Appendix G – patient/carer organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Rivaroxaban for the prevention of adverse outcomes in patients after the acute management of acute coronary syndrome

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: Pumping Marvellous Foundation

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- 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)
- other? (please specify)

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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.

Reduction in stroke risk / thrombotic event – psychological effect of having a drug that reduces the risk of stroke

(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 – **(We don't believe this therapy will affect the course or outcome of the condition apart from marginalisation of thrombotic events.)**
- Physical symptoms – **(We don't believe that this therapy has any effect on physical symptoms of ACS)**
- Pain **(We don't believe that this therapy has any effect on pain)**
- level of disability **(As the therapy doesn't require constant measurement of INR like warfarin then as a disabled person this has to be benefit and reduce frequency and costs of trips to the anti-coagulation clinic)**
- mental health – **(We are not aware of this therapy affecting people with mental health issues however we can see the positive QOL benefits by reducing dependency of person on engaging with an NHS anti-coag clinic)**
- Quality of life **(lifestyle, work, social functioning etc.) (We believe the therapy has a significant impact on the overall QOL measures for both the patient and carers and family. Using Warfarin requires sometimes weekly checks depending on INR stability and is therefore a real drain both on social, work and lifestyle requirements of the patient and family)**
- other quality of life issues not listed above – **(We believe that Rivaroxaban will help patients with managing their QOL not just on the lifestyle, work and social setting but also the sometimes un-detected social stigma of taking warfarin which has psychological impact. Rivaroxaban testing can be introduce into the patients usual regime of blood tests which makes it more socially acceptable)**
- Other people (for example family, friends, employers) **(The impact of somebody taking Rivaroxaban on their surroundings including carers, family and employers is vast. The impact on carer and family is often immeasurable and sometimes intangible but on the employer we are sure it has a significant impact over a long term.)**
- Other issues not listed above

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)

We feel that a rain check needs to be taken, as the benefits over taking warfarin are huge based around QOL indicators. Apart from the stated potential side effects which may exacerbate the conditions symptoms we only see a number of negatives which we feel are part and parcel of any anti-coagulation / anti-platelet therapy e.g.

- **Increased risk of bleeds**
- **We are not aware of an antidote**
- **Ensuring regular taking of therapy to ensure efficacy**

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

We don't believe that there are any differences of opinion.

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?

Benefit more –
Long term therapy
Patients with AF
Patients with an increased thrombotic risk

Benefit less –
People who are prone to bleeds
People who may have drug interactions

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.

Warfarin
Anti-platelets e.g. Aspirin, Clopidigrel, Prasugrel, Tricagrelor etc. etc.

(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)

We don't think the therapy is about improving the condition more around prevention of thrombotic events.
Reference ease of use then all seem to be administered orally in tablet format. Warfarin has the obvious issues around INR monitoring therefore with an unstable INR this can become very demanding reference appointments leading to increased cost for the patient. Therefore ease of use impacts significantly on QOL.
We believe the side effects are similar to all other anti-coagulants or antiplatelets.

(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).

The only disadvantage for the patient is that we are unsure whether there is an antidote?

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.

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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?

This has been stated above.

If on warfarin and changes to Rivaroxaban then no frequent trips to the anti-coag clinic.
Routine maybe 6 monthly bloods which would be in the patient's routine and would be planned and regular.
Reducing the cost of frequent journeys to the anti-coag clinic

We feel as a charity that the safety information given out to patients on warfarin according to feedback from our beneficiaries can be misleading reference the dietary impact on warfarin and INR stability. We hope that Rivaroxaban and its accompanying patient information would be more concise and considerate.

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

If the patient was given warfarin then this impacts on the QOL of the patient, carer and family is significant. It has a cost implications for the patient and family as well a time issue certainly for carers and family that may have to provide transport. We also believe due to the current patient information that accompanies the taking of warfarin has a detrimental effect on diet.

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

As Rivaroxaban is administered via an oral tablet then it should be easily administered by the patient, carer or family member. Difficulties will arise with other therapy contradictions and specific conditions that may bring up doubt as to whether Rivaroxaban can be prescribed. We do realise that these conditions must be very similar for all anti-coagulation and antiplatelet therapies however for reference purposes we have included the appropriate sections referenced from the NHS Choices website
Whether this medicine is suitable for you
Rivaroxaban is not suitable for everyone and some people should never use it. Other people should only use it with special care. It is important that the person prescribing this medicine knows your full medical history.

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Your prescriber may only prescribe this medicine with special care or may not prescribe it at all if you:

- are allergic or sensitive to or have had a reaction to any of the ingredients in the medicine
- are bleeding
- are breast-feeding
- are elderly
- are pregnant
- are prone to bleeding
- have a malignant tumour which is at high risk of bleeding
- have an aneurysm
- have bleeding problems
- have certain types of gastrointestinal problems
- have certain types of surgery
- have circulation problems
- have eye problems
- have had bleeding from the lungs
- have high blood pressure which is not well controlled
- have kidney problems
- have lesion or a condition which is at high risk of bleeding
- have liver problems and have problems with blood clotting
- have lung problems
- have or having investigations for oesophageal varices
- have recently had a bleed in the brain or spine
- have recently had brain or spinal injury
- have recently had brain, spine or eye surgery
- have recently had or are about to have a procedure which involves the insertion of a needle into the spinal cord
- have, have recently had or have risk factors for developing gastrointestinal ulcer

Potential other medicine interactions

The following medicines may interact with Rivaroxaban:

- apixaban
- aspirin
- carbamazepine
- clarithromycin
- clopidogrel
- dabigatran etexilate
- dalteparin
- dronedarone
- enoxaparin
- erythromycin
- fluconazole
- fondaparinux
- heparin, if injected into a vein
- itraconazole

- **ketoconazole**
- **naproxen**
- **phenobarbital**
- **phenytoin**
- **posaconazole**
- **rifampicin**
- **ritonavir**
- **voriconazole**
- **warfarin**

The following types of medicine may interact with Rivaroxaban:

- **anticoagulants**
- **azole antifungal agents**
- **cytochrome P450 enzyme inducers**
- **cytochrome P450 enzyme inhibitors**
- **heparins derivatives**
- **low molecular weight heparins**
- **medicines that affect blood clotting**
- **non-steroidal anti-inflammatories**
- **other anticoagulants**
- **other antithrombotic agents**
- **p-glycoprotein inhibitors**
- **platelet inhibitors**
- **protease inhibitors**
- **vitamin K antagonists**

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.

There is a concern around the reference made on the NHS Choices website on Rivaroxaban and prescribing it with caution or not at all to –

- **The Elderly**
- **Those that have circulation problems**
- **Those that do not have well managed hypertension**
- **Those that have kidney problems**

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	All the above points can be typical problems for people with heart problems.

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

Evidence should be obtained to indicate Rivaroxaban is effective in a large enough patient group. Not sure how you want us to answer this question.

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