

June 2, 2024

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Sent electronically via www.regulations.gov

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1808-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare and Medicaid Programs and the Children's Health Insurance 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 2025 Rates; Quality Programs Requirements; and Other Policy Changes (CMS-1808-P)

Dear Administrator Brooks-LaSure:

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

We agree with CMS' assessment that EVOQUE, LimFlow, Paradise™ Ultrasound Renal Denervation System, Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter, TriClip all meet the requirements for NTAP payment.

Upon review of the submitted NTAP applications, we were surprised that there was not one for Agent Coronary Drug Coated Balloons as we understood an application had been submitted. We are aware that Agent received full FDA approval on

February 29, 2024 and was previously granted Breakthrough Designation. We have patients who would benefit from this therapeutic option and request that CMS review this therapy for the NTAP program in this cycle.

As CMS reviews Agent for NTAP and DRG placement, SCAI would also note that this drug coated balloon technology is considered a percutaneous coronary intervention (PCI) and as such should be situated within the PCI DRGs.

MS-DRG Changes for Atherectomy

Last year, CMS conducted a detailed analysis of the costs and resources required for coronary intravascular lithotripsy (IVL). Based on this analysis, CMS determined that new MS-DRGs should be created to account for the differences in procedure costs. SCAI appreciates CMS' decision but still recommends that CMS undertake a similar analysis for all ICD-10-PCS codes for atherectomy to determine if these procedures also warrant their own MS-DRG. It is our understanding that the pipeline for additional technologies in this family is expanding and that prudent public policy making would allow for appropriate adjustments in the future.

Concomitant Procedures with Surgical Ablation

SCAI appreciates the creation of MS-DRG 317 for ablation when performed concomitantly with LAO. We agree that there should be a mechanism for differentiated payment when procedures are performed concomitantly, when it is best for the patient. SCAI would also like to propose the inclusion of the ICD-10-PCS code which describes pulsed field ablation (02583ZF) which was just established on April 1, 2024.

We 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 also look at other procedure combinations where concomitant payment could also provide benefit to the patient.

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,

A handwritten signature in black ink, appearing to read 'James Hermiller', with a stylized flourish at the end.

James Hermiller, MD, MSCAI
President