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: Beating Bowel Cancer

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) ✓

  Head of Patient Services

- 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 median survival for patients with metastatic colorectal cancer (mCRC) is 20 months[1]. For patients who either present with metastatic disease or go on to develop advanced disease, it is imperative that they have immediate access to the treatment options which their multidisciplinary team believe will allow them the best possible patient outcome.

An overwhelming advantage of a positive appraisal of bevacizumab in combination with oxaliplatin and either 5fu or capecitabine is that it will allow clinically appropriate patients to have immediate availability of a monoclonal antibody treatment option to which they currently do not have access.

A positive appraisal of bevacizumab in the metastatic setting will allow clinicians greater variety in their treatment options. Additionally, clinically appropriate patients will immediately be able to start a treatment which, if successful, can have a significant and positive impact on quality of life and life expectancy. Its lack of availability in the NHS, despite its licensed indication and demonstrable clinical value in the management of mCRC is the subject of great concern to clinicians and urgently needs review.

Psychological Impact/Mental Health
To receive a diagnosis of mCRC is devastating and immediately has a huge psychological impact on the patient and their family. Given the poor prognosis for mCRC patients, treatment options aim primarily to manage the range of related physical and psychological symptoms in order to maximise quality of life and extend survival. Following such a diagnosis it is vital that patients know that they have access to the best known and clinically proven treatment options for their stage of diagnosis. Patients who contact Beating Bowel Cancer often tell how they were horrified when they discovered that treatment that has shown to have significant potential benefits is not automatically and readily available to them; options are denied which have enormous potential to improve their survival and their quality of life for their remaining months.

The result of a positive NICE appraisal will have a greatly positive impact on the psychological state of patients as they can gain immediate access to the most effective treatment options, if clinically appropriate. Patients need to know that they are not being denied access to treatment, due to cost only, that could either save their life, or increase the length of their life.

[1] Saunders M and Iveson T 'Management of advanced colorectal cancer: state of the art': Br J Cancer 2006 95: 131-38

(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.

Please refer to the response to Question 1(a) where the benefits of the technology for patients with mCRC have been covered.

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).

We acknowledge the following disadvantages of the treatment, however Beating Bowel Cancer does not believe there to be major disadvantages of the technology in comparison to the current available treatment choices, for those who are clinically appropriate.

- Bevacizumab cannot be give for 4 weeks before and after major surgery and until after any surgical incisions are fully healed
- Minor side effects experienced by those who have received bevacizumab include nosebleeds, high blood pressure and proteinuria.
- Reported adverse effects during clinical trials have included gastrointestinal perforation and slow or incomplete wound healing

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

In our experience, patients want access to the best possible treatment choice clinically appropriate to their diagnosis including those that may extend their life.

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?

At this time, there are no identifiable biomarkers (e.g. K-RAS, B-RAF) which have demonstrated which patients are most likely to respond to bevacizumab.

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.

Current guidance from NICE recommends 5-fluorouracil plus folinic acid (5-FU/FA) in combination with oxaliplatin (FOLFOX) or irinotecan (FOLFIRI) as first line treatment options and FOLFOX or irinotecan alone as subsequent therapy in advanced colorectal cancer (technology appraisal 93). The oral analogues of 5-FU, capecitabine and tegafur, in combination with uracil (and folinic acid) are also recommended as first-line treatment options for metastatic colorectal cancer (technology appraisal 61).

(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.)

Please refer to the response to Question 1(a) for the advantages of the technology compared with current standard practice.

(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).

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.

Beating Bowel Cancer is unable to answer this question as the technology has only been available under clinical trial conditions, and not as routine NHS care.

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

Beating Bowel Cancer is unable to answer this question as the technology has only been available under clinical trial conditions, and not as routine NHS care.

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.

Beating Bowel Cancer is not aware of any research on this subject.

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?

As detailed throughout this submission, NICE approval of bevacizumab in the metastatic setting will allow clinically appropriate patients to have immediate availability of a recombinant monoclonal antibody treatment option to which they currently do not have access. This is a treatment option that has clinically proven benefits for mCRC patients who would significantly benefit from the availability of the treatment, leading to improved quality of life and patient outcomes. This is a treatment option which has a vital role in supporting chemotherapy in the treatment of colorectal cancer in the UK.

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

If this treatment was not made available to patients on the NHS, patients will continue to be denied access to a treatment which will have the potential to increase their quality of life and their life expectancy.

Patients would continue to be denied the possibility of contributing positively and actively during their illness. This may mean the premature loss of ability to continue working, supporting their families and sharing valuable quality time with those close to them. They would, in fact, suffer premature death at a time when a suitable treatment could be available to them and most probably would be in other major European countries.

Additionally a two tier service would remain as patients who can afford to privately fund the treatment would have access to options denied to those who cannot afford to pay. At Beating Bowel Cancer we regularly speak to patients and their families who are enduring the psychological and financial burden of seeking out ways to obtain this treatment option. Patients should not have to fight for treatments whilst they are fighting for their lives.

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

Beating Bowel Cancer does not believe that there are groups of patients that will have difficulties using the technology, if they are clinically appropriate to be prescribed the treatment.

Other issues

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

As a patient organisation, we are committed to ensuring that patients have immediate access to those treatment options which have been clinically proven to extend life expectancy beyond those currently available.

Whilst we recognise that costs have to be taken into consideration, we strongly recommend that the Appraisal Committee fully considers the wider and crucial issues surrounding the value of prolonged quality life. We urge the appraisal committee to consider all possible options to find a way to make this treatment an option for those affected by metastatic colorectal cancer. It is imperative that the therapeutic value of treatments is placed at the heart of any assessment criteria, rather than the current strong focus on additional life years. Improved quality of life, regardless of the resulting length of life, is immeasurable for most patients.

With regards to the future, it is vital that treatment options such as bevacizumab are adopted as routine treatment to ensure that the medical community in England and Wales can take part in clinical trials. England and Wales are at risk of being excluded from taking part in clinical trials as the 'standard of care' is different to that of the rest of Europe. Already trials are starting to take place with bevacizumab (Avastin) included in the 'control arm'; it will not be possible for NHS researchers in England and Wales to apply to join clinical trials such as these, if these treatments are not given routinely to NHS patients.