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Single technology appraisal (STA)

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

Please sign and return to:

Marcia Miller, Technology Appraisal Administrator
Email: TACommA@nice.org.uk

Fax: +44 (0)20 7061 9721
Post: NICE, MidCity Place, 71 High Holborn, London, WC1V 6NA

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name:
Jo Jerrome

Name of your organisation:

Atrial Fibrillation Association

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- a carer of a patient with the condition for which NICE is considering this technology?
- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc)

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Single technology appraisal (STA)

- other? (please specify)

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Single technology appraisal (STA)

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. **Advantages**

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

Trials suggest that apixaban will significantly reduce the risk of a stroke in patients with AF. Although in the past year, two new oral anticoagulants (NOAC) have received positive appraisal by NICE, there is still very limited therapy option for AF patients at risk of stroke, and apixaban would be a safe alternative for many AF patients assessed to be at risk.

For individuals, apixaban also offers far greater ease and safety than the most commonly prescribed therapy – warfarin. It is fast acting, has few interactions with food, drink or medication and usually well tolerated, with very few side-effects. This is a welcome alternative to warfarin and of huge benefit to the well being and quality of life of AF patients in need of OAC.

Trials have also shown it to be both more effective than the currently most used option – warfarin and very significantly safer and effective than aspirin.

Apixaban is an innovative technology that could result in potential, significant and substantial health-related benefits which may are not always easy to reflect in a QALY.

These include:
- Benefit to AF patients with mobility issues, to individuals with AF in care home settings and/or reliant on carers to manage their medication, to those currently not prescribed appropriate OAC which optimise their reduction in risk of stroke, who require a variety of medications all of which interact with the commonly used option, those who struggle to regularly remain within therapeutic levels (TTL), those who currently are inappropriately taking aspirin when an anticoagulant would be safer and much more effective.

Data on the challenges of anticoagulation in AF and the benefits of this therapy can be found in reports and papers including:
The AF Report, 2011
The Burden of AF Report 2009
AFA has also gathered anecdotal evidence via research based interviews, surveys and case accounts available via www.afa.org.uk

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology.

- Significantly reduced risk of stoke
- Reduced risk of a bleed due to falling outside of TTL

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Single technology appraisal (STA)

- Less negative interaction with daily activities, medications and food items
- Reduced need to visit surgeries for INR tests
- Simpler medicine management – set dose
- Reduced anxiety and worry regarding effectiveness of medication
- Reduced scaring through repeated blood tests
- Improved home and work life balance from fewer medical appointments and ease of managing the drug
- Less worry when travelling / attending social events
- Reassurance for close family members and carers

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)

2. **Disadvantages**
Please list any problems with or concerns you have about the technology. Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse.
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

None that I am aware of.

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

None that I am aware of.

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

Those who would benefit more:

- Those with poor TTL
- Those in care homes or reliant on close family members to manage their medication
- Those with families or who are employed and whose quality of life and choice options are negatively affected by regular testing / drug and food interaction from existing therapy
- Those who are unable to tolerate or who are contraindicated for other options
- Those who are currently given an antiplatelet therapy

Those who may benefit less:

- Those who may be contraindicated for this therapy

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Single technology appraisal (STA)

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

Dabigatran
Rivaroxaban
Warfarin

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

- improvement in the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

Not all patients are suited to these options.
Trial evidence compares apixaban against aspirin and shows a significant benefit.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:

- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

None that I am aware of.

Research evidence on patient or carer views of the technology

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

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Single technology appraisal (STA)

I am not aware of this evidence since this therapy is currently not available in the UK.

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

None that I am aware of.

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

Living with Warfarin Report 2011

Availability of this technology to patients in the NHS

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

Safer protection for AF patients who have an increased risk of stroke
Almost immediate protection (within hours)
Reassurance that TTL would be constant
That interaction from other medications would cease
Far fewer medical appointments
Simple, regular dosage
Simplicity of administering dose

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

While there are alternatives available, they simply are not being prescribed or considered for the vast number of AF patients at increased risk of stroke, who are unable to well-manage or tolerate the most commonly used therapy – warfarin.

Almost 50% of patients who require OAC are still not receiving them, and frequently this is due to fear of using the most commonly prescribed one – warfarin.

AF patients, especially those over the age of 80, and so at very high risk of stroke, are being prescribed an antiplatelet which has been shown to increase risk of bleeds and be of little benefit in reducing the risk of a stroke. Apixaban has trial evidence to show the huge benefit it would be on this high risk group currently using aspirin.

Without NICE guidance, many AF patients will continue to remain at risk

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Single technology appraisal (STA)

Many due to the difficulty of remaining within TTL – so are at either increased risk of a bleed or a stroke
Many will continue to require close monitoring by a carer to administer medication
Far more medical appointments will be needed
AF patients will continue to suffer a preventable event stroke / death

Are there groups of patients that have difficulties using the technology?

Those who may have an allergy to the therapy or be contraindicated

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

This is the first anticoagulant treatment which shows extensive trial data for a significant improvement in safety and effectiveness against both warfarin and aspirin.

Minimal monitoring is required.

Use of this therapy would reduce:

i) the event of strokes,
ii) is likely to reduce the event of bleeds due to falling dangerously outside of TTL
iii) likely to reduce the negative impact on mental health and well being caused through fear and constant concern over what is eaten, drank, changed, from a flu jab to antibiotics, change in medication, glass of wine, portion of vegetables.

Life cannot be simple or risk free for tens of thousands of AF patients. Currently, the commonly used therapy – warfarin, can ultimately have a greater impact on an AF patient's life than the condition itself.

AF related strokes are more likely to be devastating and life-threatening. The cost of an AF stroke to the NHS is high (£12,000 in the first year for essential care alone); to the individual and their family, it changes life forever. At least three quarters of stroke events due to AF are preventable.

Apixaban has been shown to be very effective in significantly reducing this risk for AF patients. This technology will save lives and avoidable suffering. Furthermore, it will reduce the burden of anticoagulation on everyday life for an AF patient and those close to them. Patient outcomes are the key factor in care – trial data for this new technology suggests that patient outcomes will be improved, and in turn, costs the NHS would be reduced.

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