STS Headquarters
633 N Saint Clair St, Suite 2100
Chicago, IL 60611-3658
(312) 202-5800
sts@sts.org

Washington Office
20 F St NW, Suite 310 C
Washington, DC 20001-6702
(202) 787-1230
advocacy@sts.org

June 9, 2023

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

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,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Fiscal Year (FY) 2024 Inpatient Prospective Payment System (IPPS) Proposed Rule. Founded in 1964, STS is a not-for-profit organization representing more than 7,700 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

Changes to Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights

- **MDC 04 (Diseases and Disorders of the Respiratory System)**

  Ultrasound Accelerated Thrombolysis for Pulmonary Embolism

  For FY 2024, CMS proposes to create new base MS-DRG 173 (USAT and Other Thrombolysis with Principal Diagnosis Practice Expense). Based on its review and various claims data analysis for cases in MS-DRGs 163-165 and MS-DRGs 166-168, CMS states the differences in resource consumption warrants reassignment of these cases. However, CMS does not believe that patients undergoing a thrombolysis (CDT or USAT) procedure for practice expense (PE) are clinically aligned with patients and resources as cases in MS-DRGs 166-168 and concluded that a new MS-DRG would reflect more appropriate payment for USAT and standard CDT procedures in the treatment of PE.

  STS agrees with CMS that the creation of new base MS-DRG 173 (USAT and Other Thrombolysis with Principal Diagnosis PE) will result in better clinical alignment for patients undergoing a

thrombolysis (CDT or USAT) procedure for PE and ensure that these cases are appropriately reimbursed and supports creation of new MS-DRG 173.

- **MDC 05 (Diseases and Disorders of the Circulatory System)**

  Surgical Ablation

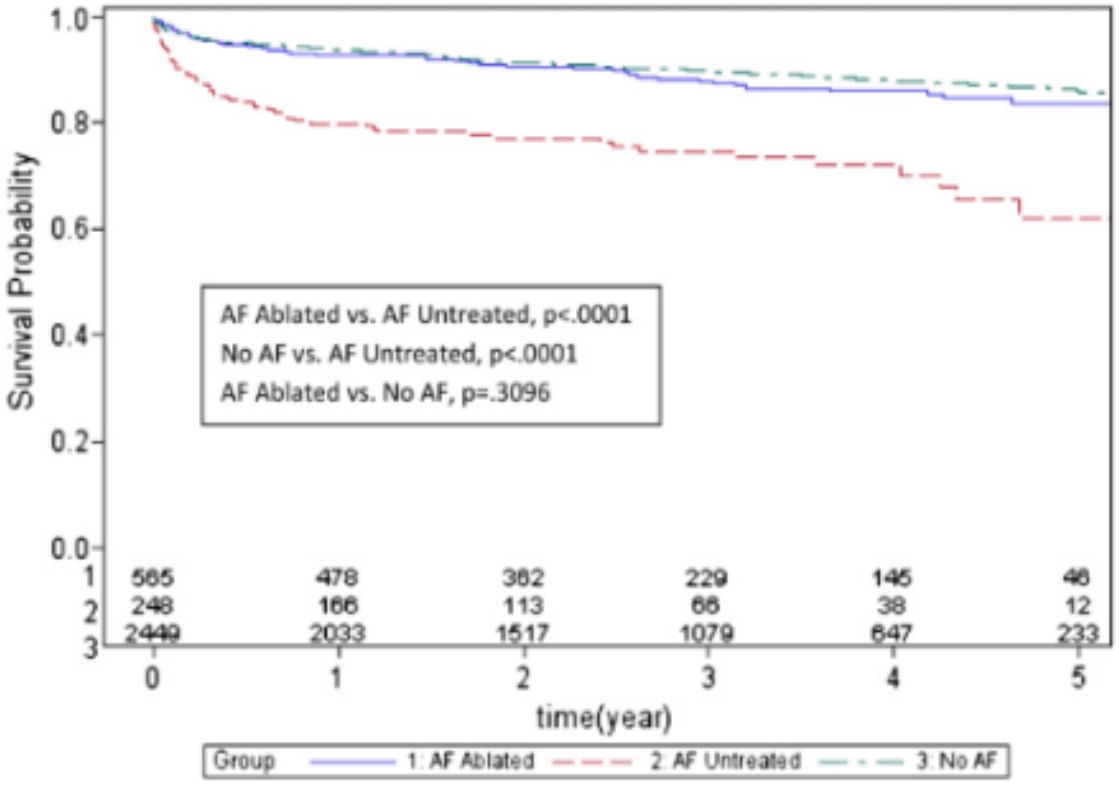
  For FY 2024, CMS proposes to create a new base MS-DRG 212 (Concomitant Aortic and Mitral Valve Procedures) based on its conclusion that clinically greater resources are required to perform an aortic valve repair (AVR) or replacement procedure, a mitral valve repair (MVR) or replacement procedure, and another concomitant procedure. CMS indicates that its analysis of the claims data suggests that it is the performance of an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure plus another concomitant procedure that is associated with increased hospital resource utilization compared to all cases in their assigned MS-DRG, not the performance of open surgical ablation as suggested by the requestor, when compared to other cases in their respective MS-DRGs. CMS concludes that it clinically requires greater resources (higher average costs and generally longer lengths of stay) to perform an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure and recommends that a new base MS-DRG be created for these cases.

  STS is supportive of CMS' proposal to create new MS-DRG 212 to address increased clinical cohesiveness and resource utilization for patients who require treatment of open AVR, MVR in combination with another concomitant procedure such as coronary artery bypass grafting (CABG) and/or open surgical ablation for atrial fibrillation (Afib). However, we are concerned that the proposed definition for MS-DRG 212 requiring open AVR and MVR is to narrow and excludes the majority of Medicare beneficiaries who are at risk for open surgical ablation to treat Afib when performed in an addition to a single open valve AVR or MVR procedure. Specifically, we are concerned that by creating the new MS-DRG that requires two open procedures, a MVR and an AVR to be performed with a third procedure such as surgical ablation, CABG, another valve or an intraoperative percutaneous ventricular assist device (pVAD), CMS is only addressing increased resource utilization for a very small subset of patients and is not factoring in the increased costs associated with the surgical ablation procedures. In addition to the increased age and comorbidities of patients who present with atrial fibrillation, there is also an inherent increase in the cost associated with the treatment of atrial fibrillation with open surgical ablation. Combined open surgical ablation and valve replacement procedures typically requires the use of a specialized medical devices such as control units, ablation clamps, cryoablation probes, left atrial appendage management tools which may include an implantable clip in addition to the implantable valve required for the valve replacement. There is also increased resource utilization due to the complexity of patients that present with multiple comorbidities requiring two or more cardiac surgery procedures involving a combination of open single or multiple valve AVR or MVR procedures, coronary artery disease and Afib. This is reflected in the increase in surgical times and resources required for each additional open cardiac surgery as well as the increased risk associated with this patient population.

Afib is a complex arrythmia that is present in > 40% of patients undergoing **open single or multi valve** MVR or AVR procedures.[1] These patients have 5x greater risk of stroke and heart failure, and increased mortality risk with only 50-60% being eligible to receive oral anticoagulation than those without Afib. These patients also have a 2-3x greater risk for hospitalizations and multiple admissions if their Afib goes untreated. It is estimated that hospitalized patients with Afib add more than $8,000 per admission.[2] Untreated Afib also increases risk of readmission. In FY22 and FY23 CMS recognized the increased resource utilization for surgical ablation with CABG or multi valve procedures and surgical ablation and moved the cases for clinical coherence.

Midterm survival in patients treated for atrial fibrillation: A propensity-matched comparison to patients without a history of atrial fibrillation

Richard Lee, MD, MBA, Patrick M. McCarthy, MD, Edward C. Wang, PhD, Muthiah Vaduganathan, BA, Jane Kruse, RN, S. Chris Malaisrie, MD, and Edwin C. McGee, Jr, MD



Lee R, et al. Midterm survival in patients treated for atrial fibrillation: a propensity-matched comparison to patients without a history of atrial fibrillation. *J Thorac Cardiovasc Surg*. 2012 Jun;143(6):1341-51

[1] McCarthy, P. M., Davidson, C. J., Kruse, J., Lerner, D. J., Braid-Forbes, M. J., McCrea, M. M., Elmouelhi, A. M., & Ferguson, M. A. (2020). Prevalence of atrial fibrillation before cardiac surgery and factors associated with concomitant ablation. The Journal of thoracic and cardiovascular surgery, 159(6), 2245–2253.e15. https://doi.org/10.1016/j.jtcvs.2019.06.062

[2] Kim, M. H., Johnston, S. S., Chu, B. C., Dalal, M. R., & Schulman, K. L. (2011). Estimation of total incremental health care costs in patients with atrial fibrillation in the United States. Circulation. Cardiovascular quality and outcomes, 4(3), 313–320. https://doi.org/10.1161/CIRCOUTCOMES.110.958165

A data analysis of the MEDPAR 2022 Data grouped to MSDRG V41 performed by Watson Policy Analysis for Atricure in the table below demonstrates that untreated Afib adds costs and average length of stay (ALOS) in **single valve** MVR or AVR patients compared to non-Afib **single valve** MVR or AVR patients in MS-DRG 216-221

MS-DRG	MVR or AVR w/o Afib count	MVR or AVR w/o Afib mean costs	MVR or AVR w/o Afib mean ALOS	MVR or AVR w Afib count	MVR or AVR w Afib mean costs	Mean cost Δ between Afib and non-AFib	MVR or AVR mean ALOS	Mean ALOS Δ between Afib and non-Afib
219	4,417	$63,214	10.60	2,581	$69,098	$5,884 (9.3%)	11.81	1.21 (11.4%)
220	4,329	$42,813	6.19	1,853	$48,478	$5,664 (13.2%)	7.20	1.02 (16.4%)
221	522	$37,919	4.82	105	$43,569	$5,650 (14.9%)	5.63	0.81 (16.9%)
Totals Weighted								
216-221	11,304	$56,542	9.33	5,651	$64,105	$7,562 (13.4%)	11.00	1.67 (17.9%)

From a clinical standpoint, concomitant management of atrial fibrillation has a Class I guideline recommendation at the time of MV repair or replacement (Level of Evidence A), and CABG and/or AV replacement (Level of Evidence B). Over the last five years, we have very clear national registry and randomized trial data that outlines that, compared to no treatment, concomitant management of Afib at the time of these operations (MV and/or AV and/or CABG) is safe, associated with mortality reduction at 30-days, associated with lower readmissions for stroke, and associated with improved longitudinal survival. Despite these data, surgical adoption of concomitant treatment of Afib at the time of MV repair/replacement and/or AV repair/replacement and/or CABG has been slow. STS feels that one reason for the slow adoption is due to inadequate reimbursement. The increased costs associated with performing multiple procedures on older, sicker patients that are device intensive procedures are significant and there is currently not a mechanism in place to adequately reimburse hospitals for this type of care.

Reviewing the data CMS provided from Tables 6P.3b and 6P.3c in the FY 2024 IPPS Proposed Rule, the data overall supports an increased ALOS for some cases and increased average costs for a majority of claims reporting procedure code combinations describing open concomitant surgical ablations in MS-DRGs 216, 217, 218, 219, 220 and 221. These include the following:

- For MS-DRG 216, cases for
  - CABG and MVR with open surgical ablation had an ALOS of 20.3 days compared to 19.6 days and an average cost of $111,439 compared to $101,193 for CABG and AVR with no open surgical ablation.
  - AVR with open surgical ablation had an ALOS of 16.9 vs 16.1 days and average costs of $82,926 vs $78,789 for just AVR.

- For MS-DRG 217, cases for
  - CABG and MVR with open surgical ablation had an ALOS of 12.8 days compared to 11.5 days and an average cost of $80,697 compared to $68,998 for CABG and MVR with no open surgical ablation.
  - CABG and AVR with open surgical ablation had an ALOS of 11.0 days compared to 10.0 days and an average cost of $74,241 compared to $58,959 for CABG and AVR with no open surgical ablation.
  - CABG, AVR and MVR with open surgical ablation had a shorter ALOS of 14.0 days compared to 15.8 days but an increased average cost of $98,001 compared to $82,797 for CABG, AVR and MVR with no open surgical ablation.
  - AVR with open surgical ablation had an ALOS of 8.5 days compared to 8.1 days and an average cost of $54,351 compared to $48,425 for AVR with no open surgical ablation.
  - AVR and MVR with open surgical ablation had an ALOS of 12.3 days compared to 11.5 days and an average cost of $80,578 compared to $66,669 for AVR and MVR with no open surgical ablation.

- For MS-DRG 218, cases for AVR with open surgical ablation had an ALOS of 6.5 days compared to 5.2 days and an average cost of $38,519 compared to $30,046 for AVR with no open surgical ablation.

- For MS-DRG 219, cases for
  - CABG with open surgical ablation had an ALOS of 11.7 days compared to 10.9 days and an average cost of $66,531 compared to $63,527 for CABG with no open surgical ablation.
  - CABG and MVR with open surgical ablation had an ALOS of 13.2 days compared to 12.7 days and an average cost of $78,963 compared to $72,933 for CABG and MVR with no open surgical ablation.
  - CABG and AVR with open surgical ablation had an ALOS of 11.4 days compared to 10.7 days and an average cost of $76,838 compared to $64,615 for CABG and AVR with no open surgical ablation.
  - CABG, AVR and MVR with open surgical ablation had a shorter ALOS of 13.6 days compared to 14.0 days but an increased average cost of $94,572 compared to $91,918 for CABG, AVR and MVR with no open surgical ablation.
  - MVR with open surgical ablation had a shorter ALOS of 10.8 days compared to 11.3 days but an increased average cost of $68,042 compared to $66,638 for MVR with no open surgical ablation.

- For MS-DRG 220, cases for
  - CABG with open surgical ablation had an ALOS of 7.9 days compared to 7.0 days and an average cost of $50,543 compared to $43,377 for CABG with no open surgical ablation.
  - CABG and MVR with open surgical ablation had an ALOS of 8.0 days compared to 7.7 days and an average cost of $59,989 compared to $51,067 for CABG and MVR with no open surgical ablation.

- CABG and AVR with open surgical ablation had an ALOS of 7.2 days compared to 6.8 days and an average cost of $53,958 compared to $41,197 for CABG and AVR with no open surgical ablation.
- CABG, AVR and MVR with open surgical ablation had an ALOS of 9.6 days compared to 7.9 days and an average cost of $84,293 compared to $66,378 for CABG, AVR and MVR with no open surgical ablation.
- MVR with open surgical ablation had an ALOS of 7.3 days compared to 6.9 days and an average cost of $49,900 compared to $46,200 for MVR with no open surgical ablation.
- AVR with open surgical ablation had an ALOS of 6.7 days compared to 6.0 days and an average cost of $53,334 compared to $42,415 for AVR with no open surgical ablation,

- For MS-DRG 221, cases for
  - CABG with open surgical ablation had a shorter ALOS of 4.5 days compared to 5.9 days but an increased average cost of $50,543 compared to $43,377 for CABG with no open surgical ablation.
  - CABG and AVR with open surgical ablation had an ALOS of 5.8 days compared to 5.4 days and an average cost of $59,024 compared to $43,087 for CABG and AVR with no open surgical ablation.
  - MVR with open surgical ablation had a shorter ALOS of 4.7 days compared to 5.3 days but a slightly increased average cost of $38,870 compared to $38,207 for MVR with no open surgical ablation.
  - AVR with open surgical ablation had an ALOS of 5.5 days compared to 4.6 days and an average cost of $48,666 compared to $37,041 for AVR with no open surgical ablation.

The table below shows areas highlighted in yellow that have higher LOS and or cost with open concomitant surgical ablation procedure.

Table 6P.3b - Data analysis of claims reporting procedure code combinations describing open concomitant surgical ablations in MS-DRGs 216, 217, 218, 219, 220 and 221 in the FY 2022 MedPAR file				**Table 6P.3c - Data analysis of claims reporting procedure code combinations describing open concomitant procedures without reporting surgical ablation in MS-DRGs 216, 217, 218, 219, 220 and 221 in the FY 2022 MedPAR file**			
	September 2022 update of the FY 2022 MedPAR file				**September 2022 update of the FY 2022 MedPAR file**		
Description open concomitant surgical ablation code combination	**# of Cases**	**Avg LOS**	**Avg Costs**	**Description with open concomitant code combination in MS- without reporting surgical ablation**	**# of Cases**	**Avg LOS**	**Avg Costs**
216 - Valve Cardiac and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC							
ALL CASES	**5311**	**14.9**	**$ 84,327**	**ALL CASES**	**5311**	**14.9**	**$ 84,327**
CABG with Open SA	57	16.9	$ 78,586	CABG	271	16.6	$ 84,554
CABG with Open SA & MVR	59	20.3	$ 111,439	CABG & MVR	305	19.6	$ 101,193
CABG with Open SA & AVR	83	16.7	$ 85,418	CABG & AVR	842	16.0	$ 87,551
CABG with Open SA & AVR & MVR	12	17.4	$ 98,612	CABG & AVR & MVR	70	24.8	$ 130,323
Open Ablation & MVR	127	17.9	$ 86,664	MVR	462	18.4	$ 87,976

Open SA & AVR	73	16.9	$ 82,926	AVR	639	16.1	$ 78,789
Open SA & AVR & MVR	28	18.1	$ 109,596	AVR & MVR	170	21.8	$ 110,965
All cases reporting an open concomitant surgical ablation code combination in MS-DRG 216	**439**	**17.7**	**$ 89,877**	**All cases reporting an open concomitant code combination in MS-DRG 216 without reporting surgical ablation**	**2759**	**17.5**	**$ 89,334**
217 - Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC							
ALL CASES	**1736**	**7.3**	**$ 56,143**	**ALL CASES**	**1736**	**7.3**	**$ 56,143**
CABG with Open SA	13	9.8	$ 54,802	CABG	83	9.9	$ 59,383
CABG with Open SA & MVR	4	12.8	$ 80,967	CABG & MVR	38	11.5	$ 68,998
CABG with Open SA & AVR	24	11.0	$ 74,241	CABG & AVR	346	10.0	$ 58,959
CABG with Open SA & AVR & MVR	1	14.0	$ 98,001	CABG & AVR & MVR	8	15.8	$ 82,797
Open Ablation & MVR	21	8.7	$ 43,221	MVR	86	10.0	$ 55,405
Open SA & AVR	21	8.5	$ 54,351	AVR	268	8.1	$ 48,425
Open SA & AVR & MVR	8	12.3	$ 80,578	AVR & MVR	23	11.5	$ 66,669
All cases reporting an open concomitant surgical ablation code combination in MS-DRG 217	**92**	**10.0**	**$ 60,975**	**All cases reporting an open concomitant code combination in MS-DRG 217 without reporting surgical ablation**	**852**	**10.7**	**$ 56,208**
218 - Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC							
ALL CASES	**309**	**3.1**	**$ 50,208**	**ALL CASES**	**309**	**3.1**	**$ 50,208**
CABG with Open SA	-	-	$	CABG	4	4.3	$ 68,835
CABG with Open SA & MVR	-	-	$	CABG & MVR	1	7.0	$ 57,022
CABG with Open SA & AVR	-	-	$	CABG & AVR	26	8.3	$ 47,629
CABG with Open SA & AVR & MVR	-	-	$	CABG & AVR & MVR	0	0.0	$ -
Open Ablation & MVR	-	-	$	MVR	2	7.5	$ 26,490
Open SA & AVR	2	6.5	$ 38,519	AVR	31	5.2	$ 30,046
Open SA & AVR & MVR	-	-	$	AVR & MVR	0	0.0	$ -
All cases reporting an open concomitant surgical ablation code combination in MS-DRG 218	**2**	**6.5**	**$ 38,519**	**All cases reporting an open concomitant code combination in MS-DRG 218 without reporting surgical ablation**	**64**	**6.5**	**$ 39,924**
219 - Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC							
ALL CASES	**12149**	**10.8**	**$ 65,911**	**ALL CASES**	**12149**	**10.8**	**$ 65,911**
CABG with Open SA	123	11.7	$ 66,531	CABG	536	10.9	$ 63,527
CABG with Open SA & MVR	114	13.2	$ 78,963	CABG & MVR	457	12.7	$ 72,933
CABG with Open SA & AVR	177	11.4	$ 76,838	CABG & AVR	1973	10.7	$ 64,615
CABG with Open SA & AVR & MVR	25	13.6	$ 94,572	CABG & AVR & MVR	133	14.0	$ 91,918
Open Ablation & MVR	436	10.8	$ 68,042	MVR	1401	11.3	$ 66,638
Open SA & AVR	184	9.5	$ 60,495	AVR	2658	10.4	$ 62,845
Open SA & AVR & MVR	77	12.5	$ 82,603	AVR & MVR	446	13.6	$ 84,093
All cases reporting an open concomitant surgical ablation code combination in MS-DRG 219	**1136**	**11.2**	**$ 70,693**	**All cases reporting an open concomitant code combination in MS-DRG 219 without reporting surgical ablation**	**7604**	**11.1**	**$ 66,412**
220 - Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC							
ALL CASES	**9888**	**6.4**	**$ 45,839**	**ALL CASES**	**9888**	**6.4**	**$ 45,839**

CABG with Open SA	72	7.9	$ 50,543	CABG	324	7.0	$ 43,377
CABG with Open SA & MVR	51	8.0	$ 59,989	CABG & MVR	198	7.7	$ 51,067
CABG with Open SA & AVR	119	7.2	$ 53,958	CABG & AVR	1811	6.8	$ 47,197
CABG with Open SA & AVR & MVR	10	9.6	$ 84,293	CABG & AVR & MVR	67	7.9	$ 66,378
Open Ablation & MVR	279	7.3	$ 49,900	MVR	904	6.9	$ 46,200
Open SA & AVR	201	6.7	$ 50,334	AVR	2933	6.0	$ 42,415
Open SA & AVR & MVR	38	8.1	$ 62,884	AVR & MVR	193	7.8	$ 62,852
All cases reporting an open concomitant surgical ablation code combination in MS-DRG 220	**770**	**7.3**	**$ 52,456**	**All cases reporting an open concomitant code combination in MS-DRG 220 without reporting surgical ablation**	**6430**	**6.5**	**$ 45,472**
221 - Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC							
ALL CASES	**1402**	**4.0**	**$ 40,694**	**ALL CASES**	**1402**	**4.0**	**$ 40,694**
CABG with Open SA	6	4.5	$ 50,709	CABG	39	5.9	$ 47,432
CABG with Open SA & MVR	3	4.7	$ 30,725	CABG & MVR	12	5.3	$ 47,048
CABG with Open SA & AVR	9	5.8	$ 59,024	CABG & AVR	203	5.4	$ 43,087
CABG with Open SA & AVR & MVR	-	-	$	CABG & AVR & MVR	3	4.3	$ 36,451
Open Ablation & MVR	10	4.7	$ 38,870	MVR	51	5.3	$ 38,207
Open SA & AVR	10	5.5	$ 48,666	AVR	352	4.6	$ 37,041
Open SA & AVR & MVR	-	-	$	AVR & MVR	6	6.2	$ 39,008
All cases reporting an open concomitant surgical ablation code combination in MS-DRG 221	**38**	**5.1**	**$ 47,448**	**All cases reporting an open concomitant code combination in MS-DRG 221 without reporting surgical ablation**	**666**	**5.0**	**$ 39,777**

Based on the increased complexity and increased resource utilization of a single open AVR or MVR procedure performed in addition to another concomitant procedure including CABG, open surgical ablation or intraoperative pVAD, **STS strongly urges CMS to change the definition of proposed MS-DRG 212 from (Concomitant Aortic and Mitral Valve Procedures) to (Concomitant Aortic or Mitral Valve Procedures).**

STS would also like to suggest that CMS consider moving the aortic and mitral valve repair codes with the root operations of "creation", "release", "restriction" and "supplement, that are currently listed under the **Concomitant Operating Room Procedures** in table 6P.4a and in the draft version of the MS-DRG V41.0 Definitions Manual to the appropriate list of aortic valve or mitral valve procedures.

Specifically, this would include the following changes:

Moving the following ICD-10-PCS codes from the **Concomitant Operating Room Procedures** list to the **Aortic Valve Procedures** list:

024F07J	Creation of Aortic Valve from Truncal Valve using Autologous Tissue Substitute, Open Approach
024F08J	Creation of Aortic Valve from Truncal Valve using Zooplastic Tissue, Open Approach
024F0JJ	Creation of Aortic Valve from Truncal Valve using Synthetic Substitute, Open Approach

024F0KJ	Creation of Aortic Valve from Truncal Valve using Nonautologous Tissue Substitute, Open Approach
02NF0ZZ	Release Aortic Valve, Open Approach
02UF07Z	Supplement Aortic Valve with Autologous Tissue Substitute, Open Approach
02UF08J	Supplement Aortic Valve created from Truncal Valve with Zooplastic Tissue, Open Approach
02UF08Z	Supplement Aortic Valve with Zooplastic Tissue, Open Approach
02UF0JJ	Supplement Aortic Valve created from Truncal Valve with Synthetic Substitute, Open Approach
02UF0JZ	Supplement Aortic Valve with Synthetic Substitute, Open Approach
02UF0KJ	Supplement Aortic Valve created from Truncal Valve with Nonautologous Tissue Substitute, Open Approach
02UF0KZ	Supplement Aortic Valve with Nonautologous Tissue Substitute, Open Approach
02UF47J	Supplement Aortic Valve created from Truncal Valve with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
02UF47Z	Supplement Aortic Valve with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
02UF48J	Supplement Aortic Valve created from Truncal Valve with Zooplastic Tissue, Percutaneous Endoscopic Approach
02UF48Z	Supplement Aortic Valve with Zooplastic Tissue, Percutaneous Endoscopic Approach
02UF4JJ	Supplement Aortic Valve created from Truncal Valve with Synthetic Substitute, Percutaneous Endoscopic Approach
02UF4JZ	Supplement Aortic Valve with Synthetic Substitute, Percutaneous Endoscopic Approach
02UF4KJ	Supplement Aortic Valve created from Truncal Valve with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
02UF4KZ	Supplement Aortic Valve with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach

Moving the following ICD-10-PCS codes from the **Concomitant Operating Room Procedures** list to the **Mitral Valve Procedures** list:

024G072	Creation of Mitral Valve from Common Atrioventricular Valve using Autologous Tissue Substitute, Open Approach
024G082	Creation of Mitral Valve from Common Atrioventricular Valve using Zooplastic Tissue, Open Approach
024G0J2	Creation of Mitral Valve from Common Atrioventricular Valve using Synthetic Substitute, Open Approach
024G0K2	Creation of Mitral Valve from Common Atrioventricular Valve using Nonautologous Tissue Substitute, Open Approach
02NG0ZZ	Release Mitral Valve, Open Approach
02UG07E	Supplement Mitral Valve created from Left Atrioventricular Valve with Autologous Tissue Substitute, Open Approach
02UG07Z	Supplement Mitral Valve with Autologous Tissue Substitute, Open Approach
02UG08E	Supplement Mitral Valve created from Left Atrioventricular Valve with Zooplastic Tissue, Open Approach
02UG08Z	Supplement Mitral Valve with Zooplastic Tissue, Open Approach

02UG0JE	Supplement Mitral Valve created from Left Atrioventricular Valve with Synthetic Substitute, Open Approach
02UG0JZ	Supplement Mitral Valve with Synthetic Substitute, Open Approach
02UG0KE	Supplement Mitral Valve created from Left Atrioventricular Valve with Nonautologous Tissue Substitute, Open Approach
02UG0KZ	Supplement Mitral Valve with Nonautologous Tissue Substitute, Open Approach
02UG47E	Supplement Mitral Valve created from Left Atrioventricular Valve with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
02UG47Z	Supplement Mitral Valve with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
02UG48E	Supplement Mitral Valve created from Left Atrioventricular Valve with Zooplastic Tissue, Percutaneous Endoscopic Approach
02UG48Z	Supplement Mitral Valve with Zooplastic Tissue, Percutaneous Endoscopic Approach
02UG4JE	Supplement Mitral Valve created from Left Atrioventricular Valve with Synthetic Substitute, Percutaneous Endoscopic Approach
02UG4JZ	Supplement Mitral Valve with Synthetic Substitute, Percutaneous Endoscopic Approach
02UG4KE	Supplement Mitral Valve created from Left Atrioventricular Valve with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
02UG4KZ	Supplement Mitral Valve with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
02VG0ZZ	Restriction of Mitral Valve, Open Approach
02VG4ZZ	Restriction of Mitral Valve, Percutaneous Endoscopic Approach

These changes would ensure that all of the aortic valve repair and mitral valve repair codes are captured as primary procedures instead of concomitant procedures when performed.

External Heart Assist Device

For FY 2024, CMS proposes to reassign ICD-10-PCS code 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) from MDC 05 in MS-DRG 215 to Pre-MDC MS-DRG 001 and 002. Based on their data analysis and review of the clinical considerations, CMS found that overall, cases reporting a procedure code describing the open insertion of a short-term external heart assist device are generally more resource intensive, clinically distinct and may be more appropriately aligned with the average costs of the cases in MS-DRGs 001 and 002 in comparison to MS-DRG 215, even though the average length of stay is shorter.

CMS also indicates that if a new ICD-10-PCS code is finalized for the Impella 5.5 with SmartAssist System CMS would use its established process for MS-DRG assignment which examines the MS-DRG assignment for the predecessor codes to determine the most appropriate MS-DRG assignment.

The STS agrees with CMS, that the ventricular assist devices implanted surgically through the open chest via direct aortic, aortic conduit or axillary conduit are typically used to treat more complex patients than other femoral artery access pVADs. The surgically implanted pVADS are indicated for the treatment of ongoing cardiogenic shock that occurs less than 48 hours following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to

medical management and conventional treatment measures. As the data shows, the complexity of the patients treated with the surgically implanted pVADS with diagnoses of cardiogenic shock, acute kidney failure and/or cardiomyopathy requiring full cardiac and hemodynamic support with up to 5.5 liters of blood flow per minute for a longer period of time (up to 14 days) are clinically more closely aligned with MS-DRGs 001 and 002 as compared to MS-DRG 215. The data also support that there is significant variation in the resource utilization for patients treated with the surgically implanted device compared to patients treated with other femoral access pVADs assigned to MS-DRG 215.

STS supports CMS's proposal to reassign ICD-10-PCS code 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) from MDC 05 in MS-DRG 215 to Pre-MDC MS-DRG 001 and 002 to align the clinical cohesiveness and resource utilization more closely. STS agrees that CMS should continue to monitor the clinical cohesiveness of the procedures assigned to MS-DRGs 001 and 002 to ensure continued alignment on resource use and shifts in treatment practices that may warrant refinements in the future. If a new ICD-10-PCS code is finalized for the Impella 5.5 with SmartAssist System, STS encourages CMS to assign the new code(s) to Pre-MDC MS-DRG 001 and 002.

FY 2024 Applications for New Technology Add-On Payments (NTAP)

DuraGraft®

Marizyme, Inc. submitted an application for new technology add-on payment for DuraGraft®, an intraoperative vein-graft preservation solution used during the harvesting and grafting interval during CABG. The applicant indicated that use of DuraGraft® does not change clinical/surgical practice, it replaces solutions currently used for flushing and storage of the saphenous vein grafts (SVG) from harvesting through grafting, including tests for graft leakage.

In their review of DURAGRAFT® for the NTAP criteria, CMS indicated that while DURAGRAFT® met the cost criterion, they did not believe that it met the newness or substantial clinical improvement criterion. CMS cited concerns that the newness criteria were not met because the mechanism of action of DURAGRAFT® is the same or similar to other vein graft storage solutions such as various saline, blood, and electrolyte solutions. CMS expressed concerns that the substantial clinical improvement criteria were not met due to the small sample size, short follow-up period and homogeneous nature of the demographic profiles from some of the studies were not representative of the Medicare beneficiaries potentially eligible for DuraGraft® combined with one of the studies indicating that a larger cohort and longer-term evaluation was needed to validate their findings and that the study was not powered for clinical outcome events. CMS also cited concerns that there may be mixed evidence as to whether there is an association between exposure to DuraGraft® and clinical outcome improvement.

The STS has concerns that the current data does not specifically support the newness or substantial clinical criterion at this time.

VEST

Vascular Graft Solutions, Ltd. (VGS) submitted an application for new technology add-on payment for VEST, an external support device which can be fitted over the saphenous vein when used as a bypass conduit in CABG surgery. The applicant stated that VEST is the only technology that has been

proven to prevent common vein graft failures as a result of graft kinking and vein graft disease (intimal hyperplasia). According to the applicant, VEST is designed to improve the long-term clinical outcome of CABG by reducing clinical events that are associated with graft failure.

In their review of VEST for the NTAP criteria, CMS indicated that while VEST met the cost criterion, they were seeking comments as to if VEST meets the newness criterion. CMS expressed several concerns with the information presented in support of substantial clinical improvement. CMS expressed concerns that the evidence provided in the studies demonstrate clinical improvement or if some of the outcomes are only inferred from surrogate endpoints; that the impact of VEST on clinical outcomes may have been confounded by demographic, clinical, or surgical factors; that differences in baseline characteristics of the patients in the treatment and placebo group may have confounded the association between the use of VEST and clinical improvements; that surgical decisions could impact VEST on clinical outcomes. CMS also questions whether the results can be replicated in the Medicare population undergoing surgery as the study participants were predominately male noting that female CABG patients tend to have poorer outcomes than men.

The STS has concerns that the current data does not specifically support the substantial clinical criterion at this time.

Changes to MS-DRG Diagnosis Codes (MCC/CC)

Social Determinants of Health Diagnosis Codes

In FY 2023 rulemaking, CMS sought information on diagnosis codes that describe social determinants of health. This included codes that describe a patient's status as homeless:

- *Z59.00 (Homelessness, unspecified)*
- *Z59.01 (Sheltered homelessness)*
- *Z59.02 (Unsheltered homelessness)*

CMS has found that FY 2019 and 2020 data suggested that "when homelessness is reported as a secondary diagnosis, the resources involved in care for these patients is more aligned with a comorbidity and complication (CC) than a NonCC or a major comorbidity and complication (MCC)." However, CMS expressed concern that homelessness as a diagnosis code might be underreported when there is not an available field where other diagnoses are reported instead. With more recent data, CMS again found that the data suggests that when these are reported as secondary diagnoses, "the resources involved in caring for a patient experiencing homelessness support increasing the severity level from a NonCC to a CC. Therefore, CMS proposes changing the severity level for Z59.00, Z59.01, and Z59.02 from NonCC to CC.

STS supports CMS' use of social determinants of health to better capture patient health. STS has a strong commitment to addressing social determinants of health and is particularly interested in the coverage of certain health-related social needs. Allowing for homelessness as a secondary diagnosis aligned with a CC should allow for better provider coverage.

Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes

Revising the Hospital VBP Program Scoring Methodology to Add a New Adjustment That Rewards Hospitals Based on Their Performance and the Proportion of Their Patients Who Are Dually Eligible for Medicare and Medicaid

To further align with CMS' goals to achieve health equity, address health disparities, and close the performance gap on the quality of care, CMS proposes to add a Health Equity Adjustment (HEA) to a hospital's Total Performance Score (TPS) that would be calculated using a methodology that incorporates a hospital's performance across all four domains for the program year and its proportion of patients with dual eligibility status (DES), beginning with the FY 2026 program year. The HEA bonus points are designed to award higher points for hospitals that (1) serve greater percentages of underserved populations, which are defined here for the purpose of this proposal as hospital patients with DES who receive inpatient services, and (2) have higher quality performance.

The HEA bonus points would be calculated as the product of the measure performance scaler and the underserved multiplier. The maximum number of HEA bonus points that could be added to the TPS would be 10 points.

STS supports updating the Hospital VBP Program to reward hospitals and clinicians who treat a higher caseload of more complex and high-risk patients. This bonus plays a role in improving patient access by helping alleviate risk aversion. We encourage CMS not to limit the HEA solely to dual eligibility as this is not the only indicator for health disparities. There are many other indicators of social risk necessary to capture the full scope of patients who might have risk factors that contribute to the complexity of care they need. Although identifying the full scope of patients with social risk is a complex task, STS encourages CMS to continue to work with stakeholders to design a more inclusive, reliable, and accurate method to account for complex patients. Until this built out further, we encourage CMS to continue with the HEA as proposed.

Thank you for the opportunity to provide these comments. Please contact Molly Peltzman, Associate Director of Health Policy, at mpeltzman@sts.org or Derek Brandt, Vice President of Government Relations at dbrandt@sts.org should you need additional information or clarification.

Sincerely,

Thomas E. MacGillivray, MD
President