



## The Society for Cardiovascular Angiography and Interventions Foundation

1100 17th Street NW, Suite 330, Washington, DC 20036

Main: 202.741.9854 ♦ Toll Free: 800.992.7224 ♦ Fax: 800.863.5202 ♦ E-mail: [info@scai.org](mailto:info@scai.org)

September 24, 2018

### Officers

David A. Cox, MD, MSCAI  
President

Ehtisham Mahmud, MD, FSCAI  
President-Elect

Cindy L. Grines, MD, FSCAI  
Vice President

Timothy D. Henry MD, MSCAI  
Secretary

Peter L. Duffy, MD, MMM, FSCAI  
Treasurer

Kirk N. Garratt, MD, MSc, MSCAI  
Immediate Past President

### Trustees

Herbert D. Aronow, MD, FSCAI  
Janice Baker, RN, MSN, CEPS, NEA-BC  
Lyndon C. Box, MD, FSCAI  
Emmanouil S. Brilakis, MD, PhD, FSCAI  
Ronald P. Caputo, MD, FSCAI  
John C. Messenger, MD, FSCAI  
Shao-Ping Nie, MD, PhD, FSCAI  
Molly Szerlip, MD, FSCAI  
Robert N. Vincent, MD, FSCAI

### Trustees for Life

Frank J. Hildner, MD, FSCAI  
William C. Sheldon, MD, FSCAI

SCAI 2019 Scientific Sessions  
May 20–23 | Las Vegas, NV

Program Chair (Adult)  
Sunil V. Rao, MD, FSCAI

Program Chair (CHD)  
John W. Moore, MD, MPH, FSCAI

Program Co-Chairs (Adult)  
Emmanouil S. Brilakis, MD, PhD, FSCAI  
Daniel M. Kolansky, MD, FSCAI

Program Co-Chairs (CHD)  
Lee N. Benson, MD, FSCAI  
Daniel H. Gruenstein, MD, FSCAI

Francesca M. Dea, CAE  
Executive Director

Ms. Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS–1695–P  
PO. Box 8013  
Baltimore, MD 21244–1850

*\*\*Submitted electronically via*

<https://www.federalregister.gov/documents/2018/07/31/2018-15958/medicare-program-proposed-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical>  
and by email to [Seema.Verma@cms.hhs.gov](mailto:Seema.Verma@cms.hhs.gov)\*\*

**RE: “Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; [CMS-1695-P]”**

Dear Ms. Verma:

The Society for Cardiovascular Angiography and Interventions (SCAI) is a non-profit professional association with over 4,000 members representing the majority of practicing interventional cardiologists and cardiac catheterization teams in the United States including pediatric interventional cardiologists treating patients with congenital heart disease. SCAI promotes excellence in interventional cardiovascular medicine through education, representation and the advancement of quality standards to enhance patient care. SCAI, having reviewed the “*Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; [CMS-1695-P]*”, offers the following comments:

### Differential Payment for Drug Coated Balloons (DCBs)

Under HOPPS, DCB procedures are reported using CPT code 37224 (*Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty*) coupled with the DCB device code C2623. Between April 1, 2015 through 2017 device code C2623 triggered the new technology add-on payment in addition to the APC 5192 payment for DCB procedures.

SCAI was a strong advocate for the new technology add-on payments for drug-coated balloons (DCBs). Peripheral artery disease (PAD) is a chronic, progressive disease associated with significant morbidity and mortality, and 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 dilatation with long term maintenance of such patency through use of the antiproliferative drug.

The time frame afforded for the new technology add-on payment for DCBs expired at the end of 2017 and for 2018 CMS has merely left DCB procedures in the same APC class as traditional noncoated PTA technologies, APC 5192. CMS is not proposing any relief for 2019, either.

The clinical effectiveness of DCB angioplasty has been well established through 8 randomized controlled trials for three FDA-approved DCBs and large-scale, population based observational studies. Furthermore, significant amount of data in the peer-reviewed literature has emerged since the initial CMS approval of this class of devices. Specifically, DCBs have demonstrated improvements over plain balloon angioplasty (traditional PTA) as follows:

- DCBs are a major addition to the therapeutic armamentarium for treating peripheral vascular disease and are particularly useful for treating anatomic areas where stents are contraindicated.
- DCBs are a major addition to the treatment options for patients with in-stent restenosis.
- DCB therapy offers continued improvement in patency rates at three-years.
- DCB therapy offers the LOWEST reported re-intervention rate of all available SFA technologies across diverse patient populations.
- Due to better outcomes including lower readmission rates and more enduring patency associated with DCBs, even when the add-on payment was included in the cost of DCBs, the cost of treatment at 2-years was the same for DCB as non-DCB PTA.

The APC Panel discussed this issue at the August 21, 2017 APC Panel meeting with recommendation that CMS consider an APC reconfiguration for cardiovascular interventions to create additional payment tiers that would allow for a continued differential in payment and tracking of outcomes for DCBs. They understood that CMS should find a mechanism to provide a differential in reimbursement for DCBs, as compared to traditional PTA balloons.

Two different reconfigurations for cardiovascular interventions were proposed to CMS. One proposal recommended expanding the existing 4 cardiovascular APCs to 5, the other recommended CMS create 6 cardiovascular APCs. Both proposals would have resulted in perceived unfair redistribution of funding among different hospital departments. The proposed 5 APC reconfiguration would unfairly, negatively impact reimbursement rates for life-saving, percutaneous coronary interventions. The proposed 6 APC reconfiguration would unfairly negatively impact reimbursement rates for dialysis de clot procedures. CMS found both proposals to be unacceptable. SCAI also does not believe additional reimbursement for DCBs should come at the expense of other procedures. We should not have to “rob Peter to pay Paul”.

For 2019, CMS has not proposed any pathway forward to address the continued underpayment for DCBs that results from placing these procedures in APC 5192, alongside traditional PTA balloon procedures. Based upon available data, we are concerned that this policy decisions by CMS will directly result in significantly lower patency, increased need for repeat revascularization, higher readmission rates, lower quality of life, and higher overall healthcare costs.

APC 5192 does not provide an adequate reimbursement for DCBs. We have been advised that the most recent MEDPAR data shows that keeping DCBs in the current 5192 APC assignment violates the “2X rule”. SCAI recommends that CMS move DCBs to APC 5193. CMS could allow DCBs to be reported with the C-code, C2623 with C2623 assigned to APC 5193. CMS allows C-codes to be used to differentiate reimbursement between coronary bare metal stent and more expensive, but typically more enduring, drug eluting stents used in percutaneous coronary interventions. CMS can easily apply this existing precedent to differentiate DCBs from traditional PTA balloons used in lower extremity revascularization procedures.

***SCAI finds the APC payment rate for DCBs to be insufficient. We are concerned that the current decision by the CMS to leave DCBs in APC 5192 will result in lower DCB use. In support of evidence-based medicine and long-term cost-savings, SCAI recommends that CMS move DCBs to APC 5193 and allow revascularization procedures performed using DCBs to be reported with a C-code to differentiate these procedures from revascularization procedures performed using traditional PTA balloons.***

#### **Addition of Diagnostic Cardiac Catheterization Codes to ASC Eligible List**

CMS is proposing to add diagnostic cardiac catheter procedures to the list of procedures eligible for reimbursement under the Ambulatory Surgical Center payment schedule. SCAI does not oppose this proposal. CMS did not include the diagnostic congenital cardiac catheter codes in the listing of eligible codes and is asking for public comment. SCAI is not opposed to adding all of the diagnostic cardiac catheterization codes to the ASC eligible listing including the congenital catheter codes.

In addition to the non-congenital diagnostic cardiac catheterization codes, SCAI’s supports adding the congenital diagnostic cardiac codes to the ASC eligible list.

<b>CPT Code</b>	<b>Long Desc</b>
93530	Right heart catheterization, for congenital cardiac anomalies
93531	Combined right heart catheterization and retrograde left heart catheterization, for congenital cardiac anomalies
93532	Combined right heart catheterization and transseptal left heart catheterization through intact septum with or without retrograde left heart catheterization, for congenital cardiac anomalies

93533	Combined right heart catheterization and transeptal left heart catheterization through existing septal opening, with or without retrograde left heart catheterization, for congenital cardiac anomalies
93561	Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; with cardiac output measurement (separate procedure)
93562	Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; subsequent measurement of cardiac output

SCAI recommends that CMS also add the following codes describing concomitant diagnostic services that may be performed in conjunction with diagnostic cardiac catheterization procedures:

**CONCOMITANT DIAGNOSTIC SERVICES PERFORMED IN CONJUNCTION WITH  
DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES**

<b>CPT Code</b>	<b>Long Desc</b>
93463	Pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed (List separately in addition to code for primary procedure)
93464	Physiologic exercise study (eg, bicycle or arm ergometry) including assessing hemodynamic measurements before and after (List separately in addition to code for primary procedure)
93505	Endomyocardial biopsy
93563	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization (List separately in addition to code for primary procedure)
93564	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective opacification of aortocoronary venous or arterial bypass graft(s) (eg, aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (eg, internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization, when performed (List separately in addition to code for primary procedure)
93565	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective left ventricular or left atrial angiography (List separately in addition to code for primary procedure)
93566	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography (List separately in addition to code for primary procedure)

93567	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supra-avalvular aortography (List separately in addition to code for primary procedure)
93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (List separately in addition to code for primary procedure)
93571	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (List separately in addition to code for primary procedure)
93572	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel (List separately in addition to code for primary procedure)
92978	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (List separately in addition to code for primary procedure)
92979	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (List separately in addition to code for primary procedure)

Despite the addition of these codes, we do not believe any SCAI members will perform these procedures in the ASC setting, as the ASC payment rates for ALL image-guided cardiovascular procedures are believed to be woefully inadequate and not economically viable.

CMS has not yet proposed a mechanism to successfully adjust the ASC rates to allow for sufficient compensation for the “devices” used in the performance of image-guided cardiovascular services. CMS limits the definition of “devices” eligible for APC pass through payments to only permanently implantable devices and doesn’t provide any payment adjustment to account for expensive guidewires and catheters used in the performance of image-guided cardiovascular procedures which are not permanently implanted. CMS’ definition of “devices” for ASC payment rate setting is not aligned with the FDA’s definition of “devices”. The devices used in the performance of image-guided cardiovascular procedures all require FDA approval.

Based on Medicare utilization rates, the ASC rates do appear to be adequate for procedures for which there is a single expensive device for which CMS allows for direct and full pass-through payment for the device (such as joints and cornea lenses) in addition to the ~60% of the HOPPS rate, which means CMS is actually compensating ASCs 160% of the cost of these implanted “devices”.

In reviewing the already existing cardiovascular procedures allowed to be performed in the ASC setting (e.g., central venous access device procedures, peripheral arterial interventions) – the ASC site of service utilization rates for these procedures are typically less than 1%. We believe this is because ASC payment rates for image-guided, cardiovascular procedures, commonly involving multiple “devices” are just not economically viable.

***If CMS is serious about supporting the ASC site of service for image-guided, cardiovascular procedures, CMS needs to change how it calculates ASC payment rates to allow for pass-through payment for costly “devices” that are not permanently implanted.***

**In conclusion**, SCAI appreciates the opportunity to provide comment to CMS on issues of high interest to the interventional cardiology community contained in the “*Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; [CMS-1695-P]*”. If SCAI can be of any assistance as CMS continues to consider and review these issues, please do not hesitate to contact Mrs. Dawn R. Gray (Hopkins), Director of Reimbursement & Regulatory Affairs at (800) 253-4636, ext. 510 or [dgray@scai.org](mailto:dgray@scai.org).

Sincerely,

*David Cox, MD*

David A. Cox, MD, MSCAI  
SCAI President, 2018-2019

CC: Scott Talaga - CMS  
Erick Chuang - CMS  
Osvaldo S. Gigliotti, MD, FSCAI  
Dmitriy N. Feldman, MD, FSCAI  
Mehdi H. Shishehbor, DO, MPH, PhD, FSCAI  
Robert Bartel - SCAI  
Francesca Dea, CAE - SCAI  
Dawn R. Gray (Hopkins) - SCAI