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], [redacted], [redacted], [redacted], [redacted].

Name of your organisation:
Breast Cancer Care, Breakthrough Breast Cancer, Macmillan Cancer Support, Breast Cancer Campaign.

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)
- [redacted].
- 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.

Approximately two thirds of women are diagnosed with ER+ breast cancer and could potentially benefit from fulvestrant an oestrogen receptor antagonist, known as a selective oestrogen receptor down regulator. This drug gives an additional treatment option for these women living with metastatic breast cancer.

Fulvestrant has been shown to significantly delay the time to disease progression compared to anastrozole and low dose (250mg) fulvestrant[1, 2]. Delaying time to progression and knowing there are active hormonal treatment options available is very important to the women we speak with. Delayed time to disease progression can improve the quality of life of these women, allowing them to continue working and spending quality time with their families.

(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 can expect symptom control, including pain control, which brings with it improved quality of life, including social functioning (e.g. maintaining relationships and the ability to participate in activities such as going on holiday) and spending more quality time with family and friends. Patients can also expect to gain extended time to disease progression[1, 2].

Fulvestrant at 500mg is well-tolerated[2]. There is the potential for reduced side effects as high dose fulvestrant has no evidence of dose-dependence or any adverse effects compared with low dose fulvestrant[2]. The low dose has been shown to have similar side effects to anastrozole[1].

[1] Robertson JFR, Llombart-Cussac A, Rolski J, *et al.* (2009) Activity of fulvestrant 500mg versus anastrozole 1mg as first-line treatment for advanced breast cancer: results from the FIRST study. *Journal of Clinical Oncology,* 27(27): 4530-4535.

[2] Di Leo A, Jerusalem G, Petruzelka L *et al.*(2009) CONFIRM: Phase III, randomized, parallel-group trial comparing fulvestrant 250mg vs fulvestrant 500mg in postmenopausal women with oestrogen receptor-positive advanced breast cancer. *Cancer Res,* 69(24 Suppl): Abstract nr 25.

Administration via a monthly intra-muscular injection may have advantages over oral therapy as it may lead to improved compliance with the treatment as patients will not have to remember to take daily oral tablets.

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).

The current 500mg dose requires two injections of 250mg into the deep gluteus muscle. There is therefore the potential for reaction at the injection site (e.g. bruising).

Currently treatment (with fulvestrant) is given in an outpatient setting necessitating travel to the hospital and the associated financial burden of travel and car parking. While hospital trusts determine their own car parking policies, they are advised by the Department of Health to offer free or reduced price parking for patients with a serious condition requiring regular treatment. However, in practice this does not always happen and over half of cancer patients in a Macmillan survey did not access reduced or free parking while they underwent treatment[3]. This represents a considerable financial burden.

Some patients with secondary disease, due to the effects of the illness and the stage at which this drug is routinely given, may require additional physical support from a carer to attend a hospital appointment.

[3] http://www.macmillan.org.uk/Aboutus/News/Latest_News/MacmillanRespondsToFreeHospitalCarParking.aspx

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

Some patients are relieved that the administration of the drug takes place at the hospital as this enables more communication with their specialist team.

Other patients find the monthly trip to the hospital increases their anxiety levels due to fear of being told that the disease has progressed.

The mode of delivery via deep muscle injection is difficult for a small group of patients anxious about needles.

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 with ER+ metastatic breast cancer may benefit from this treatment. As fulvestrant is indicated for women whose disease has relapsed on or after adjuvant anti-oestrogen therapy, this treatment will be particularly beneficial in women who have developed treatment resistance and therefore have limited treatment options. Patients with ER- metastatic breast cancer will not benefit from this treatment (approximately one third of total metastatic patient group).

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.

Fulvestrant is considered an additional treatment option, not an alternative to another drug or type of therapy.

(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.)

The side-effects from fulvestrant have been shown to be equal in tolerability to the hormone therapy anastrozole.[1] Generally women report to us that the side-effects are tolerable, and do not outweigh the improvements in their quality of life.

Administration via a monthly intra-muscular injection has advantages over oral therapy as it may lead to improved compliance with the treatment as patients will not have to remember to take daily oral tablets.

(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).

Currently the 500mg dose requires two injections into the deep gluteus muscle, which may be disagreeable to a small group of patients who are anxious about receiving needles. It is also given in an outpatient setting at the hospital.

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.

The vast majority of women who we have talked to who are on fulvestrant feel it is beneficial to them and that the side-effects are tolerable. Many have reported an improvement in their symptoms which have enabled an improvement in their quality of life and precious time with family and friends.

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

Not that has been reported to us.

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?

If this technology was made available, fulvestrant would become an additional treatment option for patients with ER+ metastatic breast cancer. Clinical trials have shown an improvement in time to disease progression with the use of the drug[1, 2]. Quality of life is maintained and women have reported that it enables control of symptoms, which allows them to spend precious time with family and friends.

As metastatic breast cancer is not curable, it is essential that treatment options which could delay progression or improve survival are made available to this patient group. Patients typically have limited treatment options in the metastatic setting and therefore the need for safe and effective new medicines in this patient group is important. If treatments can slow disease progression they may also allow the patient to be able to continue to carry out normal daily activities such as caring for their families or continuing to work or just enjoying spending quality time with their loved ones. For patients with metastatic breast cancer this cannot be underestimated.

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

If this drug is not made available for use by the NHS the implication is that active treatment by hormone therapy will cease following completion of aromatase inhibitor therapy, which may then signal the end of active treatment and move to palliation only.

We would welcome fulvestrant being made available as an NHS treatment and therefore not restricted to women based on their ability to pay privately as it could reduce variation within this patient population regarding access to the most effective treatments.

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

A small number of women who experience needle phobia/anxiety may experience difficulties having fulvestrant due to the route of administration.

Other Issues

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