NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism

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:

Name of your organisation: AntiCoagulation Europe (ACE)

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.

Treatment of deep vein thrombosis.

This is an oral anticoagulant which can be administered immediately to a patient who presents with a DVT. Current practice recommends patients are initially treated with unfractionalised heparin or LMWH(by subcutaneous injection) followed by a vitamin K antagonist such as Warfarin. Some patients are unable to tolerate Warfarin and will have to continue with LMWH injectable options for a prescribed period of time. Some patients due to the cause of the DVT may need to remain on Wafarin indefinitely.

Subcutaneous injections can cause pain, discomfort and bruising to patients and in particular, can be difficult to administer to those patients who are needlephobic. Post discharge, a patient who is unwilling or unable to self- administer will need to be visited by a district nurse or involve carers, family and friends who will need to be trained in order to administer the treatment.

Subsequent follow-on treatment with Warfarin requires a patient to undergo regular blood tests to monitor the INR levels to ensure the patient stays in target range in order to prevent another clotting or a bleeding event. Patients need to make adjustments to their lifestyle as many foods and drugs interact with the Warfarin and it can take a considerable period of time for a patient to stabilise on this anticoagulant. The demands of attending anticoagulation clinics whether in primary or secondary care, having to adapt to new dietary requirements and the constant awareness of the importance of staying in range and dose adjusting can be stressful and impact on the physical and mental well-being of the person and, of any carers involved.

Rivaraxaban is a treatment option for medical patients who are undergoing treatment for disease or illness and may have a heightened risk of VTE due to a previous event or other defined risk factors. Avoiding another VTE is a priority for the clinicians and patients as the consequences of such an event can complicate treatment for the underlying condition and contribute to more serious health problems.

A DVT event in the lower limb can cause the patient to suffer pain, swelling and tenderness and they may be more prone to cramps and skin irritation. Impaired circulation can cause ulceration which will require clinical input. Recovering from a DVT can take time and as mobility can be affected, this can have a significant negative impact on the patient's quality of life in terms of work, travel and may limit future physical activity which could affect future health and well being

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When a PE forms in the lung – the patient will be in extreme pain and will require intensive nursing and monitoring by the clinicians as the condition could be fatal. Individuals become distressed and fearful of the risk of a PE; the likelihood of a subsequent or recurrent event can cause increased patient anxiety which can impact on their recovery and rehabilitation. People who experience a VTE are at a higher risk of another event and this does rise with age and when other risk factors present.

(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.

Short term

Can be given to the patient if diagnosed with a VTE - treatment can be commenced immediately – reassurance to patient.

Oral medicine as opposed to injection – less pain, discomfort and bruising

Benefit to needle phobic patients

Provides protection to medical patients who have experienced previous clotting event

Long term

Single drug approach – continuity and consistency in A/C treatment therapy
No requirements to monitor as required by Warfarin. No blood tests required to check INR results. No dietary adjustments required. Ability to resume normal activities without disruption of regular venous or pin prick blood tests – which can cause inconvenience and impact on patient if in employment or, carers, family and friends who may need to manage the clinic visits on patient's behalf.

Well being of patient – resume life with minimal disruption post event – quality of life restored

Continued protection in the defined 'at risk' period.

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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 noted.

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

None noted

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?

MORE…
Patients who have previously presented with a VTE

Patients who have been assessed as to being at medium or high risk of VTE due to a specific illness which may render the patient immobile for long periods of time

Individuals who are Warfarin intolerant and may not receive/be offered any pharmacological prophylaxis post discharge?

Patients who are needle phobic and can't tolerate injections of LMWH/UFH

Individuals that are resistant to taking Warfarin due to the demands of monitoring or inability to stabilise and require frequent dosing adjustments to reach TTR requirements.

Patients who are working and want to resume normal work patterns without having to negotiate time off to attend the A/C clinic – especially those who may not be office based or travel for their work abroad and therefore unable to attend clinics on designated days.

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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 existing treatments for this condition in the UK.

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

According to NICE guidelines 92 – on entry to hospital, patients who are assessed at being at medium or high risk of a VTE will be offered LMWH or Fondaprinux or unfractionated heparin(UFH)These are usually administered subcutaneously.

Patients who develop VTE are treated in the same way – with continuing A/C therapy being vitamin K antagonist such as Warfarin.

Rivaroxaban is an oral anticoagulant which does not require monitoring and starts to become effective after two hours of first treatment.

(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.)

The treatment will reduce the risk of recurrence of a VTE.

The medication is taken orally – can be administered in hospital and be continued post discharge.

The treatment is a single drug approach which will be more advantageous to the patient who will not have to undergo regular blood tests to check whether in therapeutic range and further, will not require the patient to make significant changes to dietary and lifestyle activities. At present, patients on Warfarin therapy have to be supported by a range of anticoagulant clinic services provided in primary and secondary care. The new treatment could reduce this requirement and therefore may reduce current anticoagulation clinic resources and their associated costs to the NHS

For patients who are Warfarin intolerant - this treatment is an acceptable alternative to injecting LMWH medications for long periods of time which can be distressing, painful and cause bruising to the patient. Some patients will be unable to self-administer and therefore will need support from community based nursing staff, carers and family members. This support may incur financial implications and a responsibility to the patient for those involved.

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(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 noted

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

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

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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.

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?

Availability for use

For symptomatic VTE events – oral treatment can be commenced at the earliest opportunity providing an adequate anticoagulant therapy to reduce further clotting episodes including PE which can have life threatening consequences.

Simple to administer – oral. Dispenses with the need for subcutaneous injections which can cause pain and suffering to the patients and may involve the support of community nursing staff and carers, if the patient is unable to self- administer.

Continuity of treatment – single drug approach – patients will no longer have to be 'weaned' onto dose adjusted Warfarin which requires patients to attend anticoagulation clinics for regular blood tests to assess if in therapeutic range to avoid further risk of clotting or bleeding. Some patients take considerable time to stabilise and keep within their TTR and may have to make considerable adjustments to diet and lifestyle. Reduction in resources required for provision of A/C services – cost benefit to NHS?

Patient compliance on discharge – patients more likely to keep to a treatment plan with a one dose oral anticoagulant as opposed to the need to make dose adjustments as required by Warfarin accompanied by the demanding monitoring requirements. The time and economic impact on the patient should also considered here.

As a preventative treatment to avoid recurrence of symptomatic VTE events for medical patients who are assessed as medium to high risk, this single drug approach would give protection to patients who are being treated for 'existing' conditions requiring periods of hospitalisation.

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Alternative patient friendly treatment as opposed to subcutaneous injections.

VTE can cause ongoing health problems such as Post Thrombotic Syndrome which can cause a significant negative impact on the general health and well- being of the individual and can affect the recovery and rehabilitation period as the patient will need continuing clinical support and monitoring to manage the symptomatic health issues that can occur over time.

Reassurance to the patient that their risk of a VTE will be reduced

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

Deprive patients presenting with DVT of an alternative effective and more convenient continuous therapy option to manage their condition without having to embark on a two drug treatment therapy – which will need more management, clinical monitoring, and compliance by the patient which could greatly affect the patient's quality of life.

Preventing patients who may have had previous VTE experiences from being given protection again another event whilst undergoing treatment for other illnesses or disease. Reducing further time spent in hospital.

Subjecting patients to a regime of injections and intensive a/c therapy with the added burden and anxiety of staying in TTR to avoid further clotting incidences or heightened risk of bleed

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

Not to our knowledge

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?

No

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Other Issues

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