May 12, 2021

Elizabeth Richter, Acting CMS Administrator
Centers for Medicare & Medicaid Services
Attention: C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-8016

Submitted electronically to National Coverage Analysis (NCA) Tracking Sheet for Transvenous (Catheter) Pulmonary Embolectomy (CAG-00457R) and elizabeth.richter@cms.hhs.gov

RE: "National Coverage Analysis (NCA) Tracking Sheet for Transvenous (Catheter) Pulmonary Embolectomy (CAG-00457R) - NCD 240.6"

Acting Administrator Richter:

The Society of Vascular Surgery (SVS) and the American Venous Forum (AVF) are two of the pre-eminent professional societies in the US, representing surgeons and other practitioners who provide vascular care to CMS recipients throughout the country. Our members regularly provide care for patients with pulmonary embolism as well as diseases in other vascular beds throughout the body.

The SVS and AVF appreciate the opportunity to submit comments to CMS on the National Coverage Analysis (NCA) Tracking Sheet for Transvenous (Catheter) Pulmonary Embolectomy (CAG-00457R) pertaining to NCD 240.6. As you are aware NCD 240.6 was authored nearly four decades ago and specifically denies coverage to pulmonary artery embolectomy declaring it to be experimental. While we believe that that guidance was appropriate when it was enacted, it is now woefully out of date and not consistent with either the standards of care or the scientific literature in 2021.

There are now several catheter based mechanical thrombectomy devices that are designed to remove clots from vessels and eliminate the need for thrombolytic drugs and subsequent ICU stays. For example the FlowTriever® system, which was designated by CMS as Category B (non-experimental/non-investigational) during the IDE clinical trial period, and was 510(k)-cleared by the FDA for the treatment of Pulmonary Embolism (PE) on July 27th 2018. By eliminating the need for infusion of thrombolytic agents, with their significant bleeding risks, or the significant morbidity of open surgical thrombectomy via a thoracotomy or sternotomy, these mechanical thrombectomy devices have provided a valuable tool for the management of acute pulmonary embolism.

Transvenous (Catheter) Pulmonary Embolectomy is now a well-established, lifesaving procedure that has been performed on thousands of Medicare beneficiaries. Therefore we believe that Pulmonary Embolectomy is at times reasonable and medically necessary for Medicare beneficiaries suffering from a Pulmonary Embolism. There is growing evidence that performing thrombectomy as front-line therapy, along with anticoagulation without the need for thrombolytic drugs and subsequent ICU stays, can save the healthcare system money and improve patient outcomes.[1]
In four separate clinical studies and one patient registry, Pulmonary Embolectomy was shown to be safe and effective in a broad cross-section of patients regardless of disease acuity or patient age.

- The FLARE study met both of its primary safety and effectiveness endpoints, showing large and rapid reduction in right heart strain, with no device related major adverse events in the 106 patients enrolled. Just two patients received thrombolytic drugs. The study also showed patients treated with FlowTriever® had much shorter ICU and overall length of stay compared to previously published studies in which thrombolytic drugs were used to treat PE.[2]

- In the EXTRACT-PE prospective, multicenter study, the Indigo aspiration system was associated with a significant reduction in the RV/LV ratio and a low major adverse event rate in the 119 PE patients enrolled. Intraprocedural thrombolytic drugs were avoided in 98.3% of patients.[3]

- Another clinical study showed that mechanical thrombectomy was a safe and effective treatment option for PE, which allows for rapid relief of RV strain without the use of thrombolytics.[4]

- In a multicenter retrospective analysis looking at high-risk PE patients, mechanical thrombectomy demonstrated that, in this group of patients, the procedure acutely improved hemodynamic parameters, had a low procedural failure rate, had a low therapeutic escalation rate, and a low mortality rate.[5]

- The FLASH Registry is a 500-patient prospective, multicenter, single-arm registry evaluating real world patient outcomes after treatment of PE with FlowTriever®. Interim data on the first 230 patients enrolled in FLASH showed, that unlike thrombolytic-based approaches which can take several hours to affect hemodynamics, the immediate impact of clot removal with FlowTriever® in a real-world PE patient population was shown to be safe and effective. By quickly removing the clot and avoiding the risk of bleeding associated with thrombolytic infusion, FlowTriever® enabled patients to minimize stay in critically needed ICU beds to a median duration of 0 days following intervention.[6] There were no deaths within 48 hours of treatment and the 30-day mortality was only 0.4%, which is considerably better than historical controls for any other therapy, including conservative and lytic approaches. FLASH represents the largest prospective hemodynamic study of any PE treatment ever undertaken and is the first major all-comers study of a purely mechanical thrombectomy approach to PE shown to remove thrombus and improve patient outcomes without increasing bleeding. In contrast, fibrinolytic therapy has been shown to increase the risk of major hemorrhage and stroke.[7]

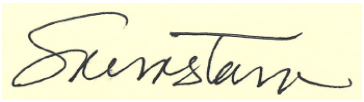
Therefore the SVS and AVF believe that NCD 240.6 should be immediately retired and removed from the CMS website, because the NCD is causing confusion about which devices, procedures, and codes are actually covered, and does not provide rationale or evidence to support the non-coverage.

Because of the current public health emergency, it is even more critical that this life saving technology be available, because mounting peer-reviewed literature has confirmed a link between COVID-19 and blood clotting disorders such as Pulmonary Embolisms (PE).[1]

Thank you again for this opportunity to request the retirement and removal of NCD 240.6 and reiterate the overwhelming evidence that Pulmonary Embolectomy is a safe and effective front-line treatment option for Medicare beneficiaries suffering from a Pulmonary Embolism.

Sincerely,

Mark Iafrati, MD
Chair, AVF Health Policy Committee



Sunita Srivastava, MD
Chair, SVS Coding and Reimbursement Committee

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