NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

Interventional procedure HTG10169 Percutaneous thrombectomy for intermediate-risk and high-risk acute pulmonary embolism

Final scope

1 Introduction

The procedure included in this NICE HealthTech evaluation is percutaneous thrombectomy for intermediate-risk and high-risk acute pulmonary embolism. Interventional procedures involve making an incision, a puncture or entry into a body cavity, or using ionising, electromagnetic or acoustic energy. NICE makes recommendations based on assessment of the efficacy and safety of new and significantly modified procedures, or established procedures if there is uncertainty about their efficacy or safety. In cases where an interventional procedure involves implanting or using a health technology, the recommendations will focus on the procedure itself rather than the specific technology used.

This assessment is a review of existing NICE interventional procedures guidance on percutaneous thrombectomy for intermediate-risk or high-risk pulmonary embolism. This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the Interventional procedures programme manual and the NICE HealthTech programme manual.

2 Summary of the procedure

An acute pulmonary (lung) embolism is a sudden blockage in an artery in the lungs. It is usually caused by a blood clot that has travelled to the lungs, typically from a deep vein in the leg. Treatment is usually determined by the severity of the pulmonary embolism. Blood-thinning drugs (anticoagulants) are given to most people with a pulmonary embolism at first. But people with a more severe pulmonary embolism (classed as intermediate or high risk) may need additional drugs to break up the clot (thrombolysis) or a procedure to remove the clot. In this minimally invasive procedure, a device is inserted through the skin (percutaneous) into a vein, usually in the groin. Imaging is used to guide the device to the artery in the lungs where the clot is located. The device then removes the blood clot (thrombectomy). The aim is to quickly remove the clot from the pulmonary artery to restore blood flow.

3 The condition

Acute pulmonary embolism is when a pulmonary artery is obstructed, usually by a blood clot formed in the veins which travels to the lungs, causing respiratory dysfunction. The most common cause of acute pulmonary embolism is deep vein thrombosis. Symptoms of an acute pulmonary embolism can vary depending on severity and location of obstruction. Some people may have no symptoms whereas others may have sudden or severe symptoms, or both. Common symptoms can include shortness of breath and chest pain. Severe obstructions can lead to cardiovascular collapse and death if not treated.

Acute pulmonary embolism has a wide range of clinical presentations. Risk assessment is required to determine prognosis and guide clinical decision-making. The European Society of Cardiology (ESC) guidelines for the diagnosis and management of acute pulmonary embolism (2019) classify pulmonary embolism according to severity and risk of early death. The ESC classification includes 4 categories:

- low risk: no right ventricular dysfunction, no serious comorbidity and the signs of pulmonary embolism are not severe.
- intermediate-low risk: clinical severity scores are raised in the absence or presence of right ventricular dysfunction and elevated troponin levels.
- intermediate-high risk: right ventricular dysfunction and elevated cardiac biomarkers indicating myocardial injury, without haemodynamic compromise.
- high risk: haemodynamic instability, defined as the presence of either cardiac arrest, sustained hypotension or shock.

Experts have noted that there are limitations with the ESC scoring system, such as right ventricular dysfunction is not necessary for pulmonary embolism to be considered intermediate-high risk. More recently (February 2026), the American Heart Association (AHA) published a classification system which provides more detailed risk categories, labelled as A to E, with subcategories B1 to B2, C1 to C3, D1 to D2 and E1 to E2. It includes respiratory parameters for clinical decision-making and identifies people at risk of cardiopulmonary failure. It is not clear if the ESC or AHA classification system is preferred in practice.

Venous thromboembolism (which comprises deep vein thrombosis and pulmonary embolism) is the third most common cardiovascular disease globally and has an overall annual incidence of 53 to 162 per 100,000 people (Konstantinides et al., 2020). The epidemiology of pulmonary embolism itself can be difficult to ascertain due to asymptomatic cases and incidental findings, but the annual incidence has been estimated to range from 39 to 115 per 100,000 people in epidemiological studies (Konstantinides et al., 2020). In England, 67,725 hospital episodes admissions for pulmonary embolism resulting in 34,755 admissions were reported in the 1 year period between 2024 to 2025 (Hospital Admitted Patient Care Activity, 2024 to 2025). Experts noted that pulmonary embolism is the third most common cause of cardiovascular mortality after myocardial infarction and stroke. In 2021,

pulmonary embolism was the underlying cause of death in 2,638 people in England and Wales (NICE CKS, 2023).

An estimated 30 to 50% of venous thromboembolism episodes do not have an identifiable risk factor (De Nisio et al., 2016). The remaining episodes are caused by factors that induce excessive blood clotting (hypercoagulability), slow flow of blood through the veins (venous stasis) or damage to the vascular wall, which increase the risk of venous thromboembolism.

Major risk factors for pulmonary embolism include:

- deep vein thrombosis (around 45 to 50% of people with a pulmonary embolism have deep vein thrombosis at the same time)
- recent surgery
- reduced mobility (including hospitalisation)
- previous venous thromboembolism
- active cancer
- antiphospholipid antibody syndrome
- lower limb trauma
- recent myocardial infarction
- increasing age
- pregnancy and postpartum (particularly 6 weeks postpartum)
- family history of venous thromboembolism.

Other risk factors include:

- combined oral contraception or hormone replacement therapy
- cigarette smoking
- long duration travel
- obesity
- blood clotting disorders.

4 Current practice

In the NHS, diagnosis and management of pulmonary embolism follows the NICE Venous thromboembolic diseases: diagnosis, management and thrombophilia testing guideline (NG158). The guideline states that a 2-level pulmonary embolism Wells score should be used to estimate the clinical probability of pulmonary embolism in those with a suspected pulmonary embolism. If the results suggest a pulmonary embolism is likely, a number of tests are recommended to confirm diagnosis. This can include D-dimer testing and CT pulmonary angiography. Once diagnosis is confirmed, pulmonary embolism can be classified according to severity and risk of early death as described in section 3. Risk classification, done by multidisciplinary teams (such as pulmonary embolism response teams), is used to guide clinical management.

First line treatment for acute pulmonary embolism is anticoagulation. Choice of anticoagulant agent depends on co-morbidities. Low-risk acute pulmonary embolisms are usually treated using anticoagulation alone, and invasive clinical intervention is not deemed clinically necessary in this group. For high-risk or intermediate-high-risk pulmonary embolism with haemodynamic deterioration, systemic thrombolysis may be used. Catheter-based therapies, including catheter-directed thrombolysis or percutaneous thrombectomy, may be used:

- if systemic thrombolysis is unsuitable or has failed to improve clinical outcomes
- if anticoagulation has failed to improve clinical outcomes

when someone has a high-risk pulmonary embolism and they cannot have surgery.

European society of vascular medicine guidelines on interventional treatment of venous thromboembolism states that catheter-based therapies should be considered in people with intermediate-high risk pulmonary embolism where clinical improvement within 24 hours of anticoagulation is insufficient and

people with a high-risk pulmonary embolism with contraindication to or failure of systemic thrombolysis.

Rarely, open embolectomy is performed when there is a thrombus in the heart (intra-cardiac) and pulmonary emboli at the same time in people with high-risk and intermediate-risk pulmonary embolism.

5 Unmet need

Percutaneous thrombectomy could offer an alternative treatment option for people who have contraindications to or increased risk of bleeding from systemic thrombolysis. It could also be beneficial when anticoagulation or thrombolysis has not successfully treated the pulmonary embolism, or could be considered alongside anticoagulation to reduce the risk of the condition getting worse. It could also improve or accelerate functional recovery of the person.

6 The procedure

Percutaneous thrombectomy is a minimally invasive procedure that may be used alone or in combination with other treatment options for acute pulmonary embolism. The aim of the procedure is to rapidly remove the obstruction and restore pulmonary circulation. This procedure is performed in a catheterisation laboratory (cath lab) lab by endovascular specialists; primarily interventional radiologists and interventional cardiologists who are trained in wire and catheter techniques in the pulmonary vasculature. The procedure is performed using local anaesthesia with or without sedation. A catheter or cannula is inserted percutaneously into a peripheral vein (usually a common femoral vein) and advanced through the right side of the heart into the pulmonary arteries under image guidance. Once the thrombus is located, it is removed by the thrombectomy device. There are several thrombectomy devices available with some variation in their mechanism of action. These include vacuum suction, aspiration with a syringe or pump, mechanical removal with a clot removal device, or a combination of methods. Some devices may fragment the thrombus before removal. Some of devices have

additional features, such as the ability to filter and separate aspirated blood from the thrombus and then return it to the patient, and the use of computer algorithms to automatically adjust the vacuum for aspiration.

6.1 Innovative aspects of the procedure

Percutaneous thrombectomy is a minimally invasive procedure. It requires only a small puncture to be made in the skin and utilises imaging to accurately locate the pulmonary embolism. The procedure could lead to faster improvement in symptoms compared to medicines as the procedure removes the clot rather than breaking it down. The procedure has the potential to reduce the time spent in hospital. This is in contrast with pulmonary embolism surgery, which requires large incisions to be made and long recovery times.

6.2 Current known use of the procedure

Use of the procedure in the NHS is currently limited. Approximately 30 hospitals currently offer the procedure in the UK, which means there is variation in access according to geographical location. In 2024 to 25, there were 135 ‘percutaneous transluminal embolectomy of pulmonary artery’ procedures performed in the NHS in England, of which 113 were the main procedure (L13.1) as reported by NHS Digital (Hospital Admitted Patient Care Activity, 2024 to 25).

7 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

7.1 Equality issues related to pulmonary embolism

Increasing age is a risk factor for incidence of, and mortality from, pulmonary embolism (NICE clinical knowledge summary on pulmonary embolism, 2023). Age is also a risk factor for complications following treatment using thrombolysis. People aged 75 and older are at increased risk of bleeding

complications, particularly intracranial haemorrhage, following treatment (NHS North Tees and Hartlepool NHS Foundation Trust, 2025).

Both pregnancy and the postpartum period give an increased risk for venous thromboembolism, particularly after caesarean section. Venous thromboembolism remains one of the main direct causes of maternal death in the UK. The confidential enquiry into maternal deaths and morbidity reported that thrombosis and thromboembolism remained the leading cause of maternal death in 2022 to 2024 in the UK, during pregnancy or up to six weeks after the end of pregnancy (MMBRRACE-UK, 2026). The rate of maternal mortality due to thrombosis and thromboembolism among black women is almost three times higher than the rate among white women (MMBRACE, 2025). In addition to the risk of venous thromboembolism, pregnancy is also a relative contraindication for thrombolysis.

The use of combined oral contraception or some types of hormone replacement therapy are risk factors for pulmonary embolism (NICE clinical knowledge summary on pulmonary embolism, 2023).

Immobility is a risk factor for developing venous thromboembolism. People with disabilities and conditions that limit their mobility could therefore be at increased risk of developing venous thromboembolism (NICE clinical knowledge summary on pulmonary embolism, 2023). People with pulmonary embolism are likely to be covered by the Equality Act if their condition is considered a disability because it has had a substantial adverse impact on normal day to day activities for over 12 months, or is likely to do so.

7.2 Equality issues relating to the procedure

The procedure is done at specialist centres with multidisciplinary teams to guide clinical management and clinicians trained to do the procedure. So access to the procedure is likely to depend on geographical location. Some people may need referral to a specialist centre, which can delay access to treatment.

8 Decision problem

The key objective for this evaluation is to assess the efficacy and safety of thrombectomy for high-risk and intermediate-risk pulmonary embolism to determine whether it works well enough and is safe enough for use in the NHS.

Table 1: Decision problem

Population	People with high-risk or intermediate-risk acute pulmonary embolism according to the ESC 2019 classification or the equivalent categories from the AHA 2026 classification. If the evidence allows the following subgroups may be considered: • People with a high-risk pulmonary embolism (or the equivalent categories from the AHA 2026 classification) • People with an intermediate-high-risk pulmonary embolism (or the equivalent categories from the AHA 2026 classification) • People with intermediate-low risk pulmonary embolism (or the equivalent categories from the AHA 2026 classification)
Intervention	Percutaneous thrombectomy using a catheter-based or cannula-based device • Mechanisms for clot removal may be considered separately depending on the available evidence • Evidence on the procedure as an adjunct to or following other treatment options may be considered separately depending on the available evidence
Key efficacy outcomes (may include but are not limited to)	• Right ventricular (RV) to left ventricular (LV) diameter ratio

	• Right ventricular function • Right ventricular systolic pressure • Pulmonary artery pressure • Modified Miller score • Cardiac index • CT obstruction index • Technical success • Clinical success • Procedure time • Use of thrombolytics • Oxygen saturation • Systolic blood pressure • Symptom burden • Recovery time • Length of hospital or intensive care unit stay • Functional outcomes (such as New York Heart Association classification) • Medium term outcomes (such as chronic thromboembolic pulmonary hypertension and post-pulmonary embolism impairment) • Quality of life • Ability to return to work • Survival
Key safety outcomes (may include but are not limited to)	• Mortality (device-related or all-cause mortality) • Vascular complications including access site complications, cardiac injury or pulmonary vasculature injury • Stroke • Bleeding • Procedure or device-related adverse events • Device failure

9 NICE team

Nancy Pursey (topic lead), Charlotte Pelekanou

Technical team

Corrina Purdue

Project team

Anthony Akobeng

Consultant clinical adviser

May 2026

Appendix A: Related evidence or guidance

Relevant registries and ongoing key trials

PEERLESS II: RCT of FlowTriever vs. anticoagulation alone in pulmonary embolism (NCT06055920). Study completion estimated July 2026.

Acute pulmonary embolism treatment with the AlphaVac multipurpose mechanical aspiration system and the AlphaReturn blood management system: evaluation of safety and effectiveness (APEX-Return) (NCT07280247). Study completion estimated November 2026.

Comparing two ways to remove blood clots from the lungs: how different catheter sizes affect heart recovery and patient outcomes in serious pulmonary embolism (ISRCTN12573451). Study completion estimated December 2026.

STRIKE-PE: A prospective multi-centre study of the Indigo Aspiration System seeking to evaluate the long-term safety and outcomes of treating pulmonary embolism (NCT04798261). Study completion estimated February 2028 (primary completion estimated December 2026)

Evaluating the efficacy, safety and long-term functional outcomes of percutaneous mechanical aspiration thrombectomy for treatment of acute pulmonary embolism using the AlphaVac multipurpose mechanical aspiration (MMA) F1885 system (RECOVER-AV) (NCT06697314). Study completion estimated June 2028.

Percutaneous embolectomy, ultrasound assisted thrombolysis or heparin for intermediate high risk pulmonary embolism (STRATIFY-II) (NCT06453876). Study completion estimated October 2029.

Registry of catheter intervention in pulmonary embolism (RiTEP) (NCT06348459). Study completion estimated December 2029.

Thrombectomy in High-Risk Pulmonary Embolism – Device versus thrombolysis Netherlands (TORPEDO-NL) (NCT06833827). Study completion estimated January 2029.

Cohort study on treatment outcomes of catheter-based therapy in patients with acute pulmonary embolism in Hong Kong (HK-PECT) (NCT07029841). Study completion estimated December 2030.

Cather directed therapy in intermediate risk pulmonary embolism patients (NCT05612854). Study completion expected December 2030.

Randomised controlled trail of high-risk pulmonary embolism comparing FlowTriever system vs. standard of care (PERSEVERE) (NCT06588634). Study completion expected August 2031.

Thrombectomy in pulmonary embolism (TiPE) registry

Related NICE guidance, standards or indicators

NICE interventional procedures guidance

- This guidance will update NICE interventional procedures guidance HTG207 on Percutaneous thrombectomy for intermediate-risk or high-risk pulmonary embolism (2023)
  (Recommendations: special arrangements for high-risk pulmonary embolism in people who cannot have other treatments; research only for people with intermediate-risk pulmonary embolism or people with high-risk pulmonary embolism who can have other treatments).
- NICE interventional procedures guidance 651 on Percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg (2019).
  (Recommendation: special arrangements for acute iliofemoral deep vein thrombosis, research only for distal deep vein thrombosis).
- NICE interventional procedures guidance 524 on Ultrasound-enhanced, catheter-directed thrombolysis for pulmonary embolism (2015)
  (Recommendation: special arrangements).

- NICE interventional procedures guidance 523 on Ultrasound-enhanced, catheter-directed thrombolysis for deep vein thrombosis (2015) (Recommendation: special arrangements).

NICE clinical guidelines

- NICE guideline 158 on Venous thromboembolic diseases: diagnosis, management and thrombophilia testing (2023).

- NICE guideline 89 on Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism (2019).

NICE technology appraisals

Technology appraisal guidance 341 on Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism (2015).

Technology appraisal guidance 327 on Dabigatran etexilate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism (2014).

Technology appraisal guidance 287 on Rivaroxaban for treating pulmonary embolism and preventing recurrent venous thromboembolism (2013).

Technology appraisal guidance 261 on Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism (2012).

Technology appraisal guidance 354 Edoxaban for treating and for preventing deep vein thrombosis and pulmonary embolism (2015)

NICE quality standards

Quality standard QS201 on Venous thromboembolism in adults (2021)

Other related documents

Non-NICE clinical guidelines

American College of Cardiology and American Heart Association Guideline for the evaluation and management of acute pulmonary embolism in adults (2026)

CIRCSE Standards of practice on endovascular treatment of acute pulmonary embolism (2026)

European Society of Cardiology Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (2019)

European Society of Vascular Medicine guidelines interventional treatment of venous thromboembolism (2025)

Clinical consensus statement on percutaneous treatment options for acute pulmonary embolism by the European Society of Cardiology Working Group on Pulmonary Circulation and Right Ventricular function and the European Association of Percutaneous Cardiovascular Interventions (2022)

SIGN Prevention and management of venous thromboembolism (2014)

British Thoracic Society Guideline for the outpatient management of pulmonary embolism (2018)

National policy documents

Getting it Right First Time Pulmonary embolism pathway (2023) Available online [accessed 27 February 2026]