SCAI
Society for Cardiovascular Angiography & Interventions

June 10, 2025

Sent electronically via www.regulations.gov

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1833-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes (CMS-1833-P)

Dear Dr. Oz:

The Society for Cardiovascular Angiography and Interventions (SCAI) has dedicated its work to advancing the profession and is the designated society for guidance, representation, professional recognition, education, and research opportunities for invasive and interventional cardiology professionals. For more than 40 years, SCAI has personified professional excellence and innovation globally, fostering a trusted community of more than 5000 members dedicated to medical advancement and lifesaving care for adults and children with cardiovascular disease.

SCAI appreciates the opportunity to comment on this proposed rule.

NTAP Applications

CMS is proposing to approve the AGENT^{TM} Paclitaxel-Coated Balloon Catheter for new technology add-on payments for FY 2026 for use after appropriate vessel preparation in adult patients undergoing PCI in coronary arteries 2.0

mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating ISR. SCAI appreciates CMS' review of this important technology and agrees with CMS' assessment that AGENT™ Paclitaxel-Coated Balloon Catheter meets all the requirements for NTAP payment.

CMS is proposing to approve the Esprit™ BTK Everolimus Eluting Resorbable Scaffold for new technology add-on payments for FY 2026 for the indication of improving luminal diameter in infrapopliteal lesions in patients with CLTI and total scaffolding length up to 170 mm with a reference vessel diameter of ≥2.5 mm and ≤4 mm. SCAI appreciates CMS' consideration, and agrees that this technology meets NTAP payment requirements.

CMS proposes to approve the Spur Peripheral Retrievable Stent System for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025. SCAI agrees that the Spur Peripheral Retrievable Stent System meets the requirements for NTAP payment.

CMS is proposing to approve the Ventura® Interatrial Shunt System for new technology add-on payments for FY 2026 subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025. SCAI agrees that the Ventura® Interatrial Shunt System meets the requirements for NTAP payment.

CMS is proposing to approve the Minima Stent System for new technology add-on payments for FY 2026 for use in the treatment of native or acquired pulmonary artery stenoses or coarctation of the aorta in neonates, infants, and children at least 1.5 kg in weight. SCAI feels that this technology is important for the pediatric population and agrees that it meets the requirements for NTAP payment.

CMS is proposing to approve the ShortCut™ for new technology add-on payments for FY 2026 for use as a splitting device of bioprosthetic aortic valve leaflets to facilitate valve-in-valve procedures for patients at risk for coronary obstruction. SCAI agrees with CMS and feels that granting Medicare coverage for the use of ShortCut™ in valve-in-valve procedures is imperative to ensure safe and effective cardiac care while ensuring its affordability and universal accessibility within the Medicare framework.

CMS has questions about whether the Neuroguard® IEP System meets NTAP requirements. The Neuroguard system introduces a novel dual embolic protection mechanism while maintaining required primary protection throughout the procedure. This integrated approach creates therapeutic capabilities not available with existing technologies. Clinical trials have demonstrated substantial improvement, with a 1.3% stroke rate compared to 2.89% for

contemporary systems, representing a meaningful advancement in patient safety for carotid interventions. SCAI urges CMS to approve the NTAP application for the Neuroguard IEP System and ensure timely patient access to this important innovation in embolic protection.

MS-DRG Changes for Atherectomy

Based on comments in response to CMS' review of the MS–DRG assignment of cases describing percutaneous coronary intravascular lithotripsy (IVL), CMS conducted a detailed review of MS-DRG assignment for percutaneous coronary atherectomy. As a result of the review, CMS is proposing to create two new MS– DRGs with a two-way severity level split for cases describing percutaneous or percutaneous endoscopic coronary atherectomy involving the insertion of an intraluminal device, and a new base MS–DRG for cases describing percutaneous or percutaneous endoscopic coronary atherectomy without an intraluminal device. **SCAI appreciates CMS undertaking the review and thanks CMS for updating the DRG assignment to more appropriately align with the complexity of the procedures.**

Paclitaxel-Coated Balloon Catheter Technology

CMS reviewed a request to reconsider the designation and MS-DRG placement of sixteen codes assigned to paclitaxel-coated balloon catheter (DCB) procedures. CMS is proposing to affirm its decision to maintain the procedures' non-OR designation and MS-DRG placement. SCAI appreciates CMS taking the time to review, however, we disagree with CMS' assertion that these procedures are for drug delivery only.

DCB is a novel percutaneous coronary intervention (PCI). Therefore, like all other PCI procedures, DCB should have an OR designation and should be situated within the PCI DRGs. DCB is a primary procedure like stenting and is not incidental to vessel preparation. The FDA classifies AGENT as a surgical permanent implant. **SCAI believes these procedures should be given an OR designation to maintain consistency within the PCI code set.**

Concomitant Single Valve Procedure with Open Surgical Ablation

CMS received a request to review MS-DRG placement of concomitant open surgical ablations. CMS concluded that cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization are clinically coherent in their currently assigned MS–DRGs

SCAI understands CMS' reasoning, but continues to believe that physicians should be able to assess the medical necessity of performing concomitant vs. staged procedures, based on the medical needs of the individual patient, and that payment should be based upon the services provided. **SCAI requests that CMS carefully review all procedure combinations where concomitant payment could provide benefit to the patient.**

Medicare Advantage (MA) Beneficiaries In Hospital Readmissions Reduction Program Measure Set

CMS is proposing to integrate MA beneficiaries into the cohorts for the Hospital Readmissions Reduction Program measure set. CMS notes that including MA beneficiaries would help ensure that hospital quality would be measured across all Medicare beneficiaries and not just the Fee-For-Service (FFS) population. SCAI agrees with this proposal and asks CMS to take the use of MA data a step further. **Medicare data should be more transparent across all beneficiaries and more MA data should be made available for both quality programs and claims data analysis.**

Conclusion

In conclusion, SCAI appreciates the opportunity to provide comment to CMS on issues of high interest to the interventional cardiology community. If SCAI can be of any assistance as CMS continues to consider and review this or related issues, please do not hesitate to contact Monica Wright, SCAI's director of regulatory affairs at mlwright@scai.org.

Sincerely,

Arnold Seto, MD, MPA, FSCAI
Chair
Advocacy Committee