NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Patient/carer organisation submission (STA)

Edoxaban tosylate for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation

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:

Name of your organisation: Arrhythmia Alliance

Your position in the organisation:

Brief description of the organisation: Arrhythmia Alliance (A-A) works with patients, carers, healthcare professionals and all parties interested and involved in arrhythmia care. The charity was first registered in the UK in 2004 and has now established Arrhythmia Alliance affiliates in many areas of the globe including South America, Australia, Russia, Italy and South Africa. While within the UK there are over 70 local patient A-A support groups. Funding is secured through a wide variety of activities the largest of which are: donations, fundraising, grants and trusts, educational grants and memberships

(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?

AF can range from ‘silent’ to being very symptomatic. Affecting over one million people in the UK, AF carries a significant stroke risk –resulting in over 15,000 AF-related strokes in the UK per year. Despite this, awareness and knowledge of AF is generally low, which means with AF can result in feeling very unwell, isolated, plagued by multiple symptoms as well as side-effects from therapies and a weighed down by a feeling of ‘premature ageing’

AF is complex with no one treatment suiting or appropriate for all. As a patient, there is suddenly the need to face personal risks – of increased stroke risk, Heart Failure, dementia and premature death.

Understanding and accessing the most appropriate clinician is often not easy and can take years. An AF survey carried out in 2011 showed an average diagnosis time from first symptoms to diagnosis of two years and an average successful symptom-management time of four years from diagnosis.

Anticoagulation is not straightforward. Despite guidance, access to therapies is restricted and falls to a postcode lottery. Equally management of warfarin and INR again varies across areas with no consideration of what best suits and is needed by the patient. So while some patients will be tested in their local GP surgery and receive their INR level and change of dosage all at the same time, others – even if unwell or less able to hear and manage their medication, will be telephoned and need to record the dosage change as follow up letters take two-four days to arrive. Furthermore, those on VKA therapy may be asked to take different dosages over different t days of the week, and these cannot be 'dossetted' because of the frequent changes. Difficult to manage when well – but many AF patients have multiple conditions.

For VKA therapy, follow up test can often be 12 weeks apart, and yet it is widely known that food and drink as well as minor illness and changes in other medications, frequently effect INR levels, and so individuals are faced with always thinking about 'balance' – the same food, activity, routine, day in, day out. Life as they once enjoyed it, becomes increasingly restricted, because un-noted changes could too easily result in a bleed, stroke or death.

Accessing therapies that minimise risks, suit the individual's medical and quality of life needs and are easy to manage, can make the difference to enabling a person diagnosed with AF to continue to enjoy a full and active life. Having health-carers who talk through therapy options and provide information on how safely and appropriately to manage the agreed therapy reduces fear, uncertainty and error.

After diagnosis of AF, life changes, but management of the medications, symptoms and side effects can be a daily burden if joined up consideration for the individual's medical and 'life' needs are overlooked.

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.

No one treatment for AF-stroke prevention, suits all and so access to a therapy that reduces risk, maintains well being and enables quality of life for that person, is very important For the individual, side-effects, frequent changes, anxiety around drug interaction or risk and complications following other illness, diet, travel, regular testing and activity are all daily worries, and so a medication that reduces risk – both of bleeds and stroke as well as minimises potentially fatal complications which are beyond their control, is extremely important.

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?

Working closely with AF Association, A-A is aware that while anticoagulation rates for AF are increasing (QOF), NHS care around AF and AF-stroke prevention, is variable across the country. Access to some NICE approved anticoagulants is severely restricted in some areas or offered only as second line options in others.

Currently there is a wide a variety in how warfarin in managed – from point of care tests to attending hospital clinics, waiting for dose changes to be made via telephone and, for some, self-monitoring – although in some areas this is very difficult to access or to receive appropriate training and support.

In areas where risk, information and options are discussed with individuals, we have very positive feedback from patients and carers on their confidence to manage their treatment and feel both well cared for and protected from risk.

3. What do patients or carers consider to be the advantages of the treatment being appraised?

- One dose per day

- Therapy is easy to manage and there are few interactions with other medications of foods causing
- Few side-effects noted by those who have been involved in the trials
- Trials (ENGAGE AF) showed reduced major bleeding rates compared to warfarin
- ENGAGE-AF showed reduced number of AF-stroke events in those taking Edoxaban even when those on warfarin has average TTL at 68.4%)
- Deaths and events due to CVD appear lower in patients taking Edoxaban than in those taking warfarin
- Single dose with few side-effects or interactions enables quality of life to be maintained or restored. Travel, variety in diet and eating-out, taking other medication even when temporary eg anti-biotics is much easier and safer
- As a carer, it is much easier to manage one dose per day and a regular dose than multiple with frequent changes
- This medication can protect from AF-stroke, reduce risks associated with anticoagulation (bleeds) and reduce CVD events, while enabling commonly enjoyed everyday activities (travel, work, eating out) to continue without fear and issues

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.

- **Far less monitoring, this is especially beneficial to those who are:**
- **Needle-phobic**
- **In a care home or isolated area and find it difficult to travel for testing**
- **Are in work or care for someone making regular clinic appointments difficult to maintain**
- **Those who need to often travel**
- **Enjoy socialising and eat a range of foods which could interact with warfarin therapy causing TTL to vary**
- Those with multiple comorbidities who may struggle with TTL on a Vit K antagonist
- Those who are inappropriate for other factor Xa inhibitors due to renal or other health issues

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

- An alternative option which requires less monitoring
- Has good trial results (ENGAGE-AF TIMI) for reduction of AF-stroke and reduction of major bleeds
- Has been used in other disease areas with no major complications (VTE following orthopaedic surgery, approved in Japan 2011)

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

4. 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.

- Accessing anticoagulation therapy – especially those more recently given NICE guidance
- Urgent reversal of an anticoagulant in an emergency
- Length of time between testing dates for warfarin
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Please list any concerns patients or carers have about the treatment being appraised.

- It would be helpful to have information that a patient can carry with them on who to contact / what information to share in case of emergency
- Re-assurance/ on half life and management in medical emergency

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.

I do not know of any differences in opinion

5. 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.

- Known AF patients in need of anticoagulation but who currently struggle to maintain TTL on a Vit K anticoagulant
- Patients who find one-dose per day easier to manage, for example, those taking many medications and so a reduction in number of doses per day really does help their personal daily management
- Newly diagnosed and assessed AF patients who would find it difficult to attend regular INR monitoring clinics and not wishing or able to self monitor
- AF patients unable to tolerate other anticoagulant options

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

- AF patients with adherence issues that might result in them missing doses and this not being identified early enough to correct
- AF patients who are unable to safely manage their doses of prescribed medication and so would be safer if regularly monitored
- Those contraindicated on medical grounds

6. 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.

In general, I believe so

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 the trial captured outcomes which are important to patients

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?

N/A

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.

Living with Warfarin survey:

http://www.atrialfibrillation.org.uk/files/file/Publications/120306-jf-FINAL-Living%20With%20Warfarin.pdf

Anticoagulation Services and Patient Access to Self-Monitoring:

http://www.atrialfibrillation.org.uk/files/file/141001-cjw-FOI%20Executive%20Summary%20ACSMA.pdf

Living with AF interviews: http://www.atrialfibrillation.org.uk/stories/living-with-af.html

7. 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 I am aware of

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.

- Those for whom anticoagulation is contraindicated .

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.

AF is a developing area where recognition and agreement on appropriate management has only been widely available in the past few years and only seen in updated NICE CG 180 in June 2014. While alternative anticoagulation therapies to warfarin, have come to market since 2012, these are still widely under prescribed

Education and providing information is still on-going to ensure NICE CG180 is understood and implemented at local level, not least around the use of anticoagulation. If given guidance by NICE, Edoxaban will further support the essential paradigm change that is needed across England and Wales, in managing AF patients assessed at increased risk of AF-related stroke.

Are there any other issues 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.

- Effective and safe therapies are essential. Ones that reduce risk by being easier to manage, help the patient
- As uptake of anticoagulation is still relatively low, it is important tp have choice to help prescriber and patient access effective and manageable therapies reducing risk, burden and cost
- Therapies which reduce AF-stroke risk and also reduce risk – of major bleeds and CVD events support better outcomes for AF patients
- AF is challenging. Carers need support too and a therapy that is safer and easier to use while also at least as effective, helps everyone
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