



September 24, 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 of Interventional Radiology (SIR) is a professional medical association that represents approximately 8,000 members, including most US physicians who are practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advances in minimally-invasive, image-guided therapies. SIR appreciates the opportunity to comment 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 with drug coated balloons (DCBs) being reimbursed the same as procedures performed with standard balloon angioplasty. In this 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 drug-coated balloons.

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SIR is concerned that the current HOPPS payment structure does 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.

SIR believes there are significant additional resources when DCBs are used, which should be recognized in the OPSS payment system. SIR recommends CMS adopt a DCB policy, similar to the cystoscopy+blue light policy. CMS 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)* and is reported with cystoscopy procedures. SIR recommends CMS allow for a complexity adjustment when HCPCS code C2623 *Catheter, transluminal angioplasty, drug-coated, non-laser* is reported with endovascular procedures.

Ambulatory Surgical Center: 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 OPSS 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 OPSS relative payment weight*”, “P3:

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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 OPFS relative payment weight” in the CY 2018 OPFS/ASC final rule. Based on their review of the CY 2017 volume and utilization data, CMS is proposing to:

- permanently designate CPT codes 36902 & 36905 as office-based;
- continue to temporarily designate CPT Code 36901 as office-based; and
- temporarily designate new FNA w/imaging CPT Codes (10X12, X14, X16 and X18) as office-based.

Permanently designate CPT codes 36902 & 36905 as office-based

SIR believes permanently designating these two new dialysis codes as office-based with a payment indicator of P3 is premature. The determination based on the goal of “site neutrality” is based on limited and incomplete data. There have been significant recent changes in the reimbursement of the dialysis access procedure as well as extensive changes in the office based procedure environment. Many practices have begun changing their office surgical suites into ASCs in order to better serve the patient population with a broader array of services in a cost effective manner (i.e. outside of the Hospital Outpatient environment). A full understanding of changing site of service distribution for the dialysis access code family cannot be attained at this time. These CPT Codes became effective in 2017. Additional sampling years is strongly suggested. SIR recommends that 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 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* not be designated as office-based at this time.

Continue to temporarily designate CPT Code 36901 as office-based

CMS also reviewed the procedures currently designated as temporary office-based. CMS 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*

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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 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.

SIR believes permanently designating the dialysis codes as office-based with a payment indicator of P3 is premature. SIR recommends that CPT Code 36901 also be temporarily designed as office-based until further data is available.

Temporarily designate new FNA w/imaging CPT Codes (10X12, X14, X16 and X18) as office based

CMS is proposing to designate several new FNA with imaging codes as office-based for CY2019, see below:

HCPCS Code		Short Descriptor	Subject to Multiple Procedure Discounting	Proposed 2019 Payment Indicator	Proposed 2019 Payment Weight	Proposed 2019 Payment Rate
10X12	NP	Fna bx w/us gdn 1st les	Y	P3		\$72.38
10X14	NP	Fna bx w/fluor gdn 1st les	Y	P3		\$223.98
10X16	NP	Fna bx w/ct gdn 1st les	Y	P2	6.4752	\$299.03
10X18	NP	Fna bx w/mr gdn 1st les	Y	R2	6.4752	\$299.03

The predecessor CPT code 10022 *Fine needle aspiration; with imaging guidance* is performed less than 50% in the office setting. We do not believe these procedures will typically be performed in the office setting. SIR recommends all four of the FNA with imaging codes be assigned payment indicator G2 *Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight*.

In closing, the Society of Interventional Radiology thanks CMS for your consideration of our comments. If we can be of any future assistance, please do not hesitate to contact Susan E. Sedory, SIR's Executive Director, at (703) 691-1805, or ssedory@sirweb.org.

Sincerely,



M. Victoria Marx, MD, FSIR
SIR President