

SUBMISSION FROM BEATING BOWEL CANCER

HEALTH TECHNOLOGY APPRAISAL BEVACIZUMAB AND CETUXIMAB FOR ADVANCED COLORECTAL CANCER

Beating Bowel Cancer is a national charity working to raise awareness of symptoms, promote early diagnosis and encourage open access to treatment choice for bowel cancer patients. Further information about us is contained in the annex to this submission.

We consider that the treatments should be made available for the following reasons:

- Both bevacizumab (Avastin[®]) and Cetuximab (Erbix[®]) have shown survival advantages for bowel cancer patients.
- Targeted therapies not only offer an extension in life expectancy to patients with advanced bowel cancer now, but also may, in the future, have the potential to work in combination with other therapies to achieve curative results for early stage bowel cancer.
- Bowel cancer patients who receive these targeted therapies enjoy an improved quality of life and can experience extra months with their family and friends, enjoying life events such as Christmas, birthdays, weddings etc that we may take for granted but the value of which should not be underestimated for a person suffering from bowel cancer.
- These new treatments are licensed in the UK and we believe therefore that they should be widely available to all bowel cancer patients, regardless of where they live or their ability to pay.

Understanding the views of bowel cancer patients

In July 2005 we carried out a survey of 110 bowel cancer patients, specifically on the issue of treatment availability, and the results of this survey reinforce the points above:

- When asked if patients thought that their doctor should tell them about all the drug treatment options that are available to treat bowel cancer, 74% said yes, so that they could have a better understanding of their disease and its treatment, and could decide jointly with their doctor what is best for them. Only 9% were happy for their doctor to prescribe the best treatment without it being a shared decision
- When asked if they believed that new drugs should be available quickly after introduction to all patients who might benefit from their use, two thirds of patients said yes they should.
- When asked what they thought should happen if the NHS cannot afford to treat all patients who might benefit from a new, effective drug treatment for bowel cancer, the overwhelming majority (93%) disagreed that the drug should only be available to private patients and most thought the NHS should find more money for cancer treatments at the expense of other less serious conditions.
- About one in four said they would have to use their life savings or re-mortgage their house to pay for treatment if it was not provided by the NHS, whilst a further one in four said they would not be able to find the money at all.
- When asked what would mean the most to them over the next five months, two-thirds of those asked wanted to spend a family holiday with their loved ones, one in four were looking forward to the wedding of a son or daughter, and around half wanted to be able to celebrate family birthdays.

Considering the patient perspective - Cetuximab (Erbbitux[®])

The five case studies listed below not only provide evidence of the effectiveness of Erbbitux in extending and improving quality of life in patients who have failed on other treatments, but also highlights the shocking disparities experienced by patients seeking to secure treatment with Erbbitux, which is currently based on where you live and your ability to pay. One of the patients detailed below has responded so well to treatment with Erbbitux (her tumour has shrunk significantly) that her oncologist is considering a surgical resection. If the surgery is successful, the patient has a very real chance of long-term survival.

Patient A
Aged 58, from Surrey
Married with two children
BUPA patient

Patient A had been remarkably fit and well throughout his life and had been actively involved with local village activities. His health deteriorated significantly between December 2002 and May 2003. During this time he noticed a significant change in his bowel habits. Encouraged by his wife to visit the GP, he was referred to his local hospital, Frimley Park Hospital within a few days.

Patient A was diagnosed with bowel cancer in May 2003, which had spread to the liver. The bowel cancer was successfully operated on in June 2003. He was then referred to a Consultant Oncologist at Mount Alvernia Hospital, Guildford and began chemotherapy to treat his condition in July 2003.

He had a number of conventional chemotherapy drugs to treat his disease. These treatments achieved stabilisation of the liver cancer for a period of time and were sufficiently tolerated. However, stabilisation was not maintained with the last chemotherapy drug and Erbbitux was then recommended by his Consultant Oncologist. Patient A experienced truly dramatic results with Erbbitux and a significant tumour reduction was achieved from July 2004.

Patient A has had very little in the way of adverse side effects while taking Erbbitux; the acne-like skin rash that shows the treatment is working correctly is a very small price to pay for the success of the treatment and is easily controlled with standard antibiotics. While on treatment with Erbbitux, Patient A was able to return to work part time as a purchasing manager and enjoy a good quality of life without the debilitating side-effects of traditional chemotherapy.

Patient A says, "I was fortunate that my private health insurance with BUPA could pay for this treatment. My quality of life has been excellent compared to what it had been. There are also no huge detrimental side effects as there are with chemotherapy. It means that I am able to go to work four days a week and do physical things like shopping. I feel quite good in myself."

Patient B
Aged 57, from Pinner
Married with two children
NHS patient – Erbbitux treatment immediately funded by PCT

Patient B was diagnosed with advanced bowel cancer in February 2002. Before her diagnosis, she was a head teacher at a local primary school. She was shocked and surprised at being diagnosed with bowel cancer. She had not felt unwell but as a teacher was always tired so may have ignored this symptom.

Surgery was undertaken to remove the cancer followed by traditional chemotherapy until the end of 2004. As Patient B was not responding to this treatment, she began treatment with Erbbitux in combination with irinotecan in February 2005. After three months treatment with Erbbitux, Patient B's consultant commented that her response to Erbbitux "had been dramatic". Patient B had significant

tumour shrinkage, including shrinkage in two liver nodules and no new disease was evident. In addition she was less breathless and had increased energy levels

Patient B has commented "I've become aware of the scandalous postcode lottery for funding new drugs and I realise how lucky I am that Harrow PCT are forward thinking to fund my treatment with Erbitux. I know of other patients who have not been so fortunate. I have been lucky. Erbitux was only licensed in June 2004 and Harrow PCT has given it to me immediately. But I have a friend in Guildford who has had to re-mortgage her house because her PCT will not fund the treatment. The delay in the NICE appraisal process is not fair and the sad fact is that many of the patients may be dead by the time it is completed."

"I feel that this amazing new drug has bought me some time and given me some hope for the future. I know it will probably not cure me but each year I live means more research is done and there may be even more new treatment options available to me."

"In January 2005 I met with Tony Blair and John Reid at the launch of the Beating Bowel Cancer Loud Tie Campaign and raised the issue of drug funding, as it is such a critical issue for the NHS in the future. I feel very strongly that there should be equal NHS drug funding across the whole country. It is morally wrong that patients are not allowed to have drugs such as Erbitux when they are available."

Patient C
Aged 51 from Surrey
Married with three children and grandchildren
NHS patient – Erbitux treatment initially refused by PCT

Patient C has a family history of bowel cancer over three generations. Her bowel cancer was first diagnosed through a screening programme at the end of 2001. She underwent surgery to remove the tumour and had six months of conventional chemotherapy.

In March 2004 a scan revealed a large secondary inoperable tumour in the abdomen, and also a spot on her liver. Patient C had two types of traditional chemotherapy to treat the new tumour which did not work. Patient C was told by her cancer specialist that Erbitux was her last hope of survival after conventional drugs failed to work.

Patient C's oncologist recommended that she start treatment on Erbitux but funding was refused by her PCT as NICE had not yet issued guidance. Patient C however discovered that a neighbouring primary care trust in Surrey was providing Erbitux for their bowel cancer patients. She then decided to pay for the treatment herself and fight the NHS afterwards to foot the bill. She had to re-mortgage her house and fundraise to pay for treatment. Patient C began a four-month battle with her PCT and it was only due to her determination and persistence over the course of four months that her PCT finally agreed to fund her first course of Erbitux. However, Patient C was exhausted and under extreme stress as a result of her four-month battle. It is completely unacceptable that she had to endure such treatment when she should have been focusing her energies on fighting the cancer and spending time with her family. Instead she has accumulated bills in excess of £13,000.

"This is the last thing you need when you are fighting cancer. Other PCTs have found a way to pay for this drug, but mine has stuck it out and made me suffer emotionally at a time when I need all my energy to fight the cancer."

"I am lucky in that I have a house to re-mortgage to raise money to pay for treatment but basically people who haven't got this will die and that is obscene. Erbitux will at least buy me more time which is so important to me and my family. I am just too young to die without fighting for this chance. What I find really hard to swallow, is that because my NHS Trust will not pay for this new treatment I must find at least £1,000 per week for Erbitux out of my own pocket which I am prepared to do by re-mortgaging my house and fund raising."

When her PCT finally agreed to pay for treatment, Patient C said, "I should feel elated at this decision and of course I am pleased but I am also exhausted and battle weary from four months of

trying to get funding for this treatment, which I feel I was entitled to through the NHS right from the start."

Patient D

Aged 62 from Worksop

Married with children and grandchildren

Private patient now being considered for surgery following a significant shrinkage in tumour size

Patient D was diagnosed with advanced bowel cancer in October 2002 when she knew "something was not quite right". Up until then, was well and led a very active life.

Treatment with chemotherapy started in January 2003 for 30 weeks to try and prevent tumour recurrence. In June 2003, a routine scan showed patches of tumour in the liver, which were resected. In October 2004, a scan showed a second tumour and so traditional chemotherapy was initiated to try and shrink the tumour before further surgery, but this was unsuccessful.

Treatment with Erbitux was initiated in March 2005. This achieved a very positive response in her tumour markers, which had not been previously achieved with other chemotherapy treatments.

Patient D received funding for Erbitux from private health insurance. Patient D has responded so well to treatment with Erbitux that she has had significant tumour shrinkage and her oncologist is considering a surgical resection at the end of her current treatment programme. If the remaining tumour can be removed, Patient D has a very real chance of long-term survival.

Patient D said "Erbitux treatment has brought the possibility of an operation on my tumour nearer. Hopefully continued treatment will mean this can happen. I feel more energised when only having Erbitux without the irinotecan".

Patient E

Aged 65, Chelmsford

Married with children

Received Erbitux as part of a clinical trial

Patient E was diagnosed with bowel cancer in Spring 2002 and had a successful operation to remove the tumour. However, Patient E was then given the devastating news that the cancer had spread to the liver and the mother-of-two battled the disease for two years as she received both chemotherapy and radiotherapy leaving her drained and tired.

The family started making plans for her funeral, but just when it looked as though all hope was lost, Patient E was offered the chance to try Erbitux as part of the MABEL clinical trial. Patient E was the first patient in the UK to be enrolled in the MABEL clinical trial in April 2004 at her local NHS hospital.

Patient E had an excellent response to treatment and her tumour shrank by a third within two months. Erbitux provided Patient E with a lifeline after initially being told that nothing more could be done for her. Treatment with Erbitux gave Patient E an extra year of good quality life, which was priceless for her husband and children.

Patient E's partner said "Within a few weeks of treatment with Erbitux we noticed the improvement. I remember one day she decided she would walk into town which was about a 20 minute walk and then wandered around town with a friend. She had some lunch, hung the washing out and went to Ongar on the bus and then suddenly thought 'hang on' I have not done anything like this for two years. She would forget she had cancer and she was so like her old self once again."

Considering the patient perspective - bevacizumab (Avastin®)

The five case studies listed below provide again evidence of the effectiveness of Avastin in extending and improving quality of life in patients who have failed on other treatments. Many of these patients are able to enjoy quality time with their family and friends, and in some cases the patients have real hope of returning to work. Most importantly, Avastin has allowed them to continue to live life as normally as possible, despite suffering with advanced bowel cancer, and these basic human rights should not be denied to any patient.

Patient A**Aged 45, from Berkshire****Married, no children****Private patient - covered by PPP Private Healthcare**

Patient A was diagnosed with advanced bowel and liver cancer in October 2003, when he was given only twelve months to live. He was an airline pilot for Virgin Atlantic Airways, and because of flying long-haul, his symptoms could have been masked for a long time. He first noticed rectal bleeding in August 2003, although his GP didn't believe it was bowel cancer at first, he did send him for further tests. Patient A's wife, a US qualified nurse practitioner was able to provide him with a second professional opinion as well as support. He was initially investigated by his local NHS hospital, however the first biopsy was negative. Using his company-provided private healthcare insurance, a further investigative test (colonoscopy) showed Patient A to have advanced bowel cancer.

Further to Patient A's diagnosis, he had major bowel & then liver surgery. He then started a course of chemotherapy in December 2003, which did not halt the multiplying & growing cancer tumours in his liver. He switched treatment in early 2004, and with the change of chemotherapy agent (oxalipatin) and taking Avastin, all the small multiplying tumours were resolved and the one remaining larger tumour shrunk from 1.6cm to 1.0cm. Patient A's oncologist was pleased with his progress on the new drug and obtained approval from PPP for a further 6 treatments, which ended in September 2004 after a good partial response

At that time, Patient A said: "Prior to getting this new drug my chances of survival looked very slim. Although I don't relish another three or four months of treatment, it is a small price to pay if it continues to work. They don't like to speculate beyond this treatment but I hope with any luck, a few more months of recovery, one or two more lots of surgery & I could be looking at returning to work next year - which is my goal."

Patient A is currently undergoing Radio Frequency Ablation treatment and in June 2005 he was awarded the Virgin Atlantic 'Heroes' award in the 'charity' category for his work in promoting bowel cancer awareness within the company

Patient B**Aged 56, from High Barnet****Married with 3 children and 2 grandchildren (with a third on the way)****Received Avastin through a clinical trial**

Patient B first noticed symptoms (constipation) in February 2004, which was relatively mild. However this developed into contractions, which prompted her to visit her GP. Patient B was immediately sent to A&E and operated on (20 June 2004), as a blockage had been identified.

Two weeks after the operation, Patient B was told that the cancer had spread to her liver. Patient B is currently on a stage III trial (enrolled in August 2004), which includes chemotherapy with placebo, or chemotherapy with bevacizumab.

Patient B says "Whatever I am on is fantastic. After the first scan I was told the tumour had shrunk by half, and again by half after the second scan. The third scan indicated that it had shrunk again by 40%, and I now have two tumours left, one which I am told is unmeasurable, which I believe

indicates it is relatively small, and the other is approximately 6mm in size. When I first heard the news, I was absolutely devastated; however I am determined to make the most of my life. Each month, my husband and I look forward to a special event and we recently just celebrated our 35th year anniversary. I feel extremely well and ensure that each day, I spend quality time with my family and friends, who have given me immense support throughout this difficult time”.

Patient C
Aged 42, from Surrey
Divorced, with 2 young sons

Patient C's diagnosis with bowel cancer came out of the blue. In February this year he went to visit his GP after waking one morning with severe stomach pains. His GP suggested that it might be an ulcer, and suggested that he take an antacid. However, the pains became much worse and that evening Patient C was admitted to his local hospital with suspected appendicitis.

The following morning, Patient C was told that he would have to undergo an emergency operation for an appendectomy, and was duly prepared for surgery. While in recovery, he was informed that during surgery doctors had in fact discovered a tumour in his large intestine and that surgeons had to remove half of his bowel.

Following recovery from surgery, Patient C was referred for further tests to the Royal Marsden Hospital in Surrey. There, he was diagnosed with advanced bowel cancer and told that his disease was in fact incurable, and that any treatment offered to him could potentially extend his life only.

Patient C's consultant initiated treatment with chemotherapy and Avastin on 7th April 2005. He has responded well to treatment and says that he “neither looks nor feels like the stereotypical cancer patient”. His most recent scan has showed that his cancer has not progressed further.

Patient D
Aged 57, from Tunbridge Wells
Married with 2 daughters
Paid for Avastin from his life savings

Patient D, aged 57, was diagnosed with advanced bowel cancer in January 2005. He worked as an anaesthetist at Tunbridge Wells Hospital and first noticed symptoms (abdominal pains and bloating) at Christmas 2004. It was originally thought that he may have silent gall stones as his blood tests were normal and there was no sign of rectal bleeding. Patient D underwent a laparotomy on 9 January 2005 and the extent of the cancer in his bowel was confirmed. He had a right hemicolectomy to remove the cancer from his bowel and a secondary tumour on his peritoneum was also removed.

Patient D started on chemotherapy (oxaliplatin + 5FU) in mid February and had one session before he started on chemotherapy combined with a course of Avastin on 24 February. He has had eleven cycles of chemotherapy with Avastin to date and has recently been given the all-clear from his last scan. Patient D first heard about Avastin when he spoke with his brother, a neuroradiologist in New York, who recommended treatment with Avastin. Patient D said he has felt no side effects from Avastin but feels the chemotherapy has made him very lethargic and slightly forgetful.

Patient D has paid for Avastin from his life savings as his health insurance company has not yet agreed to cover the cost of Avastin.

Patient D's wife has provided a great deal of support to him, as she herself was diagnosed with cancer four years ago. She was diagnosed with lung cancer but has since been given the fantastic news that she is all clear. Patient D stopped working in December 2004 and is hoping to gradually return to work at the end of this year. His last scan, which was in mid July 2005, showed no disease.

Patient E
Aged 47, from Derbyshire
Married with 3 children

Patient E was diagnosed with bowel cancer in February 2004 and was completely shocked. He first noticed symptoms 3 years earlier, which were mainly skin rashes and appeared to be related to specific foods he was eating, so he assumed it was irritable bowel syndrome. Bowel cancer never crossed his mind.

In March 2004, following a colonoscopy which confirmed the diagnosis of bowel cancer, Patient E underwent surgery, which highlighted that the cancer had spread beyond the bowel. After further surgery Patient E started a course of chemotherapy in July 2004, and in November 2004 his oncologist recommended that he tried a new course of 5FU, irinotecan and Avastin. He did experience some side effects, such as fatigue, nausea and diarrhoea, but recent scans have showed that treatment with Avastin has resulted in the disease being contained for the time being.

Patient E has since discovered that bowel cancer is in his family – further investigations have resulted in his younger brother and sister having polyps removed and his father having surgery.

Patient E says, "The most important thing for me is spending time with my family, and at the moment, since having treatment with Avastin and chemotherapy, I feel I have a new lease of life. I am able to enjoy the children and the family, walk the dog in the fields, sing in my local choir, and play golf with my friends – ultimately live as normal a lifestyle as possible which is incredibly valuable to me."

Conclusions

We believe that clinicians should have the freedom to offer as many clinically effective treatment options as possible, and patients should have the opportunity to make an informed choice at each stage of their treatment.

We are concerned that most patients are still not able to access the most effective treatments for bowel cancer, and would request that NICE address the urgent need to bring treatments into line with other developed health systems in Europe and North America.

The evidence we have from patients, both documented and anecdotal, stresses the very real benefits that they obtain when treated these new targeted therapies which have enormous potential to improve their survival and their quality of life. Patients are horrified if they discover that treatment, that has shown to have significant potential benefits, is not automatically and readily available to them.

Patients should not have to fight for treatments whilst they are fighting for their lives.

For these reasons, we believe that these treatments should not only be available to patients being treated in the private healthcare sector, but available equally to NHS patients and **we would greatly welcome a positive appraisal by NICE of bevacizumab (Avastin[®]) and Cetuximab (Erbix[®]) for the treatment of metastatic colorectal cancer.**

ANNEX: ABOUT BEATING BOWEL CANCER

Beating Bowel Cancer is a national charity working to raise awareness of symptoms, promote early diagnosis and encourage open access to treatment choice for those affected by bowel cancer. Through our work we aim to help save lives from this common cancer, which is the second biggest cancer killer in the UK and affects 35,600 people every year.

The charity was founded in 1999 and is based in Twickenham, Middlesex. We work hard to improve bowel cancer awareness amongst both the medical profession and the general public, providing authoritative information about the disease, its symptoms, what to do if diagnosed, and what treatment choices are available. The welfare of bowel cancer patients is at the core of all our work, and our key objectives are to improve outcomes for patients, at all stages of their disease.

We believe that surgeons and clinicians should have the freedom to offer as many clinically effective treatment options as possible, and patients should have the opportunity to make an informed choice at each stage of their treatment. Treatment options should be available to all patients in the UK, and not determined by geographic region or a patients' ability to pay.

We provide the UK's only national patient-to-patient support network, through our National Patient Voices Group – a network of bowel cancer patients who are willing to offer telephone or local support to other patients, and to share their experiences of the disease.

Beating Bowel Cancer is a registered charity number 1063614.

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