

The Society of Thoracic Surgeons

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Mr. Andy Slavitt Acting Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1631-FC, P.O. Box 8013 Baltimore, MD 21244-8013.

Re: Episode Groups

Dear Acting Administrator Slavitt,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Episode Groups. Founded in 1964, STS is an international not-for-profit organization representing more than 7,200 cardiothoracic surgeons, researchers, and allied health care professionals in 90 countries who are dedicated to ensuring the best surgical care for patients with diseases of the heart, lungs, and other organs in the chest. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

Thank you for the opportunity to provide feedback on these Episode Groups. The STS supports the concept that the use of measures for resource use based on episodes of care is more appropriate then the use of broad measures such as total per capita costs. However, the Centers for Medicare & Medicaid Services' (CMS) proposal for episode groups that will be used to measure resource utilization are new and untested. Therefore, more time is needed for practicing physicians and the professional organizations that represent them to review and provide necessary input to fine-tune the content of the episodes to ensure that they are representative of the care provided and resources utilized by the relevant specialties for each episode. The STS has reviewed two of the treatment episodes as well as the proposed methodology and process for episode group development and offers the following observations and concerns. The STS is willing to work with the Agency to further review and refine these episode groups and create appropriate attribution models that recognize the complex and multidisciplinary care that is often associated with the cardiothoracic patient population.

The STS National Database could be used to help refine the administrative claims based episode groups by utilizing clinical data to define episode group content. By linking the CMS administrative claims data with the clinical data from the STS National Database, the combination could be used to accurately identify clinical pathways for services, diagnoses and sequela for coronary artery bypass grafting (CABG) or valve-only procedures. In addition, clear risk corridors that should be considered within the episodes can be clarified and defined creating accurate resource utilization profiles. This will be

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extremely important if CMS uses a DRG based approach to resource utilization.

Patients presenting for open-heart surgery are increasingly complex with chronic medical conditions such as renal failure, respiratory failure and diabetes. These patients often utilize large amounts of health care resources before they even present for surgery. The concept, adoption and implementation of a heart team approach for patient safety and appropriate care utilization will be essential going forward. A coordinated health care team will be able to manage patients effectively with lower resource utilization. The STS strongly encourages CMS to include in its 30-day look-back window a mechanism by which a well-coordinated heart team can be reimbursed and the resource utilization correctly attributed.

In defining the process for episode development, diagnoses that are expected as a result of the procedure and need treatment are not a complication or a sequela. How do they fit in the model? Currently some are listed as relevant diagnoses and some are listed as sequela. Clear relationships of how they are relevant to the expected post procedural care versus complications that are directly related to the treatment episode need to be defined. For example, postoperative pain for which the surgeon would prescribe pain medication is expected and not a sequela or complication after heart surgery. Definitions and resource attribution of these anticipated costs for postoperative care should be clearly defined including a definition of a reasonable length of time for their occurrence and appropriate attribution to the prescribing physician. The STS strongly suggests that CMS work with the specialty societies to define expected occurrences versus sequela of an operation.

There needs to be clear rules and assignment to ensure that physician are only held accountable for resource utilization that they can control during the time period in which they are involved with the patient. While resource utilization can and should be attributable to physicians, costs associated with medical devices and the fees hospitals charge for particular services are not something physicians can control. As part of the bundled payment model and attribution of resource utilization, the STS strongly suggests that normalization of hospital and industry pricing should be considered. Regional analysis of cardiac surgery programs has demonstrated a large variability in the use of post-acute care. Metropolitan areas have a high use of home health while more rural centers utilize skilled nursing facilities (SNFs). If CMS uses a regional pricing methodology there will be an inordinate discrepancy in the way that post acute care delivery may occur. The STS strongly recommends that a delay in the regional pricing methodology be considered before full implementation as detailed in the proposal.

Episode Specific comments

The Society believes that simplification of the episodes for both valve surgery and CABG is essential. Currently, the episodes are too broad; they encompass resource utilization beyond the scope of typical care related to a treatment episode. For example with CABG, the clinical care pathways, preexisting and chronic condition episodes, risk corridors, related sequela and resource utilization will be significantly different for an elective CABG versus an acute CABG. Similarly, for the open valve surgery episode the clinical care pathways, preexisting and chronic condition episodes and resource utilization will be significantly different for an elective CABG versus and chronic condition episodes, risk corridors, related sequela and resource utilization will be significantly episode the clinical care pathways, preexisting and chronic condition episodes, risk corridors, related sequela and resource utilization will be significantly episode the clinical care pathways, preexisting and chronic condition episodes, risk corridors, related sequela and resource utilization will be significantly episode the clinical care pathways, preexisting and chronic condition episodes, risk corridors, related sequela and resource utilization will be significantly

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different for aortic valve disease and mitral valve disease and as such, these should not be grouped into a single treatment episode.

Patients often have multiple comorbidities that require care following CABG or valve surgery that is not directly related to the CABG or valve procedure. The need to have clear attribution methodology and clarity on open chronic episodes and treatment of patient comorbidities will be critical (e.g. relevant diagnoses and sequela). Care coordination for these patients is essential to treat their pre-existing conditions and appropriate attribution models will need to be created. Data that should be considered provide information on when cardiothoracic surgeons can make a difference to impact costs and care. Attribution models should incentivize appropriate care coordination. Careful considerations must be given to chronic conditions that have open episodes. These medical conditions and their treatment will continue throughout an episode of care for CABG or valve surgery. Attribution of the resources needed to continue care for these chronic conditions should not be relegated to the cardiac surgeon. We are very concerned that in doing so, appropriate care will not occur. The STS strongly suggests that there is a layered approach to the analysis of resource utilization for patients with open episodes involving chronic medical conditions.

Clear pathways on attribution for care and complications surrounding comorbidities and chronic disease need to be established so that pre, intra and post op services that are responsible for appropriate care associated with a treatment episode are attributed to the clinician responsible for these resources. For example, with CABG patients who have had an acute myocardial infarction and/or PTCA, they will have been out of the control of the cardiac surgeon in the 30-day look-back window. Additionally, valve patients who have been in acute and chronic congestive heart failure in the 30-day look-back window are typically managed by cardiologists, intensivists and pulmonologists and not by the cardiac surgeon. Even when the episode is triggered, and the patient goes to the operating room anesthesia is responsible for surgical airways and related complications. Throughout the pre, intra and postoperative period, cardiology is responsible for arrhythmias, heart failure and other issues surrounding the care of the patient's pre-existing condition. Intensivists are also heavily involved in the additive postoperative care of these complex patients where they provide additional treatment or order other tests to assess or treat postoperative conditions. Identifying the clinician who is responsible for ordering tests will be an important aspect of correctly assigning resource utilization.

Comments Related to Valve Surgery Episode

The STS feels that it is important to simplify the episode group for the valve population by initially focusing on patients with aortic stenosis and mitral regurgitation. The resource utilization for both of these patient populations is significantly different. Patients with aortic valve stenosis have higher incidence of heart block and will require more management utilizing pacemakers. Mitral regurgitation patients have a chronic condition of congestive heart failure requiring a different course of care and totally different resource utilization pre and post operatively. The episode groups should initially exclude patients with endocarditis, these patients have chronic infected heart valves that require prolonged preoperative and post operative antibiotics and careful monitoring, again utilizing a very different basket of resource utilization that does not exist in the elective patients (aortic stenosis and mitral regurgitation).

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Managing a patient with valvular heart disease in the 30 days leading up to surgery is complex and is usually not done by the cardiac surgeon because of the complexities of managing congestive heart failure.

Careful consideration of attribution must be addressed in these patients. Because of the existence of a chronic medical condition (open episode), the postoperative 90-day window will be very complicated and will have multiple clinicians managing their condition. Attribution of their chronic medical condition, which existed prior to surgery, will be complex and appropriate care coordination will be essential to ensuring the best care for Medicare beneficiaries. The STS recommends that two specific valve surgery episodes be created (one for aortic valve stenosis and the second for mitral valve regurgitation) in the first year and layer increased patient complexity over the remaining two years to include patients with more complex valve disease requiring different resource utilization in the remaining two years.

Comments Related to CABG Episode

Coronary artery bypass grafting is a very complex procedure because of the acuity and chronicity of patients presenting for CABG. Acute myocardial infarction (AMI) and the need for percutaneous intervention (PTCA and PCI) require enormous resource utilization, not attributable to the cardiac surgeon in the 30-day look-back window. The STS strongly recommends that in the initial phase of the episode groups for CABG the focus should be on elective CABG in the first year and layer patient complexity in the remaining two years to include AMI and PTCA in the DRG based system.

Specific Comments on Episode Methodology:

Trigger Codes

- Add-on codes, obsolete and/or deleted CPT codes should not be included as trigger codes. Episodes should not be started based on incorrect coding.
- CPT, ICD-9 procedural and DRG codes should initially focus only on the treatment episode (e.g., CABG) and not bring in multiple interventions initially (e.g. CABG with PCI or CABG w/ cardiac catheterization) due to the complicated nature of the patients and the multidisciplinary care associated with them. It is essential that clear pathways for attribution are defined before bringing in too many mixed care identifiers.

Relevant Services

- The process for identifying relevant services should review where the chronic and the acute episodes overlap and identify where resource utilization belongs (example cardiac catheterizations, contrast materials) for chronic coronary artery disease (CAD).
- For some of the imaging and supplies that are included in the relevant services list, they are related more to the management of the patient as opposed to the actual CABG or valve procedure at some point a patient may need a CABG to successfully manage the CAD, but the tools necessary to effectively manage the patient leading up to the surgical intervention are the cardiac catheterizations, with contrast and related supplies. Although

the patient may have received contrast material at some point in the past, the need for material was not related to CABG, it was related to management of the patient (example A4644) and the costs should not be attributed to the cardiac surgeon.

• For attribution of resources, the need to consider the ordering physicians in the list of relevant services will be important. The cardiothoracic surgeons should not be held accountable for services that they did not order. For example, for patients with CAD, many cardiac catheterizations may be done in management of the chronic disease but the patient usually presents to the cardiothoracic surgeon with catheterization, and unless the surgeon orders it, the resource utilization should not be attributed to the surgeon.

Relevant diagnoses

- There seems to be no harmonization between relevant diagnoses and sequela. Open chronic conditions have a large amount of relevance to cardiothoracic surgeons. Identifying those diagnoses that should be included as sequela versus relevant diagnoses is important to patient care and should never interfere with appropriate care pathways. Patients with open chronic conditions are extremely complicated and their care should never be compromised.
- Resource utilization factors that are attributable to patient comorbidities and compliance versus those factors under the control of the physician should be recognized and accounted for within the models. Cardiothoracic surgeons have and will always be committed to ensuring appropriate and high quality care in the best way possible given their influence on the patient and their caregivers.
- Many postoperative comorbidities are managed by other clinicians rather than cardiothoracic surgeons. This can lead to additional testing out of the control of the cardiothoracic surgeon; resource utilization attribution is critical and needs to be well documented and appropriately assigned.
- Many of the relevant diagnoses are comorbidity related and should be considered open chronic episodes. The use of the STS National Database in the identification of clinical risk corridors could greatly enhance the ability of CMS to identify these open chronic condition episodes and take into account risk factors that are driving increased resource utilization.

Sequela

• The current ICD-9 administrative database does not allow accurate identification of significant and meaningful preoperative risk factors. For example, acute renal failure may be the result of a patient in cardiogenic shock who has just received intravenous contrast. Data from the STS National Databases show that one of the largest cost drivers in preoperative comorbidities is renal failure. Current administrative databases do not allow accurate identification of the resources needed to treat these patients. On the other hand, renal failure may also be a postoperative complication from CABG, although quite rare.

The STS strongly believes that leveraging the STS National Database could help further clarify this situation.

- To restate our position, for acute myocardial infarction, a clinical indication bringing a patient to the OR for CABG is not a sequela. In CMS' current methodology with the 30-day look-back window, the cost of the care and resource utilization would be attributed to the cardiac surgeon. Clearly this is an inappropriate attribution methodology.
- In valve surgery many times patients have chronic conditions concerning heart block. The STS suggests that a chronic condition based on inadequate claims data should never be attributed to the cardiac surgeon as a sequela event. A chronic condition such as this should be appropriately attributed to the managing clinician-typically a cardiologist. In the current model there is not enough granularity to establish correct attribution models. Perhaps, ICD-10 will allow for more clarity, but in the meantime, the Society is strongly opposed to the sole use of claims data to assess resource utilization due to the lack of clarity and the inadequacy in defining pre, intra and post operative sequela.

The Society has reviewed and provided comment within the Workbooks for the CABG and open valve surgery treatment episodes. These two workbooks are attached. Further review and refinement of the inputs to the episode groups will be needed, but the STS comments provide an overview of some of our observations and concerns related to the inputs for each of the worksheets within the episode groups focusing on the identification, trigger codes, relevant services, relevant diagnoses and sequela for each episode group. The Society has provided comments on codes that should be deleted along with supporting rationale and identifying inputs where expected postoperative care and conditions, attribution of resources, and chronic conditions will be important. The STS will be happy to review and discuss these comments and suggestions in more detail with representatives from CMS to facilitate the refinement and eventual finalization of these episode groups.

Thank you for considering our comments. Should you have any questions, please contact STS Director of Government Relations Courtney Yohe at 202-787-1222 or cyohe@sts.org.

Sincerely,

Joseph E. Bavaria, MD President