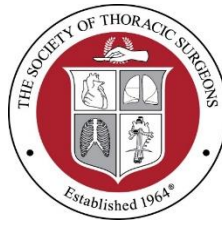


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June 20, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Fiscal Year 2020 Inpatient Prospective Payment System Proposed Rule

Dear Administrator Verma,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Fiscal Year (FY) 2020 Inpatient Prospective Payment System (IPPS) Proposed Rule. Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,500 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.

F. Proposed Changes to Specific MS-DRG Classifications

2. Pre-MDC

a. Peripheral ECMO

STS strongly supports the Centers for Medicare & Medicaid Services (CMS) proposal to reassign the peripheral extracorporeal membrane oxygenation (ECMO) procedure codes (5A1522G and 5A1522H) from their current MS-DRG assignments to Pre-MDC MS-DRG 003 (*ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure*) and change the titles for MS-DRGs 207, 291, 296, and 870 to remove the “or Peripheral Extracorporeal Membrane Oxygenation (ECMO)” terminology. While STS has significant concerns with the proposal continuing to define peripheral ECMO procedure codes as non-O.R. procedures, we recognize that these procedures may be performed in non-O.R. locations such as the ER or ICU. Although peripheral veno-venous (VV) and veno-arterial (VA) lifesaving (as opposed to intraoperative) ECMO can be done in any setting, the determining factor for the location where ECMO is initiated is typically dictated by the patient's situation. For critically ill patients who require life-saving ECMO, cannulation and initiation of the ECMO circuit is usually done in an emergent manner. These patients are often at risk of imminent death and cannot safely be moved to another location for cannulation and ECMO initiation. STS would like to request that CMS review the designation of the ECMO codes and consider the unique nature of these procedures

during their comprehensive review of the O.R – Non-O.R. status of the ICD-10 procedure codes. Regardless of the designation or the location of cannulation and ECMO initiation, these patients are critically ill and resource intensive.

We agree with the CMS clinical advisors that when claims data is available from the current procedure codes (5A1522F, 5A1522G and 5A1522H) it may provide additional information on peripheral ECMO procedures with regard to indications for treatment, a patient's severity of illness, resource utilization, and treatment difficulty. Data we have provided from The Extracorporeal Life Support Organization (ELSO) Data Registry support our assertion that the acuity of the patient, rather than the method of ECMO cannulation, is the main factor that should be considered in estimating the overall resources required to treat patients on ECMO. Resource utilization for ECMO is a result of: a) the medical complexity of patients, b) the extensive involvement of a multidisciplinary team to provide care, c) the sophistication and cost of the ECMO device, d) the prolonged ICU management, and e) subsequent hospital care. CMS reviewed claims data to ascertain the consumption of hospital resources for the cases in which ECMO was reported during a hospital stay. Those data clearly showed that the patients placed on ECMO typically have multiple major complication/comorbidity (MCC) and complication/comorbidity (CC) conditions. These data support that the conditions reported for patients requiring ECMO represent greater severity of illness, greater treatment difficulty. Therefore, ECMO patients have poorer prognoses, and have a greater need for intervention.

The above concept, derived from the ELSO Data Registry, is further bolstered by the FY 2020 IPPS Proposed Rule which states that, based upon stakeholders' comments and data provided, CMS clinical advisors agree that MS-DRG assignments should not be based on method of cannulation and that "resource consumption for both central and peripheral ECMO cases can be primarily attributed to the severity of illness of the patient, and that the method of cannulation is less relevant when considering the overall resources required to treat patients on ECMO." The CMS clinical advisors recognized that patients who require ECMO treatment are severely ill. They further stated that they "believed that a more appropriate measure of resource consumption for ECMO would be the number of hours or days that a patient was specifically receiving ECMO treatment," but this information is not available in claims data. As stated above, we disagree with the assertion that time on ECMO can serve as a proxy for severity of illness or a predictor of resources required. We do have information identifying the number (frequency) and types of principal and secondary diagnosis CC and/or MCC conditions which CMS has used as a proxy for confirming the severity of ECMO patients. More complete data on ECMO patients would be required to make any type of correlation to resource use.

CMS noted that a request and proposal to create ICD-10-PCS codes to differentiate between peripheral vessel percutaneous and peripheral vessel open cutdown according to the indication (VA or VV) for ECMO was made at the March 5-6, 2019 ICD-10 Coordination and Maintenance Committee meeting. CMS notes that in the public comments from the meeting, the ICD-10 Coordination and Maintenance Committee included an option to add duration values to allow reporting the number of hours or the number of days a patient received ECMO during the stay.

STS has the following concerns with the creation of codes adding duration values for reporting of the number of hours or the number of days a patient receives lifesaving ECMO during their hospital stay:

1. The duration of ECMO in this patient population is highly variable and not reliably associated with the severity of the patient's illness. For example, very ill patients can die within the first 24-hours on ECMO or they can be on ECMO for weeks until their organs recover.
2. ECMO patients are extremely resource intensive and there is no correlation between duration of ECMO and the patient's severity of illness. In fact, in many instances, an inverse relationship between severity of illness and duration of ECMO, may exist with short duration of therapy resulting from overwhelming severity of illness and death.
3. ECMO patients are critically ill, and until their organs recover, they have an exceedingly high risk of death. It is not uncommon for these critically ill patients to die within the 1st 24 hours.
4. Duration-based codes may increase the possibility of patients being kept on ECMO into the next duration interval. There should be no incentive to keep patients on ECMO longer than necessary.
5. Codes with duration values would add unnecessary administrative burden to providers and hospitals.

As a completely separate category of ECMO use, patients who may not be acutely ill are specifically placed on ECMO for intraprocedural hemodynamic support. In this small subset of patients, duration values could conceivably be useful. Intraoperative support ECMO is usually of a short duration during the procedure or in some cases up to 24 hours after the procedure.

STS reviewed the new ICD-10-PCS Codes for FY 2020 that were released on June 6, 2019. We notice that the ICD-10 Coordination and Maintenance Committee added a new value of "intraoperative" to the ECMO codes. STS and ELSO had proposed adding a new value using the term "intraoperative" with the intent to capture services where ECMO is used during a procedure for intraprocedural support where the patient is only on ECMO for the duration of the procedure or up to 24 hours following a procedure. Examples of procedures that may require intraprocedural support include high risk percutaneous coronary intervention (PCI) and lung transplants. Based on discussions at the ICD-10 Coordination and Maintenance Committee Meeting, STS appreciates that existing terminology requires the new codes utilize the term "intraoperative" as opposed to "intraoperative" as proposed by STS and ELSO in the ICD-10 PCS Coding Application. We understand that "intraoperative" is the value currently used in ICD-10-PCS. The Official ICD-10-PCS Coding Guideline B61.a indicates that

A device is coded only if a device remains after the procedure is completed. If no device remains, the device value No Device is coded. In limited root operations, the classification provides the qualifier values Temporary and Intraoperative, for specific procedures involving clinically significant devices, where the purpose of the device is to be utilized for a brief duration during the procedure or current inpatient stay. If a device that is intended to remain after the procedure is completed requires removal before the end of the operative episode in which it was inserted (for example, the device

size is inadequate or a complication occurs), both the insertion and removal of the device should be coded."

STS would like to encourage CMS to provide clear guidance on selecting the correct ICD-10-PCS ECMO codes for reporting the following scenarios:

1. A patient is placed on lifesaving ECMO during an inpatient stay or a patient that undergoes a cardiac procedure and cannot be weaned from cardiopulmonary bypass. Lifesaving ECMO is used to support critically ill patients who are at imminent risk of death from severe heart, lung or heart-lung failure. STS recommends that for this scenario, the current ECMO codes 5A1522F, 5A1522G or 51A522H should be reported.
2. ECMO is utilized to support a patient during a procedure such as a high-risk PCI, lung transplant, etc. Here ECMO is established at the beginning of the procedure and terminated at the end of the procedure. The place of service for the procedure may vary, eg. O.R., Cardiac Catheterization Lab, Electrophysiology Lab. STS recommends that for this scenario, the new intraoperative ECMO codes 5A15A2F, 5A15A2G or 51A5A2H should be reported.
3. A high-risk case where ECMO is utilized for the duration of the procedure but is continued for 24 hours after the procedure. STS recommends that although ECMO is used for up to 24 hours after the procedure, this would still be considered as temporary or "intraoperative" ECMO as opposed to life-saving ECMO and the new codes 5A15A2F, 5A15A2G or 51A5A2H should be reported for this scenario.

In addition to the issues outlined above, STS would like CMS to clarify that the new intraoperative ECMO support codes would include procedures done in the Cardiac Catheterization Lab, Electrophysiology Lab or other inpatient places of service as well as the O.R. This is confusing given CMS designation of the peripheral ECMO codes as non-OR.

For FY 2020, STS urges CMS to use the same logic for all the ECMO codes (5A1522F, 5A1522G, 51A522H 5A15A2F, 5A15A2G and 51A5A2H) and assign them to PRE-MCD MS-DRG 003 until claims data is available to analyze their impact on resource utilization

Finally, we would like to emphasize that the term "peripheral" should not be used interchangeably with the term "percutaneous." As per our previous comments to CMS and also addressed in the STS-ELSO ICD-10-PCS code change proposal submitted for consideration at the March 5-6, 2019 ICD-10 Coordination and Maintenance Committee meeting, peripheral ECMO may be accomplished via an open cut-down approach or by a strictly percutaneous approach. We maintain that the Coordination and Maintenance Committee must create new codes that accurately reflect all cannulation approaches. Imposing a new level of granularity to the ICD-10-PCS codes for ECMO without providing enough codes to adequately describe the procedures will result in skewed data and uninformed decision-making. Although STS supports the increased granularity for the procedures, as mentioned above, STS does not agree with creating codes based on duration values for the reasons outlined.

5. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Transcatheter Mitral Valve Repair with Implant

CMS is proposing to reassign identified ICD-10-PCS codes for endovascular (percutaneous approach) cardiac valve procedures with implant to MS-DRGs 266- 267. Most of these codes will come from MS-DRGs 216-221. The transcatheter mitral valve repair (TMVR) with implant code (02UG3JZ - Supplement Mitral Valve with Synthetic Substitute, Percutaneous Approach) will come from MS-DRGs 228-229 and code 02UG3JE (mitral valve repair with supplement) will come from MS-DRGs, 331-332 and MS-DRGs 273-274. As part of this reclassification, CMS is proposing to rename MS-DRGs 266-267 to include the terminology “and Supplement Procedures.” In addition, CMS is proposing to create two new MS-DRGs (319-320) for “Other Endovascular Cardiac Valve Procedures,” “with” and “without MCC.” Some of these ICD-10-PCS codes will be moved from MS-DRGs 216-221 and the others will be moved from MS-DRGs 273-274 along with one code (02TH3ZZ - Supplement Mitral Valve created from Left Atrioventricular Valve with Synthetic Substitute, Percutaneous Approach) which will come from MS-DRGs 228-229. The current ICD-10 codes in MS-DRGs 266-267 are percutaneous approach cardiac valve replacement procedures. With the proposed changes, CMS will be combining percutaneous cardiac valve replacement procedures and percutaneous cardiac valve repair with implant procedures.

STS agrees with the proposal to reassign the identified transcatheter cardiac valve repair with implant procedure codes from their current MS-DRGs into MS-DRGs 266-267 with the transcatheter cardiac valve replacement procedures. While we agree with the CMS clinical advisors that “transcatheter cardiac valve repair procedures are not the same as transcatheter (endovascular) cardiac valve replacement,” we support the premise that, from a clinical standpoint, these procedures are more clinically coherent. Per the CMS analysis, these procedures all represent transcatheter cardiac valve interventions that have similar lengths of stay and average costs. STS supports the proposal to further modify the MS-DRG titles for MS-DRG 266 and 267 to Endovascular Cardiac Valve Replacement and Supplement Procedures with and without MCC respectively, which clearly reflects that they include the transcatheter cardiac valve with supplement procedures.

STS also supports the proposal to reassign the ICD-10-PCS codes that CMS identified as other transcatheter (non-supplement) cardiac valve procedures to the proposed new MS-DRGs 319-320 (Other Endovascular Cardiac Valve Procedures with and without MCC). The proposed changes are also clinically reasonable in that they group other transcatheter cardiac valve procedures together resulting in a more clinically coherent organization of the procedures that have similar lengths of stay and average costs and the majority of which can be performed in a cardiac catheterization laboratory. The CMS clinical advisor(s) indicate(s) that these procedures “*require that the interventional cardiologist have special additional training and skills, and often require additional ancillary procedures and equipment, such as trans-esophageal echocardiography, be available at the time of the procedures.*” We request that CMS clarify that these procedures can be performed by both interventional cardiologists and cardiothoracic surgeons. However, we agree that, regardless of the physician providing the service, additional training and skills are required. This would be true for all of the transcatheter cardiac valve

procedures, including the transcatheter cardiac valve replacement and transcatheter cardiac valve repair with implant procedures identified by CMS in the rule.

While STS agrees with the proposed MS-DRG reassignments for the identified transcatheter cardiac valve repair with implant and other transcatheter (non-supplement) cardiac valve ICD-10-PCS codes, we would like to point out that it is difficult to determine the financial impact of these changes to institutions based on the information provided. It appears that the proposed MS-DRG reassignments could result in significant changes to reimbursement for some of identified procedures. STS recommends that CMS continue to monitor the claims data for these codes as it becomes available to ensure that these changes do not negatively impact institutions and, in turn, risk patient access to these important procedures.

13. Operating Room (O.R.) and Non-O.R. Issues

c. Non-O.R. Procedures to O.R. Procedures

(2) Endoscopic Insertion of Endobronchial Valves

CMS has received input that the designation of the endoscopic insertion of endobronchial valve ICD-10-PCS codes (0BH38GZ, 0BH48GZ, 0BH58GZ, 0BH68GZ, 0BH78GZ, 0BH88GZ, 0BH98GZ and 0BHB8GZ) should be changed from Non-O.R. procedures to O.R. procedures and assigned to MS-DRG 163 (*Major Chest Procedures with MCC*), arguing that the cases have similar costs and resource use. CMS clinical advisors previously disagreed that these procedures require the use of an O.R. CMS conducted an analysis to determine if the cases should be reassigned to MS-DRGs for *Major Chest Procedures* and an analysis on how the cases relate to procedures in the MS-DRGs for *Other Respiratory System O.R. Procedures*. In their analysis, CMS clinical advisors “agree that the subset of patients who undergo endoscopic insertion of an endobronchial procedure are complex and may have multiple comorbidities such as severe underlying lung disease that impact the hospital length of stay.” They also found that, for cases reporting a procedure for endoscopic insertion of an endobronchial valve, the volume was generally low across MS-DRGs and that there is was a wide variation in the average length of stay and average costs. Based on their claims data analysis, CMS “does not support designating endoscopic insertion of an endobronchial valve as an O.R. procedure, nor do they support assignment of these procedures to MS-DRGs 163, 164, and 165 until additional analyses can be performed for this subset of patients as part of the comprehensive procedure code review.”

CMS notes that as they “begin the process of refining how procedure codes may be classified under ICD-10-PCS, including designation of a procedure as O.R. or non-O.R., they should take into consideration whether the procedure is driving resource use for the admission.”

STS agrees that these are surgical procedures. Patients who require endoscopic insertion of endobronchial valves tend to be sicker patients with significant lung disease. Although general thoracic surgeons are a subset of providers that provide these services, they almost always perform them in an O.R. STS acknowledges that other providers of these procedures may perform them outside of the O.R. for other reasons. Regardless of the location where the procedures are performed, they are typically done on an elective basis they are performed in sicker patients, nearly all of whom have significant lung disease. STS feels that it will be

important for CMS to flag these procedures for consideration in their review of the process by which the O.R. and Non-O.R. determinations are made for the ICD-10-PCS codes.

17. Proposed Changes to Surgical Hierarchies

CMS proposes to revise the surgical hierarchy for MDC 5 (Diseases and Disorders of the Circulatory System) to reflect changes to the newly proposed MS-DRGs. CMS is proposing that MS-DRGs 319-320 for *Other Endovascular Cardiac Valve Procedures with and without MCC* would be ranked below MS-DRGs 266-267 for *Endovascular Cardiac Valve Replacement and Supplement Procedures with and without MCC* and above MS-DRGs 222-227 for *Cardiac Defibrillator Implant procedures*. STS agrees with the proposed surgical hierarchy changes to the new MS-DRGs for MDC 5. The proposed hierarchy is representative of the clinical risk to patients.

H. Proposed Add-On Payments for New Services and Technologies for FY 2020

4. Proposed FY 2020 Status of Technologies Approved for FY 2019 New Technology Add-On Payments

j. Cerebral Protection System (Sentinel® Cerebral Protection System)

The Cerebral Protection System (Sentinel® Cerebral Protection System), which is identified by ICD-10-PCS code X2A5312 (Cerebral embolic filtration, dual filter in innominate artery and left common carotid artery, percutaneous approach) was granted De Novo status by the FDA on June 1, 2017. The device is indicated for use as an embolic protection (EP) device to capture and remove thrombus and debris while performing transcatheter aortic valve replacement (TAVR) procedures. The device is percutaneously delivered via the right radial artery and is removed upon completion of the TAVR procedure. CMS approved the device for a new technology add-on payment for FY 2019 (83 FR 41348). CMS is proposing to continue the new technology add-on payments for the Sentinel® Cerebral Protection System for FY 2020. STS agrees that the Cerebral Protection System (Sentinel® Cerebral Protection System) (ICD-10-PCS code X2A5312) should continue to receive the new technology add-on payments for FY 2020.

Thank you for the opportunity to provide these comments. Please contact Courtney Yohe, STS Director of Government Relations, at cyohe@sts.org or 202-787-1230 should you need additional information or clarification.

Sincerely,



Robert S.D. Higgins, MD
President