Appendix G - professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism [ID726]

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: [redacted]
Name of your organisation: Clinical Leaders of Thrombosis

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology?

- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?

- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc)?

  Education Secretary, Clinical Leaders of Thrombosis

- 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.

At present, the main comparators to Apixaban are Low molecular weight heparin, warfarin and Rivaroxaban. Warfarin has the disadvantages of an unpredictable dose response and numerous drug and food interactions and requires frequent monitoring.

Apixaban would be particularly beneficial to those patients who find it difficult to attend regular monitoring visits. However, those patients who do not comply well would not be detected in the same way that they would be in a traditional warfarin clinic. IV drug abusers are a particular problem in this respect. This is of particular concern as the half-life of the drug is relatively short.

Apixaban could be used in both the Primary and Secondary care settings for DVT and PE treatment and secondary prevention. It would be advantageous if a specialist anticoagulant practitioner could initiate therapy in order to ensure that the patient has all of the necessary information about medicating safely and to assess their renal function and other health issues. In addition, it would also be an advantage if they could be seen at some point during therapy to ensure that they have no concerns and are complying with their medication and again before cessation of therapy to evaluate whether they are safe to stop.

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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?

Apixaban would to simpler to use than warfarin, as it does not require regular monitoring. However, input from an anticoagulation healthcare professional before initiation, during therapy and before cessation would be essential. Renal function should be checked prior to initiating therapy. Patients should be adequately counselled about safe use of the drug.

We have concerns that the categories of patient included in the AMPLIFY trial were not representative of a large percentage of the patients seen in current practice. Numerous patients present with hospital acquired thrombosis following surgery or medical treatments, many of whom require only 3 months anticoagulant therapy. These patients were excluded from the trial. In addition, many patients seen in routine anticoagulant clinics have underlying medical conditions such as cancer and again these patients were not included in the trials. Poor renal function was also an exclusion criterion which we feel limits the utility of the drug in normal patient populations. The outcomes for these cohorts of patients could be far less favourable than the results given in the trial.

We consider that the outcomes in the published trial data do look favourable as the decreased risk of major bleeding with Apixaban confers an advantage over conventional therapy.

A major concern is the lack of a valid antidote. It may be that major bleeding events are rare in the population under consideration but the inability to reverse the activity of the drug to stem a major haemorrhage rapidly puts Apixaban at a disadvantage to warfarin.

Laboratory monitoring tests for Apixaban are still not routinely available in most hospitals which means that an assessment of drug levels in the event of haemorrhage or to monitor non-compliance is not possible.

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.

No comments

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)?

Education and training for healthcare professionals in the correct initiation of therapy and patient counselling would be required. Anticoagulant clinic staff are ideally placed to take on this role and it is anticipated that no additional facilities and equipment would be required.

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Equality
NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could lead to recommendations that have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

No issues