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: Bowel Cancer UK

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.

Bevacizumab (Avastin) plays a vital role in the treatment of metastatic colorectal cancer. The drug is a biological agent, which works in combination with chemotherapy in reducing tumours that have spread from the bowel to other parts of the body, especially the liver and the lungs.

These metastatic tumours are often highly resistant to chemotherapy alone and Bevacizumab plays a vital role in helping the chemotherapy to work better, by blocking the tumour receptors that send signals out to the body to feed them (e.g. to the body's blood supply); and, as a result, inhibiting and often reversing cancer growth (a process called VEG-F). The optimum outcome of this process is, of course, resection, the possibility of which is becoming more common as clinicians become more adept at prescribing the drug and optimising its effects.

As a biological agent, Bevacizumab is much less toxic than chemotherapy and has fewer side effects. Patients often have improved quality of life on the drug as well as extension of life. These are both vital benefits, especially when most patients taking the drug will be in the advanced stages of the disease and are often in pain and discomfort, tired and anaemic and less mobile.

(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 who benefit from Bevacizumab can expect to see their metastatic tumours shrink or even disappear; to feel better and have an improved quality of life as a result of receiving the treatment; to have a greater chance of resection (e.g. of the liver); and to have a greater chance of living longer and potentially being free of the disease.

In addition to the medical benefits of Bevacizumab, there are numerous social and psychological benefits, including improved quality of life; ability to function more normally as a human being, e.g. by being more mobile; as well as the drug easing the pressure and worry felt by patients and their family and friends.

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).

While Bevacizumab, like most biological agents, is less toxic and has less side effects than chemotherapy, it isn't right for everybody, e.g. for people with stomach complaints; high blood pressure; blood clots; heart conditions; and bleeding problems. Clinicians are already very well aware of these side effects and will not prescribe the drug to a patient if they believe they are not going to tolerate it.

With the exception of oral treatments, the delivery of cancer treatments, including Bevacizumab, is often an invasive and difficult process, by its very nature. However, this is offset by the potential benefit of these treatments to patients in terms of improved quality and length of life, which are naturally of greater importance to them.

Also, a patient's oncologist and multi-disciplinary team (MDT) will know very quickly, i.e. after six doses, whether Bevacizumab is working for a patient and if it isn't, the drug will, of course, be stopped, thus keeping to an absolute minimum any related discomfort or inconvenience caused to the patient.

While there is a financial element to receiving the drug on the NHS, e.g. travel costs, these are insignificant when compared to the financial burden that bowel cancer patients and their families face when they have to pay for the drug itself, as many have had to do with Bevacizumab following NICE's negative ruling three years ago.

The financial impact of having to pay for treatments is an added burden and cause of stress to patients who are already combating bowel cancer. This issue, combined with the clear and continuing inequities in access to both NICE approved and non-approved treatments, has been a key aspect of the access to treatments debate.

The recent range of cancer treatment related reviews, e.g. of co-payments and top-ups by Professor Richards; on end of life care by NICE; and reviews by others – have all been predicated in part by NICE's previous negative guidance regarding Bevacizumab and other drugs.

If NICE approves Bevacizumab in this setting, this will significantly reduce the financial burden on patients who receive it and on their families, because they won't have to find the money to pay for the drug. A positive NICE verdict with regard to Bevacizumab will also ease the stress upon patients and their families, which is already immense, as a result of having advanced bowel cancer.

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

Each patient responds differently and with varying degrees of success to the treatments they are given. Their opinions are very much based in advance on what their clinicians tell them; on what they've heard about others' experience of the drug, e.g. in the media; and then after they begin taking the drug, upon their own experience on it.

In our experience, most patients' views of this technology are very similar to their views of all cancer treatments: they trust their oncologist to make the right decision on their behalf, i.e. whether a treatment is right for them, and then will decide, with their clinician, whether to have the drug or not. Also, while patients naturally want the treatments that can help them and hope will work for them, they also know it is impossible to know in advance whether a drug will work for them and are pragmatic about this.

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 metastatic colorectal cancer are the most likely to benefit from Bevacizumab and it is up to clinicians to determine, with each patient, whether they might personally benefit from it, a judgement that will depend upon a range of medical and other factors.

We understand, based upon available statistics and drug trial outcomes, that the number of patients that are eligible to receive Bevacizumab in this setting - within the jurisdiction of this appraisal, i.e. in England and Wales - is approximately 6,530 people per year. This is approximately 20% of the 31,000 patients diagnosed with bowel cancer each year in England and Wales.

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.

Bevacizumab is one of three biological agents currently licensed for use in bowel cancer, the other two being Cetuximab and Panitumumab.

Following NICE's recent approval of the use of Cetuximab first line (for patients with liver only metastases and the K-Ras wild type gene) it makes sense for NICE to also approve Bevacizumab in this setting, to enable those patients who don't benefit from Cetuximab (e.g. those with the K-Ras mutant gene or who don't respond to the drug) to have the choice of a biological agent in the first line treatment of the disease.

Panitumumab is only licensed in the third line treatment of the disease, so is currently not relevant to this review.

(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.)

(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).

See the answers to other questions in answer to these points.

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.

Even though Bevacizumab is currently not approved by NICE, it is in regular use, including in this setting – i.e. FOLFOX (Oxaliplatin and Leucovorin with 5FU) or XELOX (Oxaliplatin and Leucovorin with oral 5-FU/Capecitabine) - in private practice; in Europe; and in many other countries around the world.

As clinicians become more adept at prescribing Bevacizumab in combination with other treatments, so they are also finding that individual patients are having significant differences in terms of their response to the drug, both in terms of tumour shrinkage or stabilisation and improved quality of life.

This makes the average number of life months/years gained from the drug somewhat misleading, because many patients do much better than the average. These figures also do not factor in quality of life benefits, which are a significant factor for all patients, especially those in the advanced stages of the disease.

For the record, the average life months/years gained from adding Bevacizumab to the above combinations of treatments is an increase of 2.9 months.

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

To our knowledge, the adverse effects of Bevacizumab were identified and fully recognised during the extensive clinical trials of the drug. The drug's manufacturer and clinicians you speak to will be better placed to answer this question, however.

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.

As we've said elsewhere in this document, the vast majority of patients' views with regard to the treatment of their condition are exactly what you would expect them to be: they want to stay alive and to feel better while they remain alive; they trust their clinicians to give them the treatments that can help them; they know that Bevacizumab is one of those treatments; and they hope it can work for them.

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?

It would enable clinicians to make available a treatment that has a proven benefit to patients in the advanced stages of colorectal cancer.

It would complement the recent positive guidance made by NICE with regard to the other main targeted therapy, Cetuximab (Erbitux), which in turn will ensure that patients who cannot benefit from that drug have a choice of a biological agent that could benefit them.

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

A negative decision by NICE would mean that the significant number of patients who would not benefit from the already NICE approved targeted therapy Cetuximab (Erbitux) would not be able to access a drug that they might benefit from and which might prolong and improve the quality of their lives. This decision would be very unfair and inconsistent. It would also undo much of the good work NICE has done in seeking to increase access to treatments in recent months.

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

Bevacizumab is not suitable for all patients with advanced bowel cancer, e.g. those with the health conditions as set out above. However, clinicians are well aware of these conditions and will not prescribe the technology to patients who may experience difficulties using it.

Other Issues **Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.**
We strongly believe that clinicians should be able to prescribe the drugs that they believe their patients will benefit from, including Bevacizumab, without having to go through the convoluted appeals process that came about as a result of NICE's previous rejection of this and other drugs for NHS use. *We also believe that following its approval of Cetuximab first line – which we warmly welcome – NICE needs to also approve Bevacizumab, so that all patients who could benefit from a biological agent are able to do so.* *We are sure that NICE will continue to work with industry, with clinicians, with patients and carers and with other stakeholders to increase access to effective treatments, such as Bevacizumab, that have a key role to play in the improvement of patients' lives.*
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