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:
Anticoagulation Europe

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**) Project Development Manager and Patient Expert**
- 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.

1. **Reducing risk of stroke in patients based on global Rocket AF trial**. Comparator Warfarin needs regular monitoring to check INR levels(invasive venous/finger prick sampling) and can be difficult to stabilise due to interactions with foods and other medications. This oral technology is taken once daily, requires no monitoring and doesn't require restriction of certain foods like Warfarin. Beneficial especially for those at medium/ high risk

2. **Reduces Bleeding**. Lower risk of bleeding than Warfarin which requires patients to stay within a therapeutic range to prevent clotting or bleeding episodes. Perceived as 'safer less volatile than Warfarin ' by patients –less management required.Potential to reduce hospital admissions

3. **General well being**. AF patients need protection against clots – new technology will provide this treatment adequately and without the upheaval and lifestyle adjustments required by warfarin patients – attending clinics, time off work, possible reluctance or cessation of air travel and constant reminder of chronic condition. Reduction in the time spent by family and carers managing their lives to support patients requiring regular GP/ hospital appointments for blood tests and administering dosing changes to ensure patient stays within INR range. Less bruising and vein trauma from venous blood testing

(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.

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1. No monitoring required
2. Less time spent in A/C clinics in primary and secondary care – reduction in financial expenditure for travel, parking and refreshments/ carers time supporting patient
3. Isn't affected by foods and many other medications
4. One fixed dose a day – dispenses with the need to alter dosage to stay in INR range
5. Lesser risk of stroke and bleed
6. No blood tests required – less trauma to capillaries and veins
7. Helpful to those who are needle phobic
8. Could reduce psychological impact of managing chronic health condition(currently Warfarin monitoring highlights patient's condition – could lead to anxiety.
9. Self – management – empowers the patient, reassuring, and for newly diagnosed patients, 'buy in' to a new effective treatment less demanding than current Warfarin monitoring requirements

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

Disadvantages?
Non- reversible at present – no antidote
Existing patients will need to be re-educated/ reassured on how the drug works and the elimination of monitoring of INR
Half life – needs complete compliance to give maximum protection
If 'stable' on Warfarin, will HCPs recommend that existing patients remain on warfarin?

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

None that we are aware of

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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?

Benefit more

- Those who are warfarin intolerant
- Those who are needle phobic
- Vulnerable patients who need carers to manage dosing and monitoring
- Patients whose lives are greatly inconvenienced by regular INR monitoring- time off work, restricting travel, mental well being
- Those who won't consider warfarin, don't take their medication due to impact on lifestyle and patients that don't/won't attend anticoagulation clinics,
- - vulnerable and at risk.

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.

(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.)

- Oral medication – easy to take
- No monitoring required – dispenses with hospital and clinic visits.
- No known food interactions
- Reduction in potential bleeds
- Patient empowerment – psychologically assists with positive management of chronic condition

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)

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- side effects (for example nature or number of problems, how often, for how long, how severe).

Non - reversible at present?

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 knowledge – not yet available for prevention of AF

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

No knowledge – not yet available for prevention of AF

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.

General awareness – no referencing available

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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 were made available on the NHS?

- Effective option to existing treatments available especially those patients who are unable to take warfarin or antiplatelet therapy
- Timely – new anticoagulant, safer and effective treatment for new and existing patients
- Reductions of stroke for AF sufferers – those who may not benefit from surgical intervention and need to take manage their risk of having a stroke medically.
- An alternative treatment to Warfarin – a therapy that currently requires considerable monitoring and management – possible reduction of A/C clinics and cost benefit – reduction in financial burden to the patient/carer with clinic visits, transport, parking, and implications of balancing work expectations in light of the increased working age in the UK
- Reduce hospital admissions for bleeding and stroke events

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

- Patients diagnosed with AF will be at risk of a stroke and heightened risk of stroke/bleed if unable to stabilise on Warfarin.Patients unable to take Warfarin will be deprived of a technology that will keep them well and protect them against strokes
- Restrict opportunity to empower patients to manage their own condition independently of the need for constant intervention with HCPs
- Impact on NHS resources – hospitalisation and rehabilitation as risk of stroke in AF population increases with aging/growing population
- Carers would remain obligated to supporting patients by accompanying/arranging regular hospital/visits and managing patients medication to meet INR targets. The new technology will reduce this burden to the carer and lessen the patient's dependency on the carer for this condition

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

Those who may not be able to tolerate any blood thinning therapies.

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?

Not that we are aware of

Other Issues

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

After 50 years of only having one major anticoagulant available to prevent strokes in AF sufferers, we now have a new oral anticoagulant which has been subjected to extensive trials with the results indicating that this is an effective alternative to warfarin and is easy to administer and requires no monitoring or adherence to a therapeutic range.
Approx55% of AF diagnosed patients are not anticoagulated, leaving the remainder at risk. Warfarin therapy is inconsistently used in practice (due to management) and this is disadvantaging AF sufferers who are at a great risk of having a stroke. The new technology is simple to use and requires less intensive management by clinicians. No food interactions are reported and patients will be able to take a medicine that will not impose on their time or life style as warfarin currently does.

As an aging population and with the demands of working later in our lives – we need to consider all available options to help those affected by AF to manage their healthcare effectively and in a way, which lessens the need for clinical intervention.

Whilst the new technology may initially be seen to be more expensive than cheaper Warfarin, consideration should be given to the 'on costs' of monitoring and managing Warfarinised patients and the personal commitment and impact this has on patients living with a chronic condition.

To deny patients access to a potentially safer, more effective and less demanding management programme is detrimental to progression and development of new

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therapies which could have be substantially beneficially to a large cohort of AF sufferers