NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Dabigatran etexilate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism [ID483]

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: Diane Eaton

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? **Yes**
- a carer/ **Parent** of a patient with the condition for which NICE is considering this technology? **YES**
- 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**) Yes - Project Development Manager (P/T)**
- other? (please specify)

Appendix G – patient/carer organisation statement template

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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.

We note that the technology does not yet have a marketing authorisation but understand that this is being progressed by the manufacturers

Advantages:

Treatment of deep vein thrombosis and prevention of further DVT/PE
Current treatment is Low Molecular Weight Heparain(LMWH) and dose adjusted VKA warfarin thereafter or, Rivaroxaban (NOAC) which is an orally administered and given to treat an acute VTE event and for prophylaxis

Dabigatran can be given after the course of LMWH subcutaneous injections. It is given orally twice daily and does not require any dose adjustment or INR monitoring as with warfarin. Studies show that the efficacy of Dabigatran was non- inferior to warfarin when used to treat an acute 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

Patients experiencing a venous thromboembolism or pulmonary embolism need to be protected against risk of further venous thromboembolic events. Once the initial treatment of LMWH has been given, commencing an oral medication which can reduce risk and may have a slightly reduced bleeding risk as compared to warfarin is another option in treatment choice for patients.

Patients who cannot tolerate warfarin or find it difficult to maintain stable INR ranges may benefit from a treatment that does not require monitoring with regular blood tests Dabigatran(like other NOACS) does not appear to be affected by diet and other drug interactions and therefore people won't have the anxiety or stress of having to adapt to changes to accommodate warfarin which can significantly impact on lifestyle

Warfarin needs to be regularly monitored by blood tests. These tests are conducted in primary/ community or secondary care settings.
Some **long term warfarin users** choose to self monitor, buying the devices and obtaining the strips on prescription. Whilst this is personal choice, it can be prohibitive for some people in terms of cost, lack of GP support and ability/responsibility to self test.
For those that do this successfully and with support of their doctor, they may wish to stick with warfarin. NICE VTE guidelines (CCG 144) do not recommend self testing being offered routinely and therefore 'at risk' individuals may have to comply with local anticoagulation directives for monitoring(attending clinics/venous sampling etc) and therefore this NOAC will be seen as a positive alternative as opposed to the demands of warfarin.

Attendance for these appointments can impact on taking time off work or school and may necessitate family or carer support sometimes on a weekly basis if INR is not in therapeutic range which could heighten risk of bleeding or a further VTE. Venous sampling can be painful, cause bruising and contribute to scarring of the veins which can make continuous testing uncomfortable and difficult when drawing blood.

ACE is aware that attendance at such clinics can be a constant reminder to people of their vulnerability of having a condition or illness which requires intervention and this can impact on their mental health and wellbeing especially if it's for a lifetime

Potential advantage could be significant for long term anticoagulation users such as those with thrombophilia. Preventing clotting or bleeding events with a medicine that can be taken without monitoring is innovative and will be welcomed by 'life' AC users

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)

Rivaroxaban(NOAC) can be given on the onset of an acute thromboembolic event. Dabigatran treatment commences after a period of LMWH treatment.

Clinicians who are currently prescribing Dabigatran for prophylaxis for hip and knee surger or Atrial Fibrillation may choose to use this treatment as they have experience of how it works in that setting. When discussing treatment options with the clinican, patients may prefer to start with a NOAC such as Rivaroxaban which ,

doesn't require injections of LMWH and doesn't require any monitoring as with warfarin
No antidote at present. Warfarin can be reversed in event of a bleeding event

Compliance can be an issue with any drug regime. Patients must be educated as to the importance of taking the drug regularly (due to short life) not missing doses and notifying healthcare professionals of any reactions or bleeding events. Warfarin monitoring can highlight compliance issues and therefore for some people who may have experienced warfarin in the past, they will need to be informed as to the different way in which Dabigatran works.

People with thromobophilia conditions and require long term anticoagulation will need to be counselled as to the benefits of this treatment option as there is no evidence yet available for extensive long term use of the NOACS due to newness of these drugs.

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

As mentioned in 2, some patients may prefer to go straight to a oral treatment without the need for a course of LMWH which can be difficult to administer and require intervention by a nurse or family member.

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?

Patients who may benefit more:

All ages especially those working who want to return to work as soon as possible and not have to take time off to attend clinic for regular INR tests

Patients who are looked after by carers or family who have to manage dose adjusting warfarin and monitoring on person's behalf. Easier to give daily dose of medication without making arrangements for regular blood tests.

People with co-morbidities that have multiple medications and may be limited in choice by interactions with warfarin

Long term anticoagulatant users

Less … those who may have previous experience of warfarin and would prefer to take warfarin again and be monitored as they are familiar with the protocol and it gives reassurance

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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.

As mentioned – LMWH followed by warfarin or Rivaroxaban (NOAC)

(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)

Lack of monitoring as with warfarin – no blood tests(other than renal function, if necessary) Time, cost and inconvenience to patient,family and carer

No dietary interactions

Minimise drug interactions

Compliance over and above taking a dose adjusted medication

Non inferior to warfarin(evidenced based through clinical trials)
(N Engl J Med 2009: 361:2342-52)

(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).

No antidote at present although we understand that the manufacturers have presented the results from the first clinical study around the development of an antibody fragment(FAB) (INReview on file)

Potential GI bleeding?
Long term use – increased risk of coronary events?

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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?

Potential patient choice for treatment and importantly, continuance of protection of further risk of VTE either short term or long term.

Reduce clinical intervention and related costs in managing warfarin therapy – benefit to NHS resources

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Prophylaxis – reduce further VTE and consequences of re-admission, treatment and subsequent outcomes from clotting events. i.e. Post thrombotic syndrome.

Ease of use/safety – reduction in potential medicine errors by patients/carers when dose adjusting as required with warfarin use

Already available for prophylaxis for Knee and Hip surgery and Atrial Fibrillation –

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

Lessen choice of another alternative anticoagulation treatment

Clinicians currently prescribing Dabigatran for other indications may be excluded from using this as first choice as a preferred and known treatment

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

Those who may have impaired renal function

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 impacts.

Under current CCG protocols; Anitcoagulation Services are being re-designed and ACE is aware of cases where patients are being prescribed a NOAC in secondary care and then advised in primary care that they cannot continue, usually due to cost and direction of CCG. If NICE guidelines recommend a treatment and a clinical decision is made to prescribe a treatment, it should be made available to the patient. It is unacceptable that access is denied or removed for a NICE approved medicine which the patient and clinician agree will maximise patient healthcare and reduce risk of further VTE

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