Patient/carer organisation statement template

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: AntiCoagulation Europe

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)~~

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.

The accumulated safety and efficacy data for dronedarone offers a key advantage over current treatments available to AF/AFL patients, namely that of reducing the risk of negative outcomes such as hospitalisation and mortality.

(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.

The prospect of a treatment for AF/AFL which has an acceptable risk:benefit ratio is likely to be of substantial benefit to patients. A demonstrable reduction in risk of mortality and hospitalisation is by definition an improved outcome of the condition, which current treatments cannot demonstrate. AF/AFL treated with an efficacious drug with an acceptable side effect profile is likely to reduce physical symptoms of the condition and level of disability while improving quality of life for the patient and having a positive effect on carers, family, friends and employers in particular.

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)

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 their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

Provided suitable patients are selected to receive the technology, there do not appear to be specific aspects of AF/AFL that the technology cannot help with or might make worse. However, the introduction of a risk management programme to ensure suitable patient selection, should not be allowed to limit access to the technology for suitable patients. The side effect profile appears manageable. No additional financial impact/difficulties in taking the technology/impact on others are anticipated as the technology is an oral treatment.

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

N/A

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 cannot tolerate or do not respond to any of the current arrhythmia drug regimens would seem to benefit more from the technology as they may only currently have anticoagulant therapy as an option to manage the stroke risk inherent in their condition. Patients with severe disease but who are tolerating treatment with amiodarone could conceivably benefit less as efficacy may be more important to them than the long-term adverse-effect risk of the drug. This cannot, of course, be ascertained until direct head to head comparison trials are published.

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

a) treatment with beta blockers
b) treatment with antiarrhythmia drugs which maintain rate or rhythm
c) ablation therapy
d) treatment with warfarin/aspirin to reduce risk of stroke

(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 in 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.)

Current treatments for atrial fibrillation all have limitations. While several have demonstrated efficacy in maintaining sinus rhythm, all have side effect profiles that limit their use and limited data available on hard clinical endpoints. With respect to amiodarone particularly, toxicity to the lungs, eyes and thyroid function are of particular concern. In contrast, dronedarone has demonstrated positive clinical outcomes such as reduced risk of hospitalisation and mortality in patients with AF/AFL and in addition, has a manageable side effect profile, with similar numbers of patients receiving dronedarone in the ATHENA trial discontinuing due to adverse events as the group receiving placebo.

AF/AFL is associated with significant costs (both personal costs to patients and their carers and in monetary terms to the NHS) which will continue to increase as our population ages. Treatment with effective and safe options such as dronedarone in order to reduce the risk of hospitalisation and mortality offers a new option to reduce these cost burdens on both suitable patients and the health service.

(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).

Data available on dronedarone would indicate no specific disadvantages compared to current clinical practice in suitable patients. However, as certain high-risk patients are not suitable for dronedarone treatment due to an increased risk of mortality, the implementation of a risk management programme to ensure the technology is used in suitable patients will be important.

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.

No

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?

For suitable patients, dronedarone would offer an additional option for the treatment of AF/AFL with an acceptable risk:benefit profile, which many current treatments could not claim. While demonstrated improvements in the risk of mortality are an obvious advantage, the reduction of risk of hospitalisation is also an important outcome for AF/AFL patients and their carers and their quality of life.

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

We believe that if the technology was not made available to patients on the NHS there will be significant numbers of patients who will continue to suffer sub-optimal outcomes due to the limitations of current treatments for AF/AFL.

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

None anticipated.

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.
N/A