

September 11, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1678-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-1678-P: Medicare Program: Hospital Outpatient Prospective Payment System

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, offers the following comments on the Centers for Medicare and Medicaid Services (CMS) Calendar Year (CY) 2018 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule.

Proposed OPPS Ambulatory Payment Classifications (APC) Group Policies

Radiology and Imaging Procedures Services

CMS is proposing to add a fifth level within the Imaging without Contrast APCs. The agency stated that it reviewed and considered stakeholder recommendations to make additional refinements to the structure of the APC groupings of the imaging procedures classified within the imaging APCs that would maintain clinical homogeneity, while more appropriately addressing resource cost fluctuation and volatility.

The SVS strongly believes that **CMS' proposals do NOT meet their stated goal(s)**. CMS' proposed changes to the "imaging without contrast" APCs will result in an estimated \$70 million reduction to the subset of vascular ultrasound procedures, which seriously threatens hospitals' capacity to provide these services. This is an unreasonable impact on a small family of vascular ultrasound codes that often are accounted for separately in facilities as they are a separate family in the CPT manual.

Our analysis demonstrates that the mean cost data for these vascular laboratory procedures has been consistent over the past five years while the CMS payments have fluctuated. These wild fluctuations in CMS payments (for a service line that has consistent cost data) certainly does not meet CMS' stated goal of stability.

The SVS reviewed many different options including moving vascular lab codes into various levels

within the imaging without contrast APC family, varying cutlines between APC levels, and maintaining four APC levels for the group without finding satisfactory solutions. We then evaluated the Therapeutic Nuclear Medicine APC and feel that the vascular lab codes have similar characteristics. These services are clinically unique and their resource consumption similar. **We therefore recommend establishing a “Noninvasive Vascular Studies” APC consisting of two payment levels.** While we recognize CMS is hesitant to expand the list of APC families, we think it is important that CMS consider solutions that will more appropriately address resource cost fluctuation and volatility.

CMS’ methodology for determining costs for rate-setting was applied to the proposed new reconfiguration of the non-invasive vascular studies APCs. We are proposing a new APC family that would include all 26 of the non-invasive vascular study CPT Codes, over 2.5 million services and \$400 million. We recommend two levels in this new APC. Our preliminary analysis suggests that the level one payment would be approximately \$136 and the level two payment would be approximately \$198. There would be no two-times rule violations in either level, nor would there be any two-times rule violations in the APCs from which they are removed.

HCPCS	Short Descriptor	SI	Single Frequency	Total Frequency	Geometric Mean Cost
Noninvasive Vascular Diagnostic Studies					
Level 1					
93998	Noninvas vasc dx study proc	Q1	113	414	\$74.23
93922	Upr/l xtremity art 2 levels	Q1	63,180	158,394	\$96.10
93893	Tcd emboli detect w/inj	Q1	77	248	\$97.28
93892	Tcd emboli detect w/o inj	Q1	80	353	\$119.82
93990	Doppler flow testing	Q1	9,882	21,647	\$120.67
93979	Vascular study	Q1	5,283	14,663	\$128.01
93923	Upr/lxtr art stdy 3+ lvls	S	121,492	124,673	\$144.17
93888	Intracranial limited study	S	463	794	\$130.88
93931	Upper extremity study	S	6,811	11,619	\$132.37
93882	Extracranial uni/ltd study	S	4,231	5,414	\$144.80
93971	Extremity study	S	409,452	661,566	\$153.13
93924	Lwr xtr vasc stdy bilat	S	22,763	23,067	\$160.17
93926	Lower extremity study	S	46,732	74,249	\$157.12
93981	Penile vascular study	S	33	53	\$160.37
93976	Vascular study	S	23,866	36,940	\$166.60
Level 2					
93895	Carotid intima atheroma eval	E1			
93980	Penile vascular study	S	230	449	\$164.68
93886	Intracranial complete study	S	2,109	3,203	\$178.09
93978	Vascular study	S	38,366	56,342	\$181.95
93890	Tcd vasoreactivity study	Q1	10	56	\$189.73
93930	Upper extremity study	S	2,532	4,348	\$190.43
93880	Extracranial bilat study	S	382,584	676,735	\$197.65
93925	Lower extremity study	S	78,511	124,637	\$213.58
93970	Extremity study	S	204,082	351,465	\$220.09
93975	Vascular study	S	46,796	72,069	\$228.79

While this proposal does not eliminate the reductions on the vascular ultrasound procedures, it does decrease the negative impact in the out-patient setting from approximately \$69 million to \$9.6 million. This new structure would allow more predictability and stability. We recognize CMS is currently in the rule-making cycle for 2018. To that end, the SVS feels strongly that the agency has an obligation to reject the proposal that would result in an estimated \$70 million impact on a small subset of services. The SVS recommends that the vascular US codes be held harmless for CY 2018 while the agency consider our proposal for a new non-invasive vascular studies APC family. We recommend that for CY 2018, CMS maintains the 2017 payments rates for the vacular US codes included in the Imaging without Contrast APC family.

Endovenous Chemical Ablation for Lower Extremity Chronic Disease

Four new CPT codes were created at the September 2016 CPT Panel meeting to describe the work of endovenous ablation therapy by transcatheter delivery of a chemical adhesive (364X3 and 364X4) and by injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate (364X5 and 364X6). CMS is proposing to assign CPT Code 364X3 to APC 5184 Level 4 Vascular Procedures. However, **CMS is proposing to assign CPT Codes 364X5 and 364X6 to APC 5053 Level 3 Skin Procedures. SVS opposes the CMS proposal to assign CPT Code 364X5 and 364X6 to a skin APC and recommends they be assigned to the Level 3 Vascular Procedures APC (5183).**

The four new codes described above compliment the already existent vein procedures recently created:

36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent veins treated in a single extremity, each through separate access sites
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)

CPT Codes 364X5 and 364X6 are clinically similar and the anticipated costs comparable. The SVS recommends CMS assign CPT Codes 364X5 and 364X6 to APC 5183 Level 3 Vascular Procedures.

Proposed OPPS Payment for Devices

Expiration of Transitional Pass-Through Payments for Certain Devices

CMS approved HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) for outpatient add-on payments via transitional pass-through payments effective April 1, 2015; the agency also approved this code for inpatient add-on payments effective Fiscal Year 2016. The SVS believes the add-on payments have been vital to facilitating beneficiary access to an advanced new technology, which has proven to be clinically-effective relative to alternative treatments.

As proposed in the CY 2018 Hospital OPPS Proposed Rule, the transitional pass-through payments for drug-coated balloons (DCBs) will expire on December 31, 2017, be packaged into the codes related to the procedure and be reported in hospital claims data. This will result in payment rates for angioplasty procedures with DCBs being reimbursed the same as procedures performed with standard balloon angioplasty.

We are concerned that the proposed payment structure would not adequately reflect the additional costs of DCBs, thus limiting patient access to technology that reduces repeat interventions. As a result, patients may end up getting treated with lower cost alternatives, but would be subject to the risks and 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 through the antiproliferative drug.

The clinical effectiveness of angioplasty with DCBs has been established through both randomized trials and large-scale, population-based observational studies. Specifically, drug-coated balloons 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 total cost savings at two years;
- A network meta-analysis of PAD therapies demonstrated that DCBs offer the best long-term results in occlusive disease of femoropopliteal artery.

Recently, the SVS urged the Advisory Panel on Hospital Outpatient Payment to make the following recommendation to CMS, which is also relevant for this Proposed Rule: **assign a higher APC payment for DCB procedures versus percutaneous transluminal angioplasty without DCB.**

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

Sincerely,

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