NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Durvalumab in combination for neoadjuvant and adjuvant treatment of resectable gastric and gastro-oesophageal junction cancer ID6374

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of durvalumab within its marketing authorisation for treating resectable gastric and gastro-oesophageal junction cancer.

Background

Gastric cancer is a malignant tumour arising from cells in the stomach. Gastro-oesophageal junction cancer describes cancers where the centre of the tumour is less than 5cm above or below where the oesophagus meets the stomach. The most common histological subtype of gastric and gastro-oesophageal junction cancer is adenocarcinoma, with 95% of gastric cancers being adenocarcinomas.

Initial symptoms of gastric or gastro-oesophageal junction cancer are vague and are similar to other stomach conditions. Symptoms of advanced stages may include a lack of appetite and subsequent weight loss, fluid in the abdomen, vomiting blood, blood in the stool or black stool. Because of the nature of symptoms, gastric and gastro-oesophageal junction cancer are often diagnosed at an advanced stage. Between 2018 and 2020 there were an average of 5,250 new stomach cancer diagnoses in England each year.[1] Gastric cancer is more common in men than women.

For people with oesophago-gastric junctional adenocarcinoma who are having surgical resection, NICE guideline 83 recommends offering a choice of:

- chemotherapy, before or before and after surgery **or**
- chemoradiotherapy, before surgery.

For people with gastric cancer who are having surgical resection, NICE guideline 83 recommends offering chemotherapy before and after surgery. Chemotherapy or chemoradiotherapy after surgery should be considered for people who did not have chemotherapy before surgery.

NICE technology appraisal 746 recommends for nivolumab for the adjuvant treatment of completely resected oesophageal or gastro-oesophageal junction cancer in adults who have residual disease after previous neoadjuvant chemoradiotherapy.

The technology

Durvalumab (Imfinzi, AstraZeneca) does not currently have a marketing authorisation in the UK for treating resectable gastric or gastro-oesophageal junction cancer. It has been studied in a clinical trial in people with resectable gastric or gastro-oesophageal junction cancer compared with placebo in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) chemotherapy before and after surgery. Durvalumab monotherapy followed adjuvant durvalumab combination therapy

Intervention(s)	Durvalumab with chemotherapy
Population(s)	Adults with resectable gastric or gastro-oesophageal junction cancer
Subgroups	If evidence allows, results by level of PD-L1 expression will be considered
Comparators	Established clinical management without durvalumab, including but not limited to: • Chemotherapy, before and/or after surgery • Chemoradiotherapy, before and/or after surgery • Nivolumab, after surgery in adults who have residual disease after previous neoadjuvant chemoradiotherapy
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • event-free survival • response rate • 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. 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.

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:** Nivolumab for adjuvant treatment of resected oesophageal or gastro-oesophageal junction cancer. (2021) NICE technology appraisal guidance 746. Pembrolizumab with trastuzumab and chemotherapy for untreated locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma. (2024) NICE technology appraisal guidance 983. Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced HER2-negative gastric or gastro-oesophageal junction adenocarcinoma. (2024) NICE technology appraisal guidance 997. Pembrolizumab with trastuzumab and chemotherapy for untreated locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma. (2024) NICE technology appraisal guidance 983. Zolbetuximab with chemotherapy for untreated claudin-18.2-positive HER2-negative unresectable advanced gastric or gastro-oesophageal junction adenocarcinoma (2025) NICE technology appraisal guidance 1046. **Related technology appraisals in development:** Bemarituzumab with chemotherapy for untreated inoperable HER2-negative advanced gastric or gastro-oesophageal junction cancer. [ID6481] Publication date to be confirmed. Tislelizumab with chemotherapy for untreated unresectable or metastatic gastric or gastro-oesophageal junction cancer. [ID6157] Publication date to be confirmed. **Related NICE guidelines:** Oesophago-gastric cancer: assessment and management in adults. (updated 2023) NICE guideline NG83. **Related quality standards:** Oesophago-gastric cancer. (2018) QS176.

Questions for consultation

Where do you consider durvalumab will fit into the existing care pathway for resectable gastric and gastro-oesophageal junction cancer?

Will durvalumab be used in combination with chemotherapy both in the neoadjuvant and adjuvant setting, will durvalumab monotherapy be an option in the adjuvant setting?

Which chemotherapy and chemoradiotherapy regimens would be used for neoadjuvant and adjuvant treatment of gastric and gastro-oesophageal junction cancer?

What treatments are currently established clinical management in the NHS for treating resectable gastric and gastro-oesophageal junction cancer?

Would durvalumab be given as both neoadjuvant and adjuvant treatment? Are there situations where durvalumab would be given either only as neoadjuvant treatment or only as adjuvant treatment?

Please select from the following, will durvalumab be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would durvalumab be a candidate for managed access?

Do you consider that the use of durvalumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which durvalumab will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. Office for National Statistics (2022) Cancer Registration Statistics, England 2020 Accessed July 2025.