Appendix G – Patient/carer organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the treatment of pulmonary embolism and the prevention of recurrent venous thromboembolism

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(ACE) Charity

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- **See below**
- 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 for AntiCoagulation Europe (P/T)**
- **Area contact for the charity**
- other? (please specify)
- **Individual who takes long term anticoagulants to prevent further DVT**
- **Parent of young adult who has suffered a PE and DVT and takes anticoagulants**
-

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the treatment of pulmonary embolism and the prevention of recurrent venous thromboembolism

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.

Pulmonary Embolism (PE)– a clot which can form in the lungs as a consequence of a break off from a clot(that has formed in a vein elsewhere and has entered the circulatory system.
A PE can be fatal and need to be treated quickly in order to reduce risk of a subsequent venous thromboembolic event. Individuals who recover from a PE may be impaired in terms of their day to day lives and need a significant period of time to recover and resume normal activities. Some individuals will need on going additional support and care.

The risk of recurrence of a VTE can increase after the first episode.

Advantages

Rivaroxaban can be administered to patients presenting with a PE in a secondary or primary setting from onset. By contrast to the current treatment regime,of subcutaneous heparin followed by a VKA; it is a continuous treatment being an oral single dose therapy. It does not require the patient to undergo regular blood tests to monitor International Normalised Ratio (INR) levels which indicate that patient is in therapeutic range reducing the risk of further clotting or a bleed. Current treatment VKA, warfarin is contra –indicated to many other drugs and can be a challenging treatment with patients with co-morbidities. It is dose adjusted and for some patients and carers, this can be difficult to manage if they cannot stabilise and stay within the recommended range despite having frequent testing.

Clinical trials has shown that it is non –inferior to the current treatments with the advantage of having a lower risk of a major bleed.

The increased risk of another VTE which may cause serious impairment or death is of considerable concern to many people and therefore, treatment and prevention by way of an efficient, effective and safe medicine is of the upmost priority with an eligible patient group.

Disadvantages

An observation is that as this drug has a short half life, patients who may have previously been prescribed warfarin will need to be to advised of the importance of regular and timely dosing to ensure maximum protection. Patient education into drug compliance should be robust and comprehensive for all people who are eligible for this treatment.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the treatment of pulmonary embolism and the prevention of recurrent venous thromboembolism

(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

A PE can cause chest pain, shortness of breath, anxiety, coughing up blood and feeling light head and dizzy. Once diagnosed, patients have to administer subcutaneous injections with assistance if necessary and these injections can be painful and cause irritation and bruising to the skin. Following this initial treatment, they then proceed to warfarin and undergo venous blood tests which can cause pain, bruising and trauma to the veins; regular pinprick sampling can also causing bruising to the digits.
Anxiety can occur when people have to wait for test results which may require them to adjust their doses of warfarin and, the more regular testing required, the impact on managing day to day activities such as schooling, work and travel can be demanding. Some individuals will rely on family, friends and carer to administer the injections followed by organising their on- going clinic appointments for blood tests. Diligence is required in dose adjustment and warfarin patients are reminded that warfarin is affected by diet with some food groups being eliminated or avoided in their diet.

Individuals who have to have dental treatments which can include routine hygiene need to advise the clinician of the recent INR prior to treatment being commenced. In the event of it being deemed too high – the appointment may be cancelled causing inconvenience to the patient(and the dentist)

Short term benefits
One drug therapy option – orally taken, no monitoring, with a reduced risk of major bleed. Reassurance and negates the need to embark on two drug regime with the heparin/warfarin option.

Long term benefits
As above with the benefit of being able to stay on the treatment, if suitable for a period of time which will reduce risk of further VTE events.
Importantly, with no monitoring required, individuals are not subjected to the regular blood tests and attendance at clinics which are a constant reminder that they may have a chronic health condition. They can take the medicine and once recuperated, return to the normality of their lives pre – event.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the treatment of pulmonary embolism and the prevention of recurrent venous thromboembolism

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 thier family (for example cost of travel needed to access the technology, or the cost of paying a carer)

As with all anticoagulants there is a risk of a bleed and patients and prescribers would advise patients of any abnormal symptoms they may experience. We understand research has been carried out in the Netherlands relating to antidote using prothrombin complex concentrate (PCC)

Rivaroxaban has a much shorter half- life than warfarin and therefore patients must be advised and educated into the importance of taking their medication regularly to maximise efficacy in preventing clots

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

Through patient feedback received via our helpline, patients are enquiring as to whether they are eligible for the new drugs as an alternative to warfarin.

Patients who are stable on warfarin and used to and reassured by monitoring may not initially see the new treatment as a benefit to them. Patients who may have been on warfarin on a past occasion, suffer another VTE and then are offered the new drug will need to be educated into how it works by contrast to warfarin in terms of lack of monitoring but short half - life demanding stricter compliance. This should not be too onerous for the patient.

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?

Unstable warfarin users – constantly out of TTR and needing regular dose adjustments
Needle phobic people(for heparin arm of treatment)
People who cannot stabilise on warfarin
Individuals who are unable to take warfarin
People living remotely and cannot get to clinics easily
Those who have co-morbidities and drug interactions may occur with warfarin

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the treatment of pulmonary embolism and the prevention of recurrent venous thromboembolism

Young people who are studying – less disruption to live and manage their condition without attending clinics
Those travelling for work and pleasure
Family and carers who need support others with dosing adjustments, dietary adjustments and arranging/taking person to the clinic

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.

As previously stated, the current treatment for the condition is a two stage approach. Heparin followed by VKA warfarin which requires regular monitoring. This drug negates the need for blood tests, is taken daily orally and does not need dose adjustments. The global EINSTEIN- PE study demonstrated efficacy to the current standard therapy and a significantly lower rate of major bleeds

In July 2012 - Rivaroxaban has been approved for the use in treatment of deep vein thrombosis and the prevention of recurrent DVT and PE

(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 of 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)

- Can be commenced in primary or secondary care.
- No subcutaneous injections required.
- One drug from the onset, short half time so effective quickly.
- Patients may not need to be hospitalised for long periods whilst waiting to achieve an INR reading which is in therapeutic range
- No monitoring required – time off work, inconvenience, financial implications of travelling and time spent managing clinic appointments
- Less contra- indications that warfarin
- No dietary implications
- Reduced risk of major bleed

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the treatment of pulmonary embolism and the prevention of recurrent venous thromboembolism

(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 other than re-educating patients who may have previous experience of taking warfarin and ensuring that they understand the importance of taking the drug regularly to maximise effectiveness

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.

N/A

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

N/A

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.

N/A

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?

One oral single dose solution which can be given to a patient when suspected or diagnosed of having a VTE. Negates current two stage approach which can be distressing to patients with injections followed by the demands of regular testing to check in therapeutic range.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the treatment of pulmonary embolism and the prevention of recurrent venous thromboembolism

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

Prevents patients from having the option of being treated with a medicine that has demonstrated that it is as effective as current standard of treatment with the advantage of lowering the risk of a major bleed. Prevention of a near fatal or fatal PE in the future

Can improve the health and well-being on the population and, help towards preventing further healthcare issues, cost and care if patients suffer from further VTE

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

Not to our knowledge

Equality
NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could lead to recommendations that have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impac

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

Continuity for patients who require long- term anticoagulant treatment and are eligible for this treatment.

Appendix G – Patient/carer organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the treatment of pulmonary embolism and the prevention of recurrent venous thromboembolism