SCAI
Society for Cardiovascular Angiography & Interventions

July 9, 2019

Ms. Tamara Syrek Jensen, Director
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted via email to tamara.syrekjensen@cms.hhs.gov

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

Dear Ms. Jensen:

SCAI is a non-profit professional association with over 5,000 members representing the majority of practicing interventional cardiologists and cardiac catheterization teams in the United States including those with expertise in treating peripheral cardiovascular conditions such as deep vein thrombosis and pulmonary embolism that are commonly treated by catheter-based thrombectomy. SCAI promotes excellence in invasive and interventional cardiovascular medicine through education, representation and the advancement of quality standards to enhance patient care. For that reason, we have a strong interest in ensuring that Medicare coverage policy aligns with the current state of technology for cardiovascular medicine.

It has recently been brought to our attention that there exists a very old, outdated National Coverage Determination (NCD) for Transvenous (Catheter) Pulmonary Embolectomy (240.6) that is causing confusion among physicians, hospitals, and patients. We have great concern that this NCD is impeding access to potentially life-savings procedures for Medicare beneficiaries.

SCAI formally requests that CMS initiate the expedited removal process for the NCD for Transvenous (Catheter) Pulmonary Embolectomy (240.6).

In researching, the first reference we can find to NCD 240.6 is in an old Coverage Issues Manual dating back more than three decades ago to 1983, citing non-coverage as it being "experimental". The NCD posted on the CMS Coverage web site does not have an effective date. The NCD does not provide any details about the procedure or devices and fails to cite any evidence supporting non-coverage.

The NCD provides the following limited information:

> Publication Number 100-3
> Manual Section Number 240.6
> Manual Section Title: Transvenous (Catheter) Pulmonary Embolectomy
> Version: 1
> Effective Date of this Version: This is a longstanding national coverage determination. The effective date of this version has not been posted
> Benefit Category: Physicians' Services
> Item/Service Description: Transvenous (catheter) pulmonary embolectomy is a procedure for removing pulmonary emboli by passing a catheter through the femoral vein.
> Indications and Limitations of Coverage: It is not covered under Medicare because it is still experimental.

While "transvenous (catheter) pulmonary embolectomy" may have been considered "experimental" in 1983, it is now the standard of care. Numerous national and international standards and guidelines support the routine therapeutic use of catheter-based pulmonary thrombectomy (embolectomy) for pulmonary embolism. (Note: Often the terms thrombectomy and embolectomy are used interchangeably.) One such example, is the American Heart Association (AHA), ***Management of Massive and Submassive Pulmonary Embolism, Iliofemoral Deep Vein Thrombosis, and Chronic Thromboembolic Pulmonary Hypertension*****.** A Scientific Statement from the AHA available online at https://www.ahajournals.org/doi/10.1161/cir.0b013e318214914f:

> **Catheter-Based Interventions**
> Percutaneous techniques to recanalize complete and partial occlusions in the pulmonary trunk or major pulmonary arteries are potentially life-saving in selected patients with massive or submassive PE.[153] Transcatheter procedures can be performed as an alternative to thrombolysis when there are contraindications or when emergency surgical thrombectomy is unavailable or contraindicated. Catheter interventions can also be performed when thrombolysis has failed to improve hemodynamics in the acute setting. Hybrid therapy that includes both catheter-based clot fragmentation and local thrombolysis is an emerging strategy. The goals of catheter-based therapy include (1) rapidly reducing pulmonary artery pressure, RV strain, and pulmonary vascular resistance (PVR); (2) increasing systemic perfusion; and (3) facilitating RV recovery.

While some providers interpret NCD 240.6 as inapplicable to the standard-of-care, catheter-based pulmonary thrombectomy, others have expressed concern that these lifesaving, well-established procedures may be subject to non-coverage under NCD 240.6.

While catheter-based pulmonary thrombectomy (embolectomy) procedures are performed from a transvenous approach, the actual thrombectomy procedure is performed in the pulmonary artery(ies) and is considered an arterial procedure not a venous procedure. It appears many may be interpreting NCD 240.6 as not being applicable to the standard-of-care, catheter-based pulmonary thrombectomy (embolectomy) for pulmonary embolus. Based on Medicare fee-for-service national claims data it would appear at least some are making a distinction between, venous thrombectomy and arterial thrombectomy - and they are performing, billing and being appropriately compensated for pulmonary arterial thrombectomy procedures performed for pulmonary embolism. Per the 2017 Medicare Fee-for-Service claims data found in the RUC database, pulmonary embolism is one of the top five diagnosis for the arterial thrombectomy code (CPT© code 37184).

While it is unclear as to what procedure this old NCD was meant to address, we are certain that this NCD has not been reviewed in over three decades. Also, we are not aware of any experimental "transvenous (catheter) pulmonary embolectomy" procedures. In fact, SCAI members routinely provide the standard-of-care transcatheter pulmonary thrombectomy arterial procedures.

We see no need nor benefit to the continued existence of NCD 240.6 and we see grave potential harm in blocking access to a well-established, lifesaving procedure. Accordingly, we respectfully request that CMS move as quickly as possible to remove this NCD as this procedure is clearly no longer experimental, using the expedited process established in the August 7, 2013 Federal Register (78 FR 48164). If SCAI can be of any assistance as CMS considers this issue, please do not hesitate to contact Mrs. Dawn R. Gray (Hopkins), Director of Reimbursement & Regulatory Affairs at (800) 253-4636, ext. 510 or dgray@scai.org.

Sincerely,

Ehtisham Mahmud, MD, FSCAI
SCAI President, 2019-2020

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