

**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: **Arrhythmia Alliance (A-A)**

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) – My position is the Head of Strategic Projects
- 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) Significant decrease in a patient's risk of stroke.
- ii) Better protection from the risk of a bleed.
- iii) Improved patient compliancy in taking the medication because of a single daily dose.
- iv) Improved quality of life – (a) the superiority of this medication (b) the lack of interaction with this oral anticoagulant and other medications, food and drink.
- v) Reduced burden to the patient's family/carer(s) who currently help monitor and support them with the regular appointments for managing 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 and more effective therapy
  - Simpler to use as only one dose per day
  - Greater protection from stroke and bleeding
  - Fewer known side effects
  - Improved quality of life especially for those whose INR tests may have impacted on their work, mobility, travel and costs associated with their ongoing care.

**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

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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 do not know of any disadvantages.

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

I do not know of any disparity between patients and clinicians over the 'usefulness' of this 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?

Those who may benefit more:

- Those unable to tolerate the current anti-coagulant (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.

Warfarin is the only alternative I am aware of.

The treatment being reviewed could be considered as greatly 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.)

There are many advantages, in particular;

- A single, regulated dosage
- A lack of regular blood tests
- Less fear of being out of therapeutic range
- Quality of life – recipients can enjoy travel, work and diet without fear of the impact this may have on their stroke risk due to interaction with medication
- Easier to manage in care home settings or for individuals taking multiple medications and for whom it is very easy to become muddled as to which dose is required and 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).

I am not aware of any disadvantages for patients.

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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 risk-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 affect a person's work life, job opportunity, family and lifestyle.

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?

**Other Issues**

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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 balanced 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.