NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation

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: [redacted]

Name of your organisation: Atrial Fibrillation Association (AFA)

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)
- other? (please specify)

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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.

i) Increased reduction in risk of stroke.
ii) Increased protection from risk of a bleed.
iii) As this is a one dose per day, standard dose medication, increased compliancy in taking the medication.
iv) Improved quality of life as trials have not only shown the superiority of this oral anticoagulant, but also the lack of interaction with it from other medications and food/ drink, making it far easier to manage.
v) Reduce burden and worry on the family / carers who currently monitor and help with support to regular appointments required for current anticoagulation (warfarin).

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above.

- Safer therapy
- More effective medication
- Simple to use, especially as one dose per day
- Increased protection from stroke and bleeding
- Far fewer known side effects
- Enables a improved quality of life especially for those whose INR tests may have impacted on their: work / mobility restrictions / travel / costs

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:

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- 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).

I am not aware of disadvantages.

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

I am not aware of differences of opinion between patients and clinicians regarding the 'usefulness' of this new technology.

Accessing new technologies is an increasing problem for patients who may have been initiated on a new therapy by their Specialist clinician

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?

- Yes, those unable to tolerate the current option (warfarin)
- Those unable to attend regular INR clinics
- Those unable to home test INR
- Those in work for which regular testing is detrimental to their employment
- Those who are unable to manage changeable doses such as is required by the current anticoagulant
- Those requiring help in administering their medication
- Those who have a phobia of needles

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Comparing the technology with alternative available treatments or technologies

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

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

I am only aware of warfarin.

The treatment being reviewed could be considered as far superior, both in safety and efficacy and also in the improvement to quality of life outcomes for those using it and caring for someone requiring oral anticoagulants.

(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.)

Many advantages, in particular;
- the single, regulated dosage;
- no longer requiring regular blood tests
- reduced fear of being out of therapeutic range
- reassurance that you can enjoy travel, work and diet without fear of the impact this may have on your risk of stroke due to interaction with medication
- easier to administer in care home settings or for individuals taking a cocktail of medication and for whom it is very easy to become muddled as to which dose is required, when

(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.

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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.

No NHS trials that I am aware of

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.

None other than the international trials used for this (ROCKET AF)

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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?

Far easier to use medication with equal to better risks reduction for stroke
Far fewer medical appointments for INR testing
Fewer medical appointments for drug interaction
Less worry and negative impact on life style and quality of life
It is likely that more people would be able to benefit from anticoagulation and therefore have a reduced risk of stroke

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

A significant number of AF patients would remain at high risk of a stroke or a bleed. The impact of taking oral anticoagulants would continue to effect a person's work life, job opportunity, family life style.

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

Those unable to take blood thinning medication

Equality

Are there any issues that require special attention in light of the NICE's duties to have due regard to the need to eliminate unlawful discrimination and promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others?

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Other Issues

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

AF is the single greatest risk for stroke, yet currently the existing oral anticoagulant – warfarin, while being cheap, is significantly underused (estimated by DH that 50% of those who should take it are not prescribed it) and furthermore, of those who are taking it, only half are in therapeutic range at any one time – so only one quarter of the AF population who are at significant risk of stroke are suitably protected by oral anticoagulants.

The new technology – Rivaroxaban, offers equal, if not improved protection, is far easier to manage, prescribe and use alongside other medications and a balanaced diet. Its ease of use and single dosage is highly likely to mean that more people will not only be prescribed an anticoagulant, but also be protected by it ALL o they time they are taking the medication.