Appendix B

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 adenocarcinoma

Final scope

Remit/evaluation objective

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

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 adenocarcinoma are non-specific 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 adenocarcinoma 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 adenocarcinoma. It has been studied in a clinical trial in people with resectable gastric or gastro-oesophageal junction adenocarcinoma 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 (FLOT) before surgery (neoadjuvant) and after surgery (adjuvant), then adjuvant durvalumab monotherapy
Population(s)	Adults with resectable gastric or gastro-oesophageal junction adenocarcinoma
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 (FLOT), before and after surgery • For people with gastro-oesophageal junction adenocarcinoma o Nivolumab, after surgery in adults who have residual disease after previous neoadjuvant chemoradiotherapy
Outcomes	The outcome measures to be considered include: • overall 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.

References

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