

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Tenecteplase for treating acute ischaemic stroke [ID6306]

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of tenecteplase within its marketing authorisation for fibrinolytic treatment of acute ischaemic stroke.

Background

A stroke is a type of cerebrovascular disease that happens when the blood supply to part of the brain is cut off, or when there is bleeding in or around the brain. Transient ischaemic attack (or mini-stroke) is when stroke symptoms last for a short time and it is an indicator of future risk of strokes. Broadly, strokes are classified as either haemorrhagic or ischaemic. A haemorrhagic stroke occurs when a blood vessel in or around the brain ruptures causing blood to leak out.¹ An ischaemic stroke arises when there is a blockage in a blood vessel serving the brain caused by a blood clot (thrombus). Acute ischaemic stroke is characterised by the sudden loss of blood circulation to an area of the brain and a corresponding loss of neurological function. This may lead to symptoms such as numbness or weakness of the face, arm or leg on 1 side of the body, and often problems with speech and swallowing.

Each year over 100,000 people in United Kingdom have a stroke.² The prevalence rate of stroke and transient ischaemic attacks in 2021/2022 was 1.8% in England and 2.2% in Wales.³ [NICE guideline 128](#) estimates that ischaemic strokes account for over 85% of all strokes. Mortality statistics in England and Wales from 2018 indicate that approximately 31,202 people died from cerebrovascular diseases (including strokes).⁴

Treatment of acute ischaemic stroke aims to restore blood flow to the brain and includes thrombolysis with alteplase, which dissolves blood clots. If acute stroke is suspected, [NICE guideline 128](#) recommends brain imaging immediately to inform diagnosis and treatment options. Early initiation of treatment for ischaemic stroke is associated with improved functional outcomes. [NICE technology appraisal 264](#) recommends alteplase for treating acute ischaemic stroke in adults if:

- treatment is started as early as possible within 4.5 hours of onset of stroke symptoms, and
- intracranial haemorrhage has been excluded by appropriate imaging techniques.

The technology

Tenecteplase (Metalyse, Boehringer Ingelheim) does not have marketing authorisation for fibrinolytic treatment of acute ischaemic stroke. It has been studied in clinical trials where tenecteplase is compared with alteplase in people aged 18 years and over with acute ischaemic stroke. An inclusion criterion in these trials is that treatment should be offered within 4.5 hours of stroke onset.

Tenecteplase currently has marketing authorisation in the UK for the thrombolytic treatment of suspected myocardial infarction with persistent ST elevation or recent left Bundle Branch Block within 6 hours after the onset of acute myocardial infarction symptoms.

Intervention(s)	Tenecteplase
Population(s)	People with acute ischaemic stroke who can have fibrinolytic treatment
Subgroups	If the evidence allows the following subgroup will be considered: <ul style="list-style-type: none"> subgroups by time to treatment (0 to 3 hours and 3 to 4.5 hours)
Comparators	Established clinical management without tenecteplase including: <ul style="list-style-type: none"> alteplase
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none"> disability or change in daily activities status functional recovery neurological deficit mortality length of hospital stay adverse effects of treatment, including bleeding events health-related quality of life
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>

<p>Other considerations</p>	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<p>Related NICE recommendations</p>	<p>Related technology appraisals:</p> <p>Alteplase for treating acute ischaemic stroke (2012), NICE Technology appraisal guidance TA264</p> <p>Related NICE guidelines:</p> <p>Stroke and transient ischaemic attack in over 16s: diagnosis and initial management, Published: 01 May 2019, Last updated: 13 April 2022, NICE guideline NG128</p> <p>Stroke rehabilitation in adults, Published: 18 October 2023, NICE guideline NG236</p> <p>Stroke and TIA (2023) Clinical Knowledge Summaries</p> <p>Stroke rehabilitation in adults (2013) Clinical guideline CG162</p> <p>Related interventional procedures:</p> <p>Therapeutic hypothermia for acute ischaemic stroke (2019) NICE Interventional procedures guidance IPG647</p> <p>Mechanical clot retrieval for treating acute ischaemic stroke (2016) NICE Interventional procedures guidance IPG548</p> <p>Inducing and maintaining normothermia using temperature modulation devices to improve outcomes after stroke or subarachnoid haemorrhage (2021) NICE Interventional procedures guidance IPG701</p> <p>Extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults (2014) NICE Interventional procedures guidance IPG482</p> <p>Related quality standards:</p> <p>Stroke in adults (Published: 29 June 2010, Last updated: 12 April 2016) NICE Quality standard QS2</p>
<p>Related National Policy</p>	<p>National Stroke Service model May 2021 https://www.england.nhs.uk/wp-content/uploads/2021/05/stroke-service-model-may-2021.pdf</p> <p>National Stroke Clinical Guideline April 2023 https://www.strokeguideline.org/contents/</p> <p>National Stroke GIRFT report April 2022 https://gettingitrightfirsttime.co.uk/medical_specialties/stroke/</p> <p>NHS England (2019) The NHS long term plan</p>

	<p>NHS England. Service Specifications: Specialised Vascular Services (Adults). 170004/S</p> <p>NHS England. Clinical Commissioning Policy: Mechanical thrombectomy for acute ischaemic stroke (all ages). 170033P. March 2018</p> <p>NHS England. 2013/14 Standard Contract for Neurosciences: Specialised Neurology (Adult). D04/S/a.</p> <p>NHS Digital (2022) NHS Outcomes Framework England, March 2022 Annual Publication</p> <p>Department of Health and Social Care (2016) NHS outcomes framework 2016 to 2017</p> <p>NHS England (2023) Manual for prescribed specialist services (2023/2024)</p>
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References

1. Stroke Association, <https://www.stroke.org.uk/what-is-stroke/types-of-stroke> (Accessed October 2023)
2. What is the prevalence of stroke and TIA in the UK? [Stroke and TIA](#) (2023), Clinical Knowledge Summaries
3. [Quality and Outcomes Framework](#), 2021-22, NHS Digital
4. [Leading causes of death, UK, 2001 to 2018](#), Office for National Statistics (ONS), (Accessed October 2023)