NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Bevacizumab (originator and biosimilars) with fluoropyrimidine-based chemotherapy for untreated metastatic colorectal cancer (including review of TA212) [ID6465]

Final scope

Remit

To appraise the clinical and cost effectiveness of bevacizumab (originator and biosimilars) with fluoropyrimidine-based chemotherapy within its marketing authorisation for treating adults with untreated metastatic carcinoma of the colon or rectum.

Evaluation objective

This appraisal is limited to consideration of bevacizumab (originator and biosimilars) in people with previously untreated metastatic disease who would normally get chemotherapy. People who are candidates for targeted treatments or immunotherapies are excluded.

The technology

Bevacizumab (Avastin, Roche [originator] and biosimilars) with fluoropyrimidine-based chemotherapy has a marketing authorisation for treating adults with metastatic carcinoma of the colon or rectum.

Intervention(s)	Bevacizumab originator and biosimilars in combination with fluoropyrimidine-based chemotherapy
Population(s)	People with untreated metastatic carcinoma of the colon or rectum
Comparators	• Folinic acid plus fluorouracil plus oxaliplatin (FOLFOX) • Folinic acid plus fluorouracil plus irinotecan (FOLFIRI) • Capecitabine plus oxaliplatin (CAPOX) • Capecitabine
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rates • adverse effects of treatment • health-related quality of life

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** 'Bevacizumab and cetuximab for the treatment of metastatic colorectal cancer' (2012) NICE technology appraisal guidance TA118. 'Bevacizumab in combination with oxaliplatin and either fluorouracil plus folinic acid or capecitabine for the treatment of metastatic colorectal cancer' (2010) NICE technology appraisal guidance TA212. 'Laparoscopic surgery for colorectal cancer' (2006) NICE technology appraisal guidance TA105. 'Guidance on the use of capecitabine and tegafur with uracil for metastatic colorectal cancer' (2003) NICE technology appraisal guidance TA61. **Related NICE guidelines:** Colorectal cancer (2021) NICE guideline NG151 Colorectal cancer prevention: colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas (2022) NICE guideline CG118

	Related interventional procedures: Selective internal radiation therapy for unresectable colorectal metastases in the liver (2020) NICE interventional procedures guidance 672 Radiofrequency ablation for colorectal liver metastases (2009) NICE interventional procedures guidance 327 **Related quality standards:** Colorectal cancer (2022) NICE quality standard 20. Suspected cancer (2017) NICE quality standard 124.
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2023) Manual for prescribed specialist services (2023/2024)

The review will be conducted through the proportionate approach as outlined in Appendix A.

Appendix A – Biosimilar pilot process note

NICE is currently working on developing and piloting different approaches to our biosimilar appraisal processes against the process set out in the **health technology evaluation manual**. We have selected ID6465 bevacizumab (Avastin and biosimilars) with fluoropyrimidine-based chemotherapy for untreated metastatic colorectal cancer as a pilot for this "test and learn" approach to biosimilar appraisals.

We believe efficiencies can be made to the process which would result in a faster route to a recommendation, quicker access for patients and a less resource-intensive process for all involved.

We will use an expeditied version of the multiple technology appraisal (MTA) process. That is, the EAG will and will use a pragmatic approach for reviewing the evidence and developing a health economic model within a shorter than usual timeline. All subsequent steps will be in line with the usual MTA process.

As we are in the early stages of piloting the approach, further details will be developed as the pilot appraisal progresses. NICE welcomes feedback from stakeholders on new approaches.