Patient Expert Submission Template

Thank you for agreeing to give us a personal statement on your view of the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on what they would like from a technology, which is not typically available from the published literature.

To help you in making your statement we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. A short, focused reply, giving a patient's perspective, is what we need. Your statement can be as short as you like, and we suggest a maximum of 4 pages.

Breast cancer Care is UK's leading provider of information, practical assistance and emotional support for anyone affected by breast cancer. Every year we give direct support to over 22,000 people with breast cancer or breast health concerns through our helpline, peer support and other direct services. In addition, we respond to 2 million requests for support and information about breast cancer or breast health concerns through our publications, website and outreach work. All our services are free

As gemcitabine is not widely available within the NHS for the treatment of metastatic breast cancer it has not been possible to speak to patients who have received this treatment. However, in compiling this personal statement on gemcitabine I have drawn on the views of Breast Cancer Care's secondary breast cancer user advisory group about the importance of access to new treatments.

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

1. **Advantages**

(a) Please list any aspects 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.

Gemcitabine is a chemotherapy treatment licensed for use in patients with secondary breast cancer who have relapsed following chemotherapy treatment in the adjuvant or neoadjuvant setting. The JHQG phase III clinical trial compared the use of gemcitabine in combination with paclitaxel to treatment with paclitaxel alone. It demonstrated that the benefit of gemcitabine on the condition is to prevent further growth of the tumour or shrink the tumour. This leads to delayed disease progression and increased overall survival, which is incredibly important to secondary breast cancer patients.

As a monotherapy gemcitabine could also provide an option of further chemotherapy for people with advanced or secondary breast cancer.

(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.

Secondary breast cancer patients could benefit from treatment with gemcitabine by having tumour growth delayed or shrinking of tumours. This could result in an increase in time to disease progression and overall survival by several months. Having access to new treatments that could increase length of life is incredibly important to secondary breast cancer patients as well as their families and carers. However, many patients are also concerned that any increase in length of life is not at the expense of quality of life. While treatment with gemcitabine does have associated side effects the trials reported that overall quality of life was better in patients treated with gemcitabine in combination with paclitaxel that in patients treated with paclitaxel alone. The trial data also suggested that patients had less pain when treated with gemcitabine in combination with paclitaxel than when treated with paclitaxel alone and had reduced analgesic levels.

Overall gemcitabine appears to benefit patients by offering increased time to disease progression and increased survival without worsening quality of life. It is therefore important that this treatment option is available to secondary breast cancer patients. We can also report from the experience of women contacting Breast Cancer Care through our services that gemcitabine appears to be a well tolerated treatment.

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 (see list in (b) above for suggested items)
- 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 or their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

The impact of a treatment varies between individual patients and they can experience different severity and types of side effects. Patients also have individual preferences about which side effects they are willing to tolerate. Gemcitabine does have associated side effects which can be difficult for patients including nausea, fatigue, skin problems, breathlessness, skin rashes, neutropenia. However, many secondary breast cancer patients are willing to tolerate these effects if the treatment may improve their time to disease progression, length of life and overall quality of life.

Patients would like this treatment option to be available and to be able to choose with their clinician whether the treatment would be suitable for them.

Gemcitabine is given intravenously once, this will mean that patients must travel to hospital to have treatment and spend half an hour for the infusion of gemcitabine alone or longer if it is given in combination with other drugs. This can be inconvenient for patients and impact on their daily activities, it can also mean that family or carers may have to accompany them and take time off work. The cost of travel to the hospital and parking costs can also have a financial impact. However, these are the same implications as for most types of chemotherapy. Many patients are willing to accept this inconvenience to access a treatment that may benefit them.

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

Patients want to make an individual choice with their clinician about whether a treatment may benefit them and be something they wish to access, however they believe it is very important to have the treatment option available.

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?

I am not aware of any groups of patients who may benefit more or less from the technology.

The advantages and disadvantages of the technology *compared with current standard practice*

NICE is particularly interested in your views on how the technology compares with current standard practice (alternatives if any) used in the UK.

Please list any alternatives available as far as you are aware in current standard practice to the technology

(i) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe. Advantages might include:

- improvement in the condition overall or in certain aspects of the condition
- ease of use (for example tablets rather than injection, at home rather than in hospital)
- fewer side effects (for example number of problems, frequency, duration, severity)

The JHQG trial demonstrated that gemcitabine in combination with paclitaxel had an advantage over paclitaxel alone by increasing time to disease progression and overall survival. The trial also demonstrated that overall quality of life was better.

(ii) If you think that the new technology has any **disadvantages** for patients compared to current standard practice, please describe. Disadvantages might include:

- inconvenience of use (for example is it a treatment that has to be given by somebody else or in hospital?)
- more side effects (for example number of problems, how often, for how long, how severe).

Gemcitabine does not appear to have any disadvantages for patients compared to current standard practice.

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.

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

Any additional sources of evidence?

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 [or, please attach copies of the study report]

Implementation issues

Is the following an implementation issue or should we change heading?

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

The introduction of this technology could result in patients surviving for longer than with existing treatment. Quality of life could also be improved.

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

Patients would be denied the opportunity of increased life expectancy, improved quality of life and a reduction in pain.

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