



Beating Bowel Cancer response to Multiple Technology Appraisal (MTA) Consultation

Cetuximab (mono- or combination chemotherapy), bevacizumab (combination with non-oxaliplatin chemotherapy) and panitumumab (monotherapy) for the treatment of metastatic colorectal cancer after first-line chemotherapy (review of technology appraisal 150 and part-review of technology appraisal 118)

Beating Bowel Cancer is dedicated to raising awareness of symptoms, promoting early diagnosis and encouraging open access to treatment choice for those affected by bowel cancer. The charity represents bowel cancer patients throughout the UK, and works hard to ensure that patients are fully informed about all treatment choices which may be available to them.

We also promote equality of choice and access to specialist opinion and treatment modalities, regardless of where patients live. Our mission is reflected in the principles of the government's Improving Outcomes Strategy for Cancer.

Beating Bowel Cancer offers a variety of support services to patients, their families and carers through online support and a confidential nurse advice line. The Patient Voices group is the only UK national patient-to patient network for people affected by bowel cancer. The group has expanded to include close relatives and carers.

Setting the scene for bowel cancer

Bowel cancer is the UK's second biggest cancer killer. Of the 100 people diagnosed every day, almost 50 will die. However advances in treatment in recent years mean that bowel cancer can be beaten if it is diagnosed at an early stage. A study by the National Cancer Intelligence Network found that 93.2% of patients diagnosed with early stage bowel cancer will survive five years from diagnosis compared to just 6.6% of patients diagnosed with late stage disease.¹

Advances in treatment have made bowel cancer a more manageable condition. However, not all treatments are available to all patients. For example, not all patients with a more advanced disease are able to gain access to the drugs their clinicians wish to prescribe. Access to cetuximab is a vital treatment at a stage when there are limited options and short life expectancy.

Access to treatments

Improving access to – and the uptake of – best practice in bowel cancer treatments will also be critical to improving outcomes at every stage of the pathway.

For many patients with early stage bowel cancer, there is now a range of treatments available with comparable clinical efficacy but different side effect / recovery profiles. These include the choice of open or laparoscopic surgery and oral or intravenous chemotherapy. Patients, particularly those with more advanced cancer, should also have access to the treatments which their clinician, informed by the evidence base and published guidelines, feels has potential benefit for them.

Beating Bowel Cancer is aware of groups of patients who have benefited significantly from access to cetuximab, in combination with chemotherapy or as monotherapy in the third and subsequent line setting. The case study below highlights the good quality of life a patient can experience with cetuximab.

A PATIENTS STORY

"I had no idea how ill I was when I started feeling constipated on holiday. Initially I thought it was nothing to worry about, but it just kept getting worse until I felt I had to keep rushing off to the toilet every 30 minutes, even though I couldn't "go" when I got there.

I went to see my GP as soon as I got home, and he referred me to a specialist straight away, thinking I had a polyp. It was a huge shock to learn that not only did I have a large tumour in my rectum, but also that it had spread right to my liver. The radiologist said he did not think it was operable. I had an anterior resection of the affected part of my bowel done.

Then, luckily, I was able to take part in a clinical trial and was given a punishing round of chemotherapy plus a new monoclonal antibody, cetuximab. It took 6 weeks to recover from the operation to remove the tumour from my bowel, and I had a temporary colostomy for 4 months. At the same time, I was having chemotherapy treatment with 5FU and oxaliplatin, combined with cetuximab, which continued for a total of 6 months.

But all the time the follow up scans showed the numbers of lesions in my liver reducing, which gave me hope. In fact, the treatment worked so amazingly well for me that after 6 months the surgeons were delighted to find that not only had all signs of the rectal tumour completely gone, but also that the liver was completely clear of all cancer too. Since then, I have never looked back, and I am just getting stronger and stronger."

On access to treatment, the options available to patients change significantly, allowing time for:

- Improvement in the overall performance status
- Initiation and sustained remission from disease progression
- Demonstration of clinically significant shrinking of the tumour
- Referral to specialists in other disciplines for symptom control and metastatic disease management
- Enrolment in Clinical Trials, including other novel treatment modalities
- Potential to increase overall survival, even modestly, enabling the patient and their family to put their personal affairs in order.

The result of a positive NICE appraisal will have a positive impact on the psychological state of patients and their families; there are so few options available to them at this very advanced stage. However, if NICE applies the supplementary advice for appraising end of life treatments (End of Life criteria) cetuximab in combination with chemotherapy and monotherapy should be judged as a cost effective use of resources.

End of life criteria:

1. There is sufficient evidence to indicate that the treatment offers an extension of life (of greater than 3 months)
2. Treatment is indicated for patients with a short life expectancy (less than 24 months)
3. The treatment is indicated for small populations (the size of which is not specified by NICE)

When these conditions are met, the Appraisal committee will consider:

- The impact of giving great weight to QALYS achieved in the later stages of terminal diseases
- The magnitude of the additional weight that would need to be assigned to the QALY benefits in this patient group for the cost effectiveness of the technology to fall within the current threshold range.

However, there are regional variations in obtaining access to the drugs. A number of networks in the UK have already approved the use of cetuximab as a third line treatment for KRAS wild-type mCRC patients ahead of NICE guidance or are in the process of providing funding through the Interim Cancer Drugs Fund (and most likely through the full Cancer Drugs fund from April 2011).



This inevitably leads to variations in treatment access across the NHS with some Trusts allowing access to cetuximab therapy in the third line setting, and others being forced to appeal to exceptional case panels causing anxiety and distress to patients.

Liver Mets Programme

Over the last year Beating Bowel Cancer has been developing a programme to improve outcomes and save more lives for people diagnosed with liver metastases. We have been working with clinicians and stakeholders, from across all disciplines and specialities, to identify key issues in the patient pathway for the management of metastatic liver disease from a primary colorectal cancer. This project will encourage oncology and colorectal teams to consider automatic referral to specialist liver MDTs for every patient with a new diagnosis of liver metastases.

The patient pathway has been reviewed and critiqued by a diverse cross-section of medical and clinical practitioners as well as the Beating Bowel Cancer Medical Board, to ensure a broad agreement on what is considered to be best practice. Included in this guidance is a very strong recommendation for clinicians to be able to prescribe cetuximab as both 2nd and 3rd line treatment for both liver limited disease and extra-hepatic metastases. It is clear that while PCTS in some parts of the country are currently able to make the drug available through the interim cancer drugs fund, the total coverage of equality in access is estimated to only be around 60% by leading oncologists within the group.

Much is made of the importance of individualised plans of care and disease management within all of the recent white papers released by government, including Liberating the NHS and the Improving Outcomes: A Strategy for Cancer (IOSC). Patient reported outcomes will be the measure of success, and through our "Liver metastases project: Saving Lives" we aim to encourage oncologists and colorectal teams to make an automatic referral of every patient with liver metastases for review by a specialist liver MDT. The expertise of the liver MDT will include hepatobiliary surgeons and specialist radiographers able to make expert judgements on potentially resectable disease, which could be rendered operable by treatment with cetuximab, even as a 2nd or 3rd line intervention. Where there is clear indication that the use of the medications will be instrumental in successfully downstaging tumours to make them resectable or open to other treatment modalities, there will be a greater evidence base for the prescription of cetuximab in a controlled way that can be audited and evaluated, helping to accrue evidence in much greater numbers than has previously been possible.

Summary

We have many supporters who have lived for many years with advanced bowel cancer, having had access to non-NICE approved treatment options, including cetuximab in the 3rd line setting, and we believe that widespread involvement and multi-disciplinary support in this project will help to maximise the adoption of the resulting pathway in the NHS, and hence improve the outcomes in terms of overall survival for a greater number of patients in the most cost efficient way.



As a patient focused 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 recognize that costs have to be taken into consideration in this financially challenging time, we strongly recommend that the re-review fully considers the wider and crucial issues surrounding the value of prolonged quality of life and the consequences of denying patients a treatment which could result in them being disease-free after treatment and surgery.

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ⁱ National Cancer Intelligence Network, Colorectal Cancer by Survival Stage, webpage:
http://library.ncin.org.uk/docs/090623-NCIN-colorectal_survival-databriefing.pdf Accessed September 2010