Appendix G -Professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Apixaban for the prevention of stroke and systemic embolism in people with non-valvular atrial fibrillation

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: AntiCoagulation Europe
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)?**
  Project Development Manager
- other? (please specify)

Appendix G -Professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Apixaban for the prevention of stroke and systemic embolism in people with non-valvular atrial fibrillation

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.

This technology will be an alternative anticoagulant therapy for patients with Atrial Fibrillation.

It will complement the preferred treatment option of Warfarin which requires regular monitoring with patients undertaking blood tests in order to check if in the narrow window of therapeutic range.

It will provide an alternative treatment option to two new anticoagulants - Dabigatran and Rivaroxaban which now have NICE approval with guidelines in place for use in Atrial Fibrillation.

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?

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Apixaban for the prevention of stroke and systemic embolism in people with non-valvular atrial fibrillation

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 is an alternative treatment for AF patients who are at moderate to high risk of Stroke and systemic embolism. The treatment will also benefit warfarinised patients who are unable to stabilise their INR to meet the therapeutic range demands in place to prevent risk of clotting or bleeds. Without the need to monitor and consider dietary management as required by Warfarin; patients will benefit by avoiding the pain and discomfort of venous and pin prick testing which can affect veins and digits causing bruising.

Time spent on visits to the GP or a secondary care setting which can impact on the patient's general state of health and wellbeing will be greatly reduced.

In clinical trials (ARISTOTLE) Apixaban demonstrated superiority to Warfarin with a reduction in risk of stroke and embolism, major bleeding and mortality.

Apixaban is twice daily medication as is Dabigatran. Rivaroxaban is a once daily treatment which may be preferred by some patients. It is reported that Dabigatran may cause an increased risk of gastrointestinal bleeds. All treatments appear to reduce intracranial bleeds which is a positive outcome for patients with AF

There are no antidotes to rapidly reverse bleeds for all three new orals, however, we note that they have much shorter half lives than Warfarin which can be reversed.

The advantages of non- monitoring and limited drug and food interactions make Apixaban a viable option for AF suffers. Patients will need to be educated as to critical importance of taking drugs within the dosing recommended time frame.

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.

N/A

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)?

All healthcare professionals within primary and secondary care settings will need to undergo training on this technology*.*

A consistent approach to prescribing will need to be adopted by all the healthcare professionals involved in the care of AF patients. Patients who are diagnosed with AF and given Apixaban as the recommended therapy in a secondary care setting will need confirmation and reassurance that they can access the treatment when returning to primary care. Where ever possible, NICE guidelines should recommend continuity of treatment if deemed appropriate and effective for the patient's well-being.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Apixaban for the prevention of stroke and systemic embolism in people with non-valvular atrial fibrillation

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.

AF patients with mental impairments that affect their ability to make decisions relating to treatment options should not be denied or refused access to a treatment that could reduce their risk of stroke and systemic embolism. The outcome of such an event could impact greatly on the overall health and wellbeing of the individual and not withstanding, present as a further burden ofr cost to NHS services.

Healthcare professionals who are responsible for patient care should give due consideration to the benefits of the new treatments which provide enhanced protection against stroke in addition to reducing the stress, discomfort and management required by regular INR testing.