SVS | Society for Vascular Surgery

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September 21, 2018

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013, 7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted electronically: http://www.regulations.gov

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Administrator Verma,

The Society for Vascular Surgery (SVS), a professional medical society composed of 5,800 specialty-trained vascular surgeons and other medical professionals who are dedicated to the prevention and cure of vascular disease. SVS offers the following comments on the Centers for Medicare and Medicaid Services (CMS) Notice of *Proposed Rule* Making (*Proposed Rule*) on the revisions to Medicare payment policies under the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems for calendar year 2019, published in the Federal Register as a proposed rule on July 31, 2018.

Endovascular Procedures (APCs 5191 through 5194)

Effective January 1, 2018 the transitional add-on payment for HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) expired, thus resulting in payment rates for angioplasty procedures performed with drug-coated balloons (DCBs) being reimbursed the same as angioplasty procedures performed with standard uncoated balloons. In this CY 2019 OPPS/ASC proposed rule, CMS is proposing to maintain the existing four-level structure for the endovascular C-APC family. However, CMS is inviting public comments on maintaining the four-level structure, as well as comments on stakeholder-requested five-level and six-level structures to address issues related to DCBs.

SVS is concerned that the current OPPS payment structure does not adequately reflect the additional costs of DCBs, thus limiting patient access to technology that has been shown to reduce repeat interventions. As a result, patients may end up being treated with lower cost alternative balloons and subject to the risks and additional costs associated with re-intervention procedures.

Peripheral arterial disease (PAD) is a chronic, progressive disease associated with significant morbidity and mortality, along with higher vascular-related hospitalization rates and costs compared to coronary artery and cerebrovascular disease. DCBs have emerged as an effective treatment option for patients with symptomatic PAD, combining acute restoration of vessel patency by balloon dilation with long-term maintenance of such patency because of the antiproliferative drug coating.

The clinical effectiveness of angioplasty with DCBs has been established through both randomized trials and large-scale, population-based observational studies. Specifically, DCBs have demonstrated improvements as follows:

- DCB therapy offers continued improvement in patency at three years;
- DCB therapy offers the lowest reported reintervention rate of all available superficial femoral artery technologies;
- DCB therapy offers better clinical outcomes, reduced reinterventions and reduced total cost savings at two years;
- DCBs offer the best long-term results in occlusive disease of the femoropopliteal artery as demonstrated by a network meta-analysis of PAD therapies.

SVS believes there are significant additional resource costs when DCBs are used, which should be recognized in the OPPS payment system. SVS recommends CMS adopt a DCB policy, similar to the cystoscopy+blue light policy which currently allows for a complexity adjustment when HCPCS code C9738 (*Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure))* is reported with cystoscopy procedures. SVS recommends CMS update C2623 to reflect the add-on nature of the service (i.e. *List separately in addition to code for primary procedure)* and then allow for a complexity adjustment when HCPCS code C2623 (*Catheter, transluminal angioplasty, drug-coated, non-laser)* is reported with an APC 5191-5194 endovascular procedure, similar to the cystoscopy+blue light policy.

Endovenous Lower Extremity Arterial Reconstruction

In this CY 2019 OPPS/ASC proposed rule, CMS is soliciting public comments on the proposed APC and status indicator assignments for CY 2019 for the CPT and Level II HCPCS codes implemented on July 1, 2018, including HCPCS code 0505T (*Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion).* SVS supports CMS' proposal to assign 0505T to APC 5193 Level 3 Endovascular Procedures, with a J1 status indicator.

Imaging Procedures and Services (APCs 5521 through 5524 and 5571 through 5573)

For CY 2018, CMS proposed to add a fifth level within the Imaging without Contrast APCs (82 FR 33608). However, based on public comments, CMS did not finalize this proposal. In general, commenters disagreed with CMS' proposal to add a fifth level within the Imaging without Contrast APC

series because they believed that the addition of a fifth level would reduce payment for several imaging services, including vascular ultrasound procedures (82 FR 59309 through 59311). Commenters also noted that the lower payment rates under the OPPS would also apply under the PFS. For CY 2019, CMS is proposing to maintain the seven Imaging APCs, which consist of four levels of APCs for Imaging without Contrast and three levels of APCs for Imaging with Contrast.

SVS commends CMS for proposing CY2019 OPPS payments for the vascular laboratory codes, included in the "Imaging APCs" (e.g. 5522, 5523), consistent with their cost data. The cost data for the vascular laboratory procedures included within these imaging APCs has been consistent for many years. SVS believes establishing payments that fluctuate dramatically from year to year (while cost data remains conistent) does not support CMS' stated goal of stability and seriously threatens hospitals' capacity to provide these services.

Proposed Changes for CY 2019 to Covered Surgical Procedures Designated as Office-Based

CMS reviewed CY 2017 volume and utilization data and the clinical characteristics for all covered surgical procedures that are assigned payment indicator "G2" (nonoffice-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2017, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically "P2: *Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight*", "P3: *Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs*", or "R2: *Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight*" in the CY 2018 OPPS/ASC final rule. Based on review of the CY 2017 volume and utilization data, CMS is proposing to permanently designated CPT codes 36902 (*Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty) and code* 36905 (*Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty)* as office based.

CMS also reviewed the procedures currently designated as temporary office-based and believes the volume and utilization data for CPT code 36901 (*Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report;)* is sufficient to indicate that the procedure is performed predominantly in physicians' offices. As such, CMS is proposing to permanently designate CPT code 36901 as office-based and assign a P3 payment indicator for CY 2019.

SVS believes permanently designating CPT codes 36902 and 36905 as office-based with a payment indictor of P3 is premature. SVS recommends CPT codes 36902 and 36905 be designated as temporary officed-based, with a payment indicator of P2 (consistent with CMS' current 36901 policy). SVS also believes CMS should maintain the temporary office-based status for CPT code 36901. These CPT codes became effective in 2017 and thus the Agency does not have trend data to accurately predict future utilization. We believe that, at a minimum, three years of data should be reviewed to show a consistent site of service.

The SVS appreciates the opportunity to provide comments on this Proposed Rule. If you have any questions or need additional information, please contact Mindi Walker, Director of the SVS Washington Office at mwalker@vascularsociety.org or 202-787-1220.

Sincerely,

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