NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Patient/carer expert statement (STA)

Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism

Thank you for agreeing to give us your views on this treatment that is being appraised by NICE and how it could be used in the NHS. Patients, carers and patient organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of receiving NHS care for the condition
- the experience of having specific treatments for the condition
- the outcomes of treatment that are important to patients or carers (which might differ from those measured in clinical studies, including health-related quality of life)
- preferences for different treatments and how they are given
- expectations about the risks and benefits of the treatment.

We have already asked your nominating organisation to provide an organisation's view. We are asking you to give your views as an individual whether you are:

- a patient
- a carer (who may be voicing views for a patient who is unable to) or
- somebody who works or volunteers for a patient organisation.

To help you give your views, we have provided a questionnaire. You do not have to answer every question — the questions are there as prompts to guide you. The response area will expand as you type. The length of your response should not normally exceed 10 pages.

1. About you

Your name: [redacted]
Name of your nominating organisation: AntiCoagulation Europe
Do you know if your nominating organisation has submitted a statement?

☐x Yes ☐ No

Do you wish to agree with your nominating organisation's statement?

x☐ Yes ☐ No

(We would encourage you to complete this form even if you agree with your nominating organisation's statement.)

Are you:

- a patient with the condition?

x☐ Yes ☐ No

- a carer of a patient with the condition?

☐ Yes ☐ No

- a patient organisation employee or volunteer?
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☐x Yes ☐ No

Do you have experience of the treatment being appraised?

☐ Yes ☐ No x

If you wrote the organisation submission and do not have anything to add, tick here ☐ (If you tick this box, the rest of this form will be deleted after submission.)

2. Living with the condition

What is your experience of living with the condition as a patient or carer?

I have a congenital antithrombin deficiency disorder that causes my blood to clot more than normal. In my teenage years, I developed a DVT in my leg and was told I would require life long anticoagulation therapy. At the time of diagnosis, my leg became red, swollen and extremely painful to touch. I was unable to walk on the leg and was hospitalised for a two week period. I was advised that I would be at risk of further DVT or pulmonary embolism in my lifetime and my chronic disorder would need careful clinical management during surgery. I was given compression stockings to wear to help with impairment to the circulation and swelling and told to restrain from playing sport (netball and hockey). I was advised not to have children…

The impact of the diagnosis at this time of my life was significant; it influenced educational decisions around moving away from the hospital that was managing my care and whilst knowing I had no option, I struggled with sitting in anticoagulation clinics for long periods of time being constantly reminded that I had a chronic health condition which required blood thinners for my lifetime. It was difficult to come to terms with and subsequently, I had to adjust to this new development and learn how to manage my health to reduce anxiety around potential risk of another VTE.

For the last 40 years plus, I have been taking warfarin, a VKA oral anticoagulant which requires regular monitoring to check that my blood levels are in range to prevent further clotting or a bleeding event. For 25 years, I attended secondary and primary care settings for my blood tests and this could have been as frequent as weekly visits to 6 weekly visits. After a bleeding event following a holiday, I embarked upon a self –testing regime using a handheld device which monitors INR levels using a pin –prick of blood. Depending on the readings, I am able to adjust my daily dosage, if necessary. I undertake this will the consent of my prescribing GP. I have several family members who are affected by this condition (including a child) and all take warfarin for this condition having suffered a range of DVT, PE and

One self-manages with the others combining self testing with testing at GP/hospital clinic as required. When my teenage son presented with a DVT and PE, I knew from my personal experience the impact and anxieties that he may encounter in coming to terms with heightened VTE risk and anticoagulation for life. He struggled with attending the AC clinic at the hospital and eventually was allowed to self test which he continues to do today. For any individual who has had a VTE event, the priority is to know that you have the most effective treatment available to help you manage your condition and prevent any future risk of pain, distress and anxiety which impacts on physical and mental well-being and I am pleased that there are now new oral treatments available for patients which have been clinically proven to be safe, effective and don't require regular monitoring for the treatment or prevention of VTE

3. Current practice in treating the condition

Which treatment outcomes are important to you? (That is, what would you like treatment to achieve?) Which of these are most important? If possible, please explain why.

Efficacy and safety – a treatment that can be given on diagnosis(suspected) from the onset and will treat and prevent recurrences of further clots protecting and reassuring patients, essential for those on short term and long term anticoagulation treatments for many conditions

Oral treatments which are easy to use (fixed dose) and do not require monitoring which can affect individuals who may be working, studying, caring for others and needing to factor the monitoring visits into their everyday lives.

No dietary interactions (as with warfarin) which can greatly impact on what people eat and can cause elimination of healthy food groups(vegtables/fruit) from diet

Less interactions with other medications that may be required for treating co-morbidities as with warfarin. This is especially of concern now due to the

aging process and need medication for other conditions. I research as much as possible to look for options which do not interact with warfarin.

What is your experience of currently available NHS care and of specific treatments? How acceptable are these treatments – which did you prefer and why?

Currently available

Low molecular weight heparin (LMWH) Injection needs patient to administer or intervention from healthcare professional or family/carer

Low molecular weight heparin (LMWH) administered by subcutaneous injection proceeded by warfarin for treatment and secondary prevention (as above) with regard to the LMWH. Warfarin needs regular monitoring either by attending anticoagulation clinics or using self –testing/management options. NICE has recently issued guidelines around the use of Coagulometers for monitoring INR levels for warfarin users. I am aware as warfarin taker and through my work with AntiCoagulation Europe, self –testing is not routinely offered to new or existing warfarinised patients across the UK with some patients who would like to be considered for self – monitoring being denied access to the test strips by their CCGs/ GPs even when purchasing their own devices.

Warfarin as prevention – given lifelong

Dabigatran – LMWH and then oral daily dose (NOAC)

Rivaroxaban – oral daily dose (NOAC)

4. What do you consider to be the advantages of the treatment being appraised?

Benefits of a treatment might include its effect on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health

- quality of life (such as lifestyle and work)
- other people (for example, family, friends and employers)
- ease of use (for example, tablets rather than injection)
- where the treatment has to be used (for example, at home rather than in hospital)
- any other issues not listed above

Please list the benefits that you expect to gain from using the treatment being appraised.

Treatment can be given on diagnosis or suspected in secondary or primary care setting

Fixed dosing – reduces confusion for people when having to change doses of warfarin to stay within therapeutic range

No monitoring required to check INR levels which greatly impacts and can cause disruption for individuals in terms of time, travel, cost and convenience.e.g. taking time off work for clinic visits, parking costs, finger prick or venous sampling(pain and anxiety) damage to veins and digits occurring. Attending clinics for INR monitoring are a constant reminder that an individual is 'unwell' and waiting for results and dose alterations can cause anxiety and concern coined The 'yellow book syndrome'

General Well – being, daily dose, return to normal everyday activities as quickly as possible

Please explain any advantages that you think this treatment has over other NHS treatments in England.

Twice daily treatment, no monitoring, proven efficacy and safety. Can be started immediately upon diagnosis of DVT or PE

If you know of any differences in opinion between you and other patients or carers about the benefits of the treatment being appraised, please tell us about them.

5. What do you consider to be the disadvantages of the treatment being appraised?

Disadvantages of a treatment might include:

- aspects of the condition that the treatment cannot help with or might make worse
- difficulties in taking or using the treatment (for example, injection rather than tablets)
- side effects (for example, type or number of problems, how often, for how long, how severe. Please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- where the treatment has to be used (for example, in hospital rather than at home)
- impact on others (for example, family, friends and employers)
- financial impact on the patient and/or their family (for example, the cost of travel to hospital or paying a carer)
- any other issues not listed above

Please list any concerns you have about current NHS treatments in England.

Access to NOACS are inconsistent across the UK with local CCG directives leaning towards prescribing warfarin and only considering a NOAC if patient cannot reach therapeutic time in range or cannot tolerate warfarin. Patients should be advised of all anticoagulant options available and have an informed discussion as to the most suitable for their clinical needs in addition to taking into account their personal preferences

Please list any concerns you have about the treatment being appraised.

None at this stage

If you know of any differences in opinion between you and other patients or carers about the disadvantages of the treatment being appraised, please tell us about them.

None known

Do you think some patients might benefit more from the treatment than others? If so, please describe them and explain why.

Patients who present with a VTE who would not want to undertake a course of LMWH injections and then have to be weaned onto either to warfarin or a NOAC.

Patients on warfarin who cannot maintain therapeutic range with INR levels

Individuals who would not want to make considerable adjustments to meet warfarin regimes such as attending for regular blood tests and changing dietary and lifestyle habits. Vitamin K containing foods influence warfarin's blood thinning effect.

Do you think some patients might benefit less from the treatment than others? If so, please describe them and explain why.

Some people may have had previous experience of warfarin treatment and therefore would consider warfarin unless they had experienced any adverse effects. They may also be concerned about the lack of monitoring required? Apixaban is twice daily. Antidotes are not yet available for any of the new oral anticoagulants.

6. Research evidence on patient or carer views of the treatment

Are you familiar with the published research literature for the treatment?

☐x Yes (from lay perspective) ☐ No

If you answered 'no', please skip the rest of section 7 and move on to section 8.

Please comment on whether your experience of using the treatment as part of routine NHS care reflects the experience of patients in the clinical trials.

No knowledge

Do you think the clinical trials have captured outcomes that are important to patients? Are you aware of any limitations in how the treatment has been assessed in clinical trials?

Safety and efficacy are important outcomes from the patient perspective. From clinical studies it appears that Apixaban is as effective as warfarin with less major bleeding with Apixaban compared to warfarin

Agnelli G et al. Oral Apixaban for the Treatment of Acute Venous Thromboembolism. N Engl J Med 2013, 369j:799 - 808

If the treatment being appraised is already available in the NHS, are there any side effects that were not apparent in the clinical trials but have emerged during routine NHS care?

Not to my personal knowledge. Aware of NICE guidelines for Apixaban for prevention of VTE in hip and knee surgery and for Atrial Fibrillation

Are you aware of any relevant research on patient or carer views of the condition or existing treatments?

☐ Yes ☐x No

If yes, please provide references to the relevant studies.

7. Equality

NICE is committed to promoting equality of opportunity and eliminating discrimination. Please let us know if you think that recommendations from this appraisal could have an adverse impact on any particular groups of people, who they are and why.

8. Other issues

Do you consider the treatment to be innovative?

☐ **Yes** ☐ No

If yes, please explain what makes it significantly different from other treatments for the condition.

LMWH/Warfarin v Apixaban no monitoring, fixed dose

Dabigatran requires LMWH before initiation with treatment

Is there anything else that you would like the Appraisal Committee to consider?

9. Key messages

In no more than 5 bullet points, please summarise the key messages of your submission.

- Efficacy and safety. Can provide an effective alternative anticoagulant therapy to other treatments available. Non inferior to warfarin with less bleeding outcomes
- No monitoring required
- Fixed dose
- No known food interactions and limited drug interactions