

January 31, 2019

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

**Re:** CMS-1694-P Fiscal Year 2020 Inpatient Prospective Payment Systems for Acute Care Hospitals – Coding and MS-DRG Classification for Extracorporeal Membrane Oxygenation (ECMO)

Dear Administrator Seema Verma,

The American Society of Transplantation is in support of the coalition of professional societies which is led by the Society for Thoracic Surgeons (STS) and Extracorporeal Life Support Organization (ELSO) in regard to a change in the CMS codes that significantly reduced DRG reimbursement for extracorporeal membrane oxygenation (ECMO), which became effective on October 1<sup>st</sup>, 2018.

It is the contention from the American Society for Transplantation (AST) that this change should be reconsidered. It is our understanding that the change was based on an assessment that ECMO placement commonly employs peripheral vascular access (rather than central access) and is therefore a simple procedure that should be reimbursed at a lower rate than previously established. However, the data and established practice in the cardiothoracic transplant community does not support this assessment. ECMO is a major procedure involving a large team of personnel, complex devices, extracorporeal circulation for days or weeks and is used when all other modes of treatment have failed, and death is imminent. The method of vascular access depends on clinical circumstances and is irrelevant for the purposes of reimbursement.

As such, while we believe that it is prudent and appropriate for CMS to separate reimbursement codes for peripheral vs. central access ECMO, we urge CMS to consider keeping reimbursement identical regardless of the method of vascular access, as was the case prior to October 1<sup>st</sup>, 2018. While separating the codes will allow for better tracking of charges for the four common combinations of ECMO in terms of type and method of access (veno-arterial vs. veno-venous / peripheral vs. central access), keeping reimbursement identical will more accurately reflect the complexity of the procedure performed, including the need for extensive personnel to administer and manage this care for these extremely sick patients.

### **Our Contention**

Cardiogenic shock is pragmatically defined as a state in which ineffective cardiac output caused by a primary cardiac disorder results in both clinical and biochemical manifestations of inadequate tissue perfusion. The clinical presentation is typically characterized by persistent

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hypotension unresponsive to volume replacement, medical therapies such as inotropic and/or pressor support, and is accompanied by clinical features of end-organ hypoperfusion requiring intervention with pharmacological or mechanical support. (Ref. 1) It is the leading cause of death after acute myocardial infarction.

Historically, ECMO has been widely employed for cardiogenic shock refractory to usual resuscitative techniques such as inotropes and/or intra-aortic balloon pumps and is particularly effective for patients with reversible etiologies of shock. ECMO therapy can stabilize and improve renal, hepatic, and pulmonary functions, and be used as a bridge for patients to durable MCS or transplantation.

Importantly, ECMO may also be used after cardiac transplantation for the treatment of primary graft dysfunction or severe rejection. Inotropic support is often inadequate and the use of an intra-aortic balloon pump (IABP) may be ineffective due to biventricular heart failure. In such patients, extracorporeal membrane oxygenation (ECMO) may be used as a bridge to recovery in heart transplant recipients with refractory cardiogenic shock. (Ref 2)

ECMO is also a treatment for severe pulmonary failure, Acute Respiratory Distress Syndrome (ARDS), when the lungs have failed and can no longer be improved with mechanical ventilation. Oxygenation is poor and at time carbon dioxide is elevated and inhibits good oxygenation. Both of these states cause hypoperfusion of other organs and can cause multi-organ failure as well. In this acute setting, veno-venous ECMO can often be used, especially during the flu season and for those who are extremely ill with pneumonia or asthma, as a bridge to lung transplantation or for treatment of lung transplant rejection or lung failure unresponsive to medical therapy.

We urge CMS to review data available through the ELSO Registry, which includes outcomes for 5500 cases of ECMO in adults in the United States each year. This registry data demonstrates that peripheral access is used in 89% of cases, with acceptable outcomes for patients with this level of acuity. It is important to note that hospital length of stay, including ICU length of stay, is not notably different in patients who receive ECMO via peripheral versus central access. When appropriate, peripheral access is preferable as it allows for better rehabilitation improvement while on ECMO. Some patients who require ECMO may be able to ambulate with assistance. This is especially true with veno-venous ECMO placement. The ability to ambulate while on ECMO, prevents patients from becoming debilitated and prevents bed sores.

ECMO is an essential tool to improve survival in these critically ill patients. The reduced reimbursement currently in place will potentially reduce access to this important therapy for many patients, as the procedure will be unaffordable to most centers, as the cost of equipment and personnel will exceed reimbursement.

The AST represents the cardiothoracic transplant community in the United States and we believe our position on the use of ECMO, both centrally and peripherally placed, in pre and post-transplant patients in cardiogenic shock reflects best care therapy and should be appropriately reimbursed by CMS. We look forward to your response.

Sincerely,



Dianne B. McKay MD  
President

Cc: Jonathan Haft, ELSO ([haft@med.umich.edu](mailto:haft@med.umich.edu))

References:

1. Van Diepen et al. Contemporary Management of Cardiogenic Shock: A Scientific Statement from the American Heart Association. *Circulation*. 2017;136:e232–e268.
2. Kittleson et al. Heart Transplant Recipients Supported With Extracorporeal Membrane Oxygenation: Outcomes From A Single-Center Experience. *J Heart Lung Transplant*. 2011 Nov;30(11):1250-6.
3. Gulack BC, Hirji SA, Hartwig MG. Bridge to lung transplantation and rescue post-transplant: the expanding role of extracorporealmembrane oxygenation. *J Thorac Dise*, 2014; 6(8): 1070-9.