

Rare bowel cancer treatment combo gets initial no for NHS use in England

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A drug combination for people with a rare type of bowel cancer has received an initial rejection from the National Institute for Health and Care Excellence (NICE).

The targeted treatment combo of encorafenib and cetuximab was being considered for patients whose cancer has spread and has a rare error in the BRAF gene, once they've already had chemotherapy.

Cancer Research UK says the decision not to recommend the combination will be "disappointing" for those affected and urges manufacturers and the NHS to work together to resolve current uncertainties around its cost-effectiveness.

NICE decisions are usually adopted in Wales and Northern Ireland as well as England, so the decision is likely to affect patients in all three nations. Scotland has a separate process for reviewing drug decisions.

A 'step change' in bowel cancer treatment

Bowel cancers with this particular genetic mutation (BRAF V600E) are more likely to come back than [bowel](#) cancers that don't carry the DNA error. And once someone's cancer progresses or comes back, treatment is usually chemotherapy. Depending on their first round of treatment, this is usually either FOLFIRI or trifluridine–tipiracil.

Patients told NICE that the targeted treatment combo of encorafenib and cetuximab could significantly improve people's quality of life, as the combo had more manageable side effects compared with these current chemotherapy treatments.

And clinicians said that that the treatment represented a 'step change' in the treatment of BRAF V600E-positive bowel cancer, being the first combination to target the mutation. There has been little improvement in survival for this type of bowel cancer in recent years, despite improvements in bowel [cancer](#) survival overall.

Late-stage clinical trial results showed an overall survival benefit, with people taking the targeted duo living for an average of nine months compared to 5.4 months for those taking one of two different combinations of chemotherapy and cetuximab.

"Patients and clinicians told NICE this [drug combination](#) offers an important new way of treating the disease and could significantly improve patients' quality of life. But NICE's concerns about the results of the clinical trial mean it remains unclear how much benefit the combination offers patients over existing treatment options."—Emlyn Samuel, head of policy development at Cancer Research UK.

Concern over trial design

In delivering its initial recommendation however, NICE expressed concerns over the trial's design, which made it hard to judge whether NHS patients would see the same level of benefit from the combo as in the trial's results.

Firstly, it noted the combinations used in the control arm of the trial are not used in NHS care, and it didn't find enough [reliable data](#) to remodel the findings against standard NHS treatments. This meant it couldn't be

confident how much 'extra' benefit patients taking the new combo instead of these standard treatments would get.

And secondly, NICE explained that patients with disease progression on the trial received various follow-on treatments that would not be offered on the NHS. This meant NICE didn't have good data they could use to estimate how long patients whose disease progressed after receiving the new combo on the NHS might survive.

These uncertainties meant that NICE couldn't be confident the [combination](#) would be value for money and a good use of NHS budgets. The decision will be reviewed later this year.

"We urge NHS England, NICE and the drugs' manufacturers to continue working together to help resolve these uncertainties and ensure all patients can be offered the best possible treatment as quickly as possible," said Samuel.

More information: NICE (2020) Encorafenib in dual or triple therapy for previously treated BRAF V600E mutation-positive metastatic colorectal cancer: [www.nice.org.uk/guidance/index ... id-ta10496/documents](http://www.nice.org.uk/guidance/index...id-ta10496/documents)

Provided by Cancer Research UK

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