



May 13th, 2021

Ms. Elizabeth Richter, Acting CMS Administrator
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted via email to elizabeth.richter@cms.hhs.gov

RE: Request for Expedited Removal of National Coverage Determination (NCD) for Transvenous (Catheter) Pulmonary Embolectomy (240.6)

Dear Ms. Richter:

The Society of Interventional Radiology (SIR) is a nonprofit, professional medical society representing more than 8,000 practicing interventional radiology physicians, trainees, students, scientists and clinical associates, dedicated to improving patient care through the limitless potential of image-guided therapies.

SIR appreciates the opportunity to provide comments and requests the use of CMS' expedited national coverage determination (NCD) process to remove NCD 240.6. This policy (NCD 240.6) has not been reviewed or updated since 1987. In the original analysis of the policy, CMS indicated that the Transvenous (Catheter) Pulmonary Embolectomy procedure was experimental with little to no supporting evidence qualifying it medically necessary for coverage. However, over the last 30 years, there has been substantial evidence that proves the procedure as a concrete, medically necessary procedure to treat pulmonary embolism (PE).

Current Research supporting this procedure

Massive PE treated with anticoagulation alone leads to a greater than 50% mortality rate, which is clearly noteworthy. Percutaneous embolectomy, as opposed to systemic thrombolysis (10% rate of major bleeding and a 2% rate of catastrophic bleeding), has the potential to remove thrombus and improve patient outcomes without increasing bleeding.¹ Moreover, in patients who cannot receive fibrinolytic drugs due to the high risk of bleeding, percutaneous embolectomy is the only minimally-invasive option for patients who require rapid thrombus removal and cannot receive fibrinolytic drugs to avoid hemodynamic collapse.²

Catheter-directed therapy, including percutaneous embolectomy, has been widely reported in the literature with positive results. A meta-analysis of 594 patients with massive PE who received this therapy had an approximately 85% survival to discharge.³ A recent study found that percutaneous

thrombectomy followed by catheter-directed thrombolysis stabilized hemodynamics in 48/54 unstable (massive) PE patients.⁴

Currently, percutaneous pulmonary embolectomy is recognized, by the American Medical Association® (AMA), as a potentially life-saving procedure in patients with hemodynamic compromise and has an established procedural code (CPT® 37184). However, its appropriate use in patients is limited due to NCD 240.6 published in 1987.

NCD 240.6 – Transvenous (Catheter) Pulmonary Embolectomy

Transvenous (catheter) pulmonary embolectomy is a procedure for removing pulmonary emboli by passing a catheter through the femoral vein. It is not covered under Medicare because it is still experimental.

NCD Decision in 1987: Procedure is Not Covered, considered experimental

Source: NCD Manual (100-03)⁵

SIR recommends the removal of NCD 240.6 as it prevents access for patients with life-threatening PE to a well-established, lifesaving procedure with few other alternative options. We strongly recommend that CMS invokes the expedited process established in the August 7, 2013 Federal Register (78 FR 48164) to remove this NCD.

SIR appreciates the opportunity to provide feedback on this policy. If any additional information is required, please contact Keith M. Hume, SIR Executive Director at khume@sirweb.org.

Sincerely,



Matthew S. Johnson, MD, FSIR
President, Society of Interventional Radiology



Keith M. Hume
Executive Director, Society of Interventional Radiology

Cc: Dr. Lee Fleisher, Chief Medical Officer and Director of the Center for Clinical Standards
Tamara Syrek-Jenson, Director of Coverage and Analysis Group
JoAnna Baldwin, Acting Division Director
Lori Ashby, Deputy Director Policy and Evidence Review
Dr. Joseph Hutter, Lead Medical Director
David Dolan, Lead CMS Analyst

¹ Kucher N, Rossi E, De Rosa M, Goldhaber SZ. Massive pulmonary embolism. *Circulation*. 2006 Jan 31;113(4):577-82

²Moriarty JM, Edwards M, Plotnik AN. Intervention in massive pulmonary embolus: catheter thrombectomy/thromboaspiration versus systemic lysis versus surgical thrombectomy. *Semin Intervent Radiol*. 2018;35(2):108-115. doi:10.1055/s-0038-1642039

³Kuo WT, Gould MK, Louie JD. et al, Catheter-directed therapy for the treatment of massive pulmonary embolism: systematic review and meta-analysis of modern techniques. *J Vasc Interv Radiol*. 2009 Nov;20(11):1431-40. doi: 10.1016/j.jvir.2009.08.002.

⁴De Gregorio MA, Guirola JA, Kuo WT. et al, Catheter-directed aspiration thrombectomy and low-dose thrombolysis for patients with acute unstable pulmonary embolism: Prospective outcomes from a PE registry. *Int J Cardiol*. 2019 Jul 15; 287: 106-110. doi: 10.1016/j.ijcard.2019.02.061. Epub 2019 Feb 28.

⁵Center for Medicare and Medicaid Services (CMS). 2013. Medicare Program; Revised Process for Making National Coverage Determinations. (Expedited process). Retrieved from: <http://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf>