NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Patient/carer organisation submission (STA)

Edoxaban tosylate 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, and including health-related quality of life)
- the acceptability of different treatments and how they are given
- expectations about the risks and benefits of the treatment.

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 length of your response should not normally exceed 10 pages.

1. About you and your organisation

Your name: [redacted]

Name of your organisation: Thrombosis UK (formerly Lifeblood: The Thrombosis Charity)

Your position in the organisation: Medical Director

Brief description of the organisation: Thrombosis UK is a charity dedicated to raising awareness of venous thromboembolism, funding research into the causes, prevention and treatment of thrombosis and providing support and comfort to patients, relatives and carers of patients with thrombosis.

(For example: who funds the organisation? How many members does the organisation have?)

We are asking for your collective view as an organisation and will be asking patient experts for their individual input separately. If you have the condition, or care for someone with the condition, you may wish to complete a patient expert questionnaire to give your individual views as well.

2. Living with the condition

What is it like to live with the condition or what do carers experience when caring for someone with the condition?

Living with DVT/PE can have a profound impact on the patient, their family and/or carers. Depending on what treatment the patient is prescribed it can mean frequent trips to hospital or the GP surgery which can be very inconvenient, especially for those who are working.

3. Current practice in treating the condition

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

From our experience the patient would like the easiest, most effective and least intrusive form of treatment. The most important of these issues is invariably a treatment which has the least impact on their day-to-day lives. Many patients find frequent visits for blood tests extremely inconvenient,

especially patients with jobs or children. We have heard from patients who have lost their jobs because of having to take so much time off work.

What is your organisation's experience of currently available NHS care and of specific treatments for the condition? How acceptable are these treatments and which are preferred and why?

Thrombosis UK works directly with the NHS to improve patient care and also has Trustees who are doctors working in the NHS. New oral anticoagulants, where appropriate, are the preferred treatment for VTE as they cause the least negative impact on patient's lives. They also remove the need for bridging therapy with LMWH followed by warfarin and frequent INR testing which needs the patient to make frequent visits to hospital or their GP practice to have blood tests.

4. What do patients or carers 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 patients or carers expect to gain from using the treatment being appraised.

The benefits patients and their carers would expect to gain from using Edoxaban would be

- pain (not having to inject LNWH at the start of treatment),
- mental health (many patients experience high levels of anxiety associated with their condition and treatment),

- quality of life (many patients complain that the frequent need for hospital visits impacts detrimentally on their social and working lives),
- other people (for patients that need relatives or carers to help them to attend hospital or for those who need frequent times off work),
- ease of use (most patients find one or two tablets a day, every day, much easier than the inconvenience of injections or adjustment of medication according to INR levels – some patients never stabilise on warfarin).

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

Ease of use, less intrusion into day-to-day life, no (or very few) hospital visits or blood tests and lower levels of anxiety experiences with this.

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

None

5. What do patients and/or carers 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 patients or carers have about current NHS treatments in England.

Inconvenience of some current treatments such as warfarin. Fear associated with self-injection of LMWH.

Please list any concerns patients or carers have about the treatment being appraised.

None

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

No

6. Patient population

Are there any groups of patients who might benefit more from the treatment than others? If so, please describe them and explain why.

No

Are there any groups of patients who might benefit less from the treatment than others? If so, please describe them and explain why.

No

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

Is your organisation familiar with the published research literature for the treatment?

✓ Yes ☐ No

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

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

The patients we have spoken to in this regard have had a similar experience to those in trials

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?

Yes, we believe captured outcomes are important. We are not aware of any limitations in assessment.

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?

No

Are you aware of any relevant research on patient or carer views of the condition or existing treatments (for example, qualitative studies, surveys and polls)?

☐ Yes ✓ No

If yes, please provide references to the relevant studies.

n/a

8. Equality

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Protected characteristics are: age; being or becoming a transsexual person; being married or in a civil partnership; being pregnant or having a child; disability; race including colour, nationality, ethnic or national origin; religion, belief or lack of religion/belief; sex; sexual orientation.

Please let us know if you think that recommendations from this appraisal could have an adverse impact on any particular groups of people, such as:

- excluding from full consideration any people protected by the equality legislation who fall within the patient population for which the treatment is/will be licensed;

- having 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 treatment;
- any adverse impact on people with a particular disability or disabilities.

Please let us know if you think that there are any potential equality issues that should be considered in this appraisal.

None

Are there groups of patients who would have difficulties using the treatment or currently available treatments? Please tell us what evidence you think would help the Committee to identify and consider such impacts.

No

9. 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.

This therapy removes the need for frequent blood testing and dosage adjustment associated with warfarin therapy and daily self-injection associated with LMWH

Are there any other issues that you would like the Appraisal Committee to consider?

No

10. Key messages

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

- This medicine would impact positively on patient's day to day, social and working lives
- This medicine would have a positive impact on those patients who are unable to self-inject for a number of reasons including age, disability and fear

- This medicine has the potential to impact positively on community care costs
- This medicine has the potential to impact positively on out-patient hospital costs