NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Tenecteplase for treating acute ischaemic stroke

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 committee discussion sections 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 confidential and cannot be reported here.

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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