RE: Proposed Local Coverage Determination (LCD): Percutaneous Arteriovenous Fistula (pAVF) for Hemodialysis (DL38573)

To Whom It May Concern:

National Government Services (NGS) published a proposed local coverage determination (LCD) regarding Percutaneous Arteriovenous Fistula (pAVF) for Hemodialysis (DL38573) on June 24th, 2020 with the comment period ending July 18th, 2020. The Society for Vascular Surgery (SVS) and The Society of Interventional Radiology (SIR) offer the following comments to NGS on LCD DL38573.

Background
The Center for Medicare and Medicaid Services (CMS) established two new G Codes, effective 7/1/2020 describing percutaneous arteriovenous fistula creation (avf):

<table>
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<th>G2170</th>
<th>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</th>
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<td>G2171</td>
<td>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</td>
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CMS updated the 2020 PFS Relative Value File on June 19th, 2020 to include the two G-Codes mentioned above. The file includes an indicator for Carrier Pricing.

The societies believe NGS is making a local coverage determination on percutaneous arteriovenous fistula (pAVF) for hemodialysis at this time in response to CMS establishing these new G-Codes and setting them as Carrier Priced.
Coverage
The goal of a dialysis vascular access is to provide reliable, repeated access, with minimal complications for patients with chronic kidney disease who need hemodialysis. On October 26, 2018 the societies submitted comments to CMS regarding Hospital Outpatient Prospective Payment (HOPPS) new technology coverage for hemodialysis access. The letter was in response to the FDA approval for the two devices discussed in the current NGS LCD DL38573, Ellipsys Vascular Access System and WavelinQ EndoAVF System. SVS and SIR supported the creation of HOPPS new technology codes for dialysis vascular access to encompass both technologies, as not to provide an advantage to one company as the services were coming online and the data were being collected. As a result, CMS assigned C9754 Perc av fistula, direct and C9755 Rf magnetic-guide av fistula to APC 5193. The societies believe if both services meet the data threshold requirements established for Medicare payment, coverage should be established for both.

The societies appreciate the opportunity to provide comments on this LCD. If you have any questions or need additional information, please contact Trisha Crishock at trishacrishock@gmail.com.

Sincerely,

Ronald Dalman, MD
President, SVS

Michael D. Dake, MD
President, SIR

Matthew Sideman, MD
Chair, SVS Health Policy and Advocacy Council

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cc: Ken Slaw, PhD
    Erica Holland

Attachments