

# ICD-10 Coding Change Request for Intravascular Ultrasound Assisted Thrombolysis in the treatment of Venous Thromboembolism and Peripheral Arterial Occlusion

# Presenter

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# Additional Codes Needed for Intravascular Ultrasound Assisted Thrombolysis (USAT)

- USAT is an established treatment for Venous Thromboembolism (VTE) and Peripheral Arterial Occlusion (PAO).<sup>1-10</sup> It uses a unique catheter placed directly adjacent to thrombus, allowing localized treatment with a thrombolytic agent with uptake augmented by ultrasound pulses emitted from the catheter.
- The AHA's *Coding Clinic* specified a two-code solution. For example:
  - 6A750Z7 - Ultrasound therapy of other vessels, single
  - 3E06317 - Introduction of other thrombolytic into central artery, percutaneous approach
- We recommend CMS now establish unique ICD-10 PCS codes to describe intravascular ultrasound assisted thrombolysis.

# USAT Is Used for Treating Vascular Disease

- **Venous thromboembolism (VTE)**<sup>11</sup>, which presents as:
  - **Deep vein thrombosis (DVT)** – when a thrombus forms in a vein deep in the body, usually in the lower leg or pelvic veins
  - **Pulmonary embolism (PE)** – in the veins of the lung.
  - Over 80% of PEs originate from DVT.
- **Peripheral arterial occlusion (PAO)**<sup>12</sup> – thrombus fully or partially blocks a peripheral artery, often in an extremity.
  - PAO can lead to acute limb ischemia, leading to amputation or threatening life.
- While all three conditions share the same coding issues described in the previous slide, VTE is more common and the bulk of USAT interventions treat this disease entity.

# Thrombi and Treatments for VTE and PAO

- Anticoagulants are generally used for all VTE cases, but they do not remove an existing thrombus.<sup>12-14</sup>
- Thrombolytics are generally used to treat DVTs and submassive and/or massive PE.<sup>12</sup> They bind to fibrin threads and activate a chemical process that leads to local fibrinolysis.<sup>15</sup>
- PAOs require speedy and aggressive intervention to remove a thrombus<sup>12</sup>. Reliance on anticoagulants is usually inadequate. Thrombolytics can be effective in avoiding surgery<sup>13</sup>.
- But: thrombolytics pose risk of serious bleeding – minimizing the dose is desirable<sup>14</sup>

# Catheter-Directed Thrombolysis Can Minimize Required Dose of Thrombolytics

- Catheter-directed thrombolysis (CDT) can deliver drug to the thrombus locally, requiring much smaller doses than systemic delivery
- “Conventional” CDT relies on a catheter placed adjacent to the thrombus with multiple side holes through which thrombolytics are delivered
- “Pharmaco-mechanical” catheter directed therapy uses one of several highly specialized catheter-based systems that can assist in focused delivery of the lytic to promote dissolution of the thrombus
- USAT uses high-frequency, low-intensity ultrasound waves to loosen the fibrin of the thrombus while driving the lytic to binding sites within the thrombus

# Ultrasound Assisted Thrombolysis Uses the EKOS™ System

- EKOS includes a highly specialized catheter. It has many microscopic side holes and up to 30 ultrasound elements evenly spaced over the treatment zone. The ultrasound core emits ultrasonic pulses while the catheter releases the lytic agent through the side holes
- The acoustic pulse field unwinds and thins fibrin to expose receptor sites, while creating a pressure gradient that transports the lytic deeper into the clot than would otherwise be possible
- The interventionalist manages the procedure through a control unit, which generates and controls the delivery of radiofrequency energy to the ultrasound core while monitoring and regulating the temperature of the treatment zone

# General Approach In Using USAT

- Presence of thrombus confirmed by standard imaging technique. Patients maintained on anticoagulants as indicated
- USAT procedures performed in cardiac cath lab or angiography suite
- Catheter inserted with continuous hemodynamic and electrocardiogram monitoring
- Continuous infusion of lytic and intravascular delivery of ultrasound initiated simultaneously; patient transferred to ICU or intermediate care unit for completion of treatment
- Treatment continues for a number of hours, then catheter removed
  - In trials, treatment times ranged from 2 hours to 24 hours.
- Reference 3-5

# Investigational Results on EKOS Support Advantages Seen by Clinicians

- Speeds time to clot dissolution,<sup>6</sup> increases clot removal, and enhances clinical improvement compared to either conventional CDT or percutaneous thrombectomy.<sup>7,8</sup>
- Improves clearance of clots by comparison to conventional CDT<sup>7,9,10</sup>
  - This is in part attributable to 48% greater drug absorption within 1 hour, and 84% greater drug absorption within 2 hours<sup>15</sup>
- Lowers the risk of bleeding and other complications<sup>7,10</sup>
  - An animal study confirmed that the procedure dissolves clots without damaging vessels, valves or walls<sup>16</sup>
- Requires smaller doses of thrombolytics, minimizing risk of bleeding. The EKOS™ system reduces dosage requirements by as much as 68% compared to conventional CDT.<sup>15</sup> It requires up to four times less drug dosage than typically used in systemic delivery.<sup>4,5</sup>

# Current Coding

- AHA's *Coding Clinic* in 2014 provided guidance indicating the appropriate coding for USAT was a combination of two codes:
  - One from table 6A7, Extracorporeal or Systemic Therapies, Physiological Systems, Ultrasound Therapy; and
  - One from a code from table 3E0, Administration, Physiologic Systems and Anatomical Regions, Introduction
  - For example:
    - 6A750Z7 - Ultrasound therapy of other vessels, single
    - 3E06317 - Introduction of other thrombolytic into central artery, percutaneous approach
- This guidance was issued during the transition from ICD-9 to ICD-10, when coding revisions were temporarily suspended

# Limitations of Current Coding

- Table 6A7 mischaracterizes the action of ultrasound in this intravascular application. The codes on this table describe “Extracorporeal or Systemic Therapies.” Intravascular USAT is neither extracorporeal or systemic, and coders may not recognize use of codes from this table as appropriate
- USAT involves more than “administration” or “introduction” of a drug, so reliance on table 3E0 appears inadequate to describe the procedure
- Necessitating use of two codes risks incomplete coding
- We recommend CMS now establish unique ICD-10 PCS codes with sufficient granularity to describe intravascular ultrasound assisted thrombolysis

Questions?

*Thanks for your attention.*

# Appendix

# References

- 1) EKOS™ Peripheral Infusion System was first cleared by the FDA for “the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature” on July 22, 2004 ([K030637](#)).
- 2) EKOS™ EkoSonic Endovascular System™ was first cleared by the FDA for treatment of PE on May 21, 2014 (K140151).
- 3) Kucher, N., et al., “Randomized Controlled Trial of Ultrasound-Assisted Catheter-Directed Thrombolysis for Acute Intermediate-Risk Pulmonary Embolism,” *Circulation* 2014; 129(4): 479-486 (NCT01166997).
- 4) Piazza, G., et al., “A Prospective, Single-Arm, Multicenter Trial of Ultrasound-Facilitated, Low-Dose Fibrinolysis for Acute Massive and Submassive Pulmonary Embolism: The SEATTLE II Study,” *Journal of the American College of Cardiology: Cardiovascular Interventions* 2015; 8(10): 1382-92 (NCT01513759).
- 5) Tapson, V.F., et al., “A Randomized Trial of the Optimum Duration of Acoustic Pulse Thrombolysis Procedure in Acute Intermediate-Risk Pulmonary Embolism: The OPTALYSE PE Trial,” *Journal of the American College of Cardiology: Cardiovascular Interventions* 2018; 11(14): 1401-1410 (NCT02396758).
- 6) Schrijver, A.M., et al., “Dutch Randomized Trial Comparing Standard Catheter-Directed Thrombolysis Versus Ultrasound-Accelerated Thrombolysis for Arterial Thrombolytic Infrainguinal Disease (DUET),” *Journal of Endovascular Therapy* 2015; 22(1): 87-95.
- 7) Lin, P., et al., “Comparison of Percutaneous Ultrasound-Accelerated Thrombolysis versus Catheter-Directed Thrombolysis in Patients with Acute Massive Pulmonary Embolism,” *Vascular* 2009; 17(Supp. 3): S137-S147.
- 8) Lin, P., et al., “Catheter-Directed Thrombectomy and Thrombolysis for Symptomatic Lower-Extremity Deep Vein Thrombosis: Review of Current Interventional Treatment Strategies,” *Perspectives in Vascular Surgery and Endovascular Therapy* 2010; 22(3): 152–163.
- 9) Litzendorf, M., et al., “Ultrasound-Accelerated Thrombolysis Is Superior to Catheter-Directed Thrombolysis for the Treatment of Acute Limb Ischemia,” SVS 2011 Abstract RR20, *Journal of Vascular Surgery* 2011; 53 (6): 106S - 107S

# References, cont.

- 10) Parikh, S. et al., "Ultrasound-Accelerated Thrombolysis for Treatment of Deep Vein Thrombosis: Initial Clinical Experience," *Journal of Vascular and Interventional Radiology* 2008; 19(4): 521-528.
- 11) Blood Clots: A Serious but Preventable Medical Condition. <http://www.cdc.gov/ncbddd/dvt/documents/blood-clots-fact-sheet.pdf>. Updated May 4, 2016. Accessed May 6, 2016.
- 12) Gerhard-Herman MD, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2017 Mar 21;69(11):1465-1508.
- 13) Kearon C, et al. Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report. *Chest*. 2016 Feb;149(2):315-352.
- 14) Pulmonary Embolism Response Team (PERT) Consortium. Rivera-Lebron B, et al. Diagnosis, Treatment and Follow Up of Acute Pulmonary Embolism: Consensus Practice from the PERT Consortium. *Clin Appl Thromb Hemost*. 2019 Jan-Dec;25.
- 15) Francis, C.W., et al., "Ultrasound Accelerates Transport of Recombinant Tissue Plasminogen Activator into Clots," *Ultrasound in Medicine and Biology* 1995; 23(1): 419-424.
- 16) Soltani, A., et al., "Absence of Biological Damage from Prolonged Exposure to Intravascular Ultrasound: A Swine Model," *Ultrasonics* 2007; 46: 60–67