SCAI
Society for Cardiovascular Angiography & Interventions

June 9, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1785-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership (CMS-1785-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.

MS-DRG Changes for Coronary Intravascular Lithotripsy
In response to a request, 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 and agrees that accounting for these differences will provide greater access to this technology and could lead to improved patient outcomes.

It would seem, however, that IVL is not the only technology used in percutaneous coronary interventions (PCI) that may demonstrate similar increased costs and acuity. Therefore, SCAI recommends that for future rulemaking, 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.

SCAI appreciates the creation of the new MS-DRG 323 (Coronary Intravascular Lithotripsy with Intraluminal Device with MCC), MS-DRG 324 (Coronary Intravascular Lithotripsy with Intraluminal Device without MCC), and MS-DRG 325 (Coronary Intravascular Lithotripsy without Intraluminal Device) as supported by cost data. SCAI recommends that CMS analyze the atherectomy procedures within proposed FY2024 MS-DRGs 250, 251, 321 and 322 to determine if similar action is needed.

MS-DRG Changes for Coronary Stents
Based on further review, CMS determined that it was no longer necessary to distinguish between drug eluding and bare metal stents in MS-DRG classification. CMS is proposing to delete MS-DRGs 246, 247, 248, and 249 and create a new base MS-DRG with a two-way severity level split for cases describing percutaneous cardiovascular procedures with intraluminal device in MDC 05.

SCAI supports this change to eliminate redundancy in the current MS-DRGs. However, SCAI strongly urges CMS to monitor for unintended consequences.

New Technology Add-on Payment (NTAP) Eligibility Requirement Modifications
CMS is proposing to modify the NTAP eligibility requirements to require NTAP applicants to have either received FDA marketing authorization or have a complete, actively filed FDA marketing authorization application prior to submitting their NTAP application and moving the required deadline for having received FDA approval from the current date of July 1 to May 1 beginning in FY2025.

While SCAI understands CMS' need for more time to review the applications, SCAI feels that changing the date may unfairly disadvantage new technologies coming to market. There is already a small window in which new technologies can receive NTAP for three fiscal years. Only technologies currently receiving FDA approval in April, May, or June, can obtain three years of NTAP support. This proposed rule would reduce this window to just one month, April, to obtain three years of NTAP support. **We respectfully ask that you reconsider this matter in order to increase the potential for further improved patient outcomes.**

If CMS deems it necessary to go forward with the date change to allow CMS more time to review applications, CMS should also review the duration of NTAP, making appropriate adjustments so that all successful applicants have the ability to receive the full three years of NTAP payment.

Implantation of Bioprosthetic Valves into Right Atrium and Superior and Inferior Vena Cavas
The ICD-10 Coordination and Maintenance Committee recently established new procedure codes for the implantation of bioprosthetic valves into the right atrium and superior and inferior vena cavas: ICD10 PCS procedure codes: X2H03R9 (insertion intraluminal device, bioprosthetic valve into the inferior vena cava, percutaneous approach) and X2H13R9 (insertion intraluminal device, bioprosthetic valve into the superior vena cava, percutaneous approach). It appears these procedure codes map to DRGs 252 – 254 (other vascular procedures with MCC, CC or without MCC/CC).

CMS is defining the TricValve procedure as an insertion of an intraluminal device. This is not correct as; a portion of these implanted valves reside in the right atrium of the heart along with the large vessels (superior and inferior vena cavas) emanating from the heart – much like a percutaneous aortic valve does (residing within the left ventricle and descending aorta). Using the nomenclature of insertion vs. replacement or implantation makes it confusing. We would thus ask that the definition of the above ICD 10 PCS codes be modified to indicate a replacement or implantation.

The above ICD10 procedure codes should be assigned to DRGs 266 and 267 (endovascular cardiac valve replacement procedures) as this new procedure mimics the resources and work involved with endovascular cardiac valve replacement procedures, including their placement within the major vessels and heart. **SCAI recommends that CMS consider updating the definitions and mapping these new ICD10 procedure codes to DRGs 266 and 267.**

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 manager of coding and reimbursement at mlwright@scai.org.

Sincerely,

George Dangas, MD, PhD, MSCAI
President 2023-2024