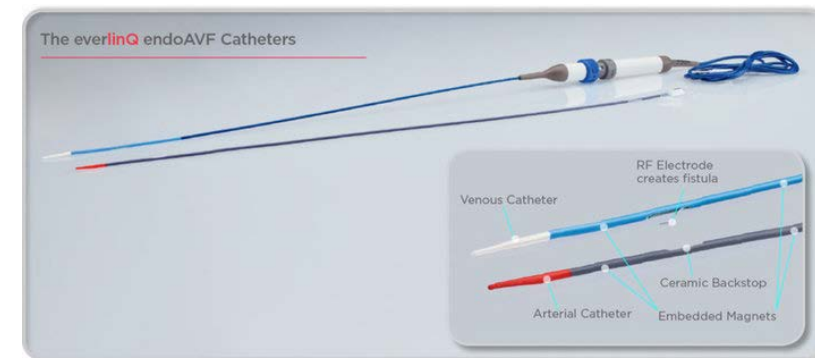
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Issue

- Recently approved devices allow for the creation of a percutaneous arteriovenous fistula (pAVF), which compares favorably with the traditional surgical procedure:
 - Less invasive
 - Improved maturation
 - Earlier cannulation
 - Fewer short-term complications
 - Improved long-term patency
- Codes for pAVF creation were first established effective January 1, 2019
- CMS proposes to reassign the code for pAVF creation using thermal resistance energy (G2170) to a new APC assignment for 2021
 - Initial claims data is extremely limited and is producing inaccurate costs estimates
- We ask the HOP panel to recommend that CMS maintain the current APC assignment for G2170 for 2021

Background

- pAVF can be performed using one of two devices, based in part on patient's anatomy
 - Ellipsys– Single catheter DC thermal resistance device, placed under ultrasound
 - WavelinQ – Dual catheter device, magnetic RF electrode, placed under fluoroscopy
- Both devices were approved in June 2018
- CMS established two separate C codes for pAVF procedures effective January 2018; these codes were replaced by G codes effective July 1, 2020



pAVF Procedures Expected to Have Similar Total Costs

- Procedures are clinically similar, while they differ in some aspects
 - Ellipsys procedure time appears to be shorter than WavelinQ for fistula creation but total procedure time, including associated ancillary procedures included in the code descriptor, is comparable
 - Ellipsys device costs are similar to WavelinQ for hospital customers
 - Invoices demonstrate Ellipsys cost to hospitals = \$6,000
- Total procedure costs to the hospital expected to be comparable
- pAVF codes should be assigned to the same APC

Current and Proposed APC Assignment for pAVF

HCPSC Code	Descriptor	Technology	2020 APC	2020 Payment Rate	Proposed 2021 APC	Proposed 2021 Payment Rate
G2170	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	Ellipsys	5194	\$15,939	5193	\$10,222
G2171	Percutaneous arteriovenous fistula creation (avf), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	WavelinQ	5194	\$15,939	5194	\$16,349

Preliminary Cost Estimates for G2170 are Inaccurate

- Based on extremely small number of claims – 57 single procedure claims (for predecessor C code)
 - Lack of coding for physician service may have limited initial access to pAVF procedures
 - CMS created G codes to allow for more specific, accurate coding and billing
- Small number of claims have yielded cost estimates that do not align with real world experience
 - Estimated device amount for G2170 = \$3,819, well below actual device cost of \$6,000
 - Estimated device amount for G2171 = \$6,397
 - Device costs are comparable and therefore device percentage for G2170 would be expected to be significantly greater than CMS' estimate of 37% if estimate of total costs were accurate
- Issues similar to those CMS has acknowledged for other device-intensive, low volume (fewer than 100 claims) procedures

Recommendation

- Given the small number of initial claims for this new procedure, the HOP Panel should recommend to CMS that G2170 continue to be assigned to APC 5194 for 2021
 - Maintains clinically and resource-appropriate APC assignment for both pAVF procedure codes (G2170 and G2171)
 - Allows CMS to gather additional data on cost of procedure under newly established G codes for another year