

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Ticagrelor for the treatment of acute coronary syndrome

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you
Your name: DICK CURZEN
Name of your organisation SOUTHAMPTON UNIVERSITY HOSPITALS NHS TRUST
Are you (tick all that apply):
<input checked="" type="checkbox"/> a specialist in the treatment of people with the condition for which NICE is considering this technology?
<input checked="" type="checkbox"/> a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?
<input type="checkbox"/> an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology?
<input checked="" type="checkbox"/> If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc.)?
<input type="checkbox"/> other? (please specify)

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What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

Standard therapy involves aspirin + clopidogrel or prasugrel. There is heterogeneity across UK amongst clinicians regarding the default P2 Y₁₂ inhibitor at present. The attraction of ticagrelor is its apparent mortality reduction compared to clopidogrel. Ticagrelor would be initiated at the point of hospital admission and then continued in secondary care. Ticagrelor is not yet available clinically & there are no UK guidelines regarding its use.

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The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

Ticagrelor will be equivalent to use to clopidogrel or prasugrel.

The PLATO study provides fairly convincing evidence for clinical benefit of ticagrelor compared to clopidogrel in the setting of ACS in a randomised trial cohort. The clinical benefit unusually includes an absolute mortality reduction.

The headline from PLATO was that there was clinical benefit for ticagrelor compared to clopidogrel without a corresponding increase in bleeding.... reading the study carefully this is

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not really true... The non-CABG bleeding rates were higher in ticagrelor groups.

There have also to be some lingering doubts about dyspnoea side effects as well – these need careful thought because will be unpopular with patients & potentially sponsor a considerable amount of investigation.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

The FDA hearing about ticagrelor raised important additional data about aspirin dosage + other potential interactions.

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Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

The administration of ticagrelor would not require much additional resource.