

Tenecteplase for treating acute ischaemic stroke

Technology appraisal guidance

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www.nice.org.uk/guidance/ta990

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

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1 Recommendations

- 1.1 Tenecteplase is recommended, within its marketing authorisation, as an option for the thrombolytic treatment of an acute ischaemic stroke in adults:
- within 4.5 hours of the onset of stroke symptoms, and
 - when intracranial haemorrhage has been excluded.
- 1.2 Use the least expensive option of the available treatments (including tenecteplase and alteplase). Take account of administration costs, dosages, price per dose and commercial arrangements. If the least expensive option is unsuitable, people with the condition, their family or carers, and their healthcare professional should discuss the advantages and disadvantages of other treatments.

Why these recommendations were made

Standard care to break up blood clots or prevent new blood clots from forming (thrombolytic treatment) after an acute ischaemic stroke is alteplase. Once bleeding in the brain (intracranial haemorrhage) has been ruled out, thrombolytic treatment is started within 4.5 hours of the onset of stroke symptoms. Tenecteplase is an alternative to alteplase.

Based on clinical trial evidence, tenecteplase is at least as effective as alteplase for the thrombolytic treatment of an acute ischaemic stroke. The evidence includes preliminary results from a large ongoing UK trial and published results from completed trials.

A cost comparison of tenecteplase with alteplase suggests that it costs less. Administration, adverse-event and other resource-use costs are expected to be similar for the 2 treatments.

So, tenecteplase is recommended.

For all evidence, see the [committee papers](#). To see what NICE did for alteplase, see the [consideration of the evidence section in NICE's technology appraisal guidance on alteplase for treating acute ischaemic stroke](#).

2 Information about tenecteplase

Anticipated marketing authorisation indication

- 2.1 Tenecteplase (Metalyse, Boehringer Ingelheim) is indicated 'in adults for the thrombolytic treatment of acute ischaemic stroke (AIS) within 4.5 hours from last known well and after exclusion of intracranial haemorrhage'.

Dosage in the marketing authorisation

- 2.2 The dosage schedule is available in the [summary of product characteristics for tenecteplase](#).

Price

- 2.3 The list price of a 25 mg vial of tenecteplase is £602.70 (excluding VAT; company submission).
- 2.4 Costs may vary in different settings because of negotiated procurement discounts.

3 Implementation

- 3.1 Section 7 of the [National Institute for Health and Care Excellence \(Constitution and Functions\)](#) and the [Health and Social Care Information Centre \(Functions\) Regulations 2013](#) requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication. Because tenecteplase has been recommended through the [cost-comparison process](#), NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication.
- 3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance.
- 3.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has acute ischaemic stroke and the healthcare professional responsible for their care thinks that tenecteplase is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by the lead team of the [highly specialised technologies evaluation committee](#), which includes the chair and vice chair.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

Chair

Paul Arundel

Chair, highly specialised technologies evaluation committee

Iolo Doull

Vice Chair, highly specialised technologies evaluation committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser and a project manager.

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