

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
Health Technology Evaluation

Trastuzumab deruxtecan for treating HER2-positive advanced gastric or gastro-oesophageal junction adenocarcinoma after trastuzumab-based treatment (review of TA879)

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of trastuzumab deruxtecan for treating HER2-positive advanced gastric or gastro-oesophageal junction adenocarcinoma after trastuzumab-based treatment.

Background

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

Stomach cancer is more common in men than women, with approximately 3,476 cases diagnosed in men, and 1,978 cases in women in England in 2023.¹ Around half of all new cases of gastric cancer in the UK are diagnosed in people aged 75 years and over.² Oesophageal cancer is also more common in men than women, with approximately 5,532 cases diagnosed in men, and 2,387 cases in women in England in 2023.¹ Around 41% of all new cases of oesophageal cancer in the UK are diagnosed in people aged 75 and over.³

Initial symptoms of gastric or oesophageal cancer are vague and are similar to other stomach conditions, but 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. The 5-year survival for people diagnosed with stomach cancer and oesophageal cancer between 2016 and 2020 was 23.9% and 18%, respectively.⁴

Over the past few years there has been an increase in incidence of tumours at the junction of the oesophagus and stomach. These tend to come from changes in the lining of the oesophagus, in turn leading to adenocarcinoma of the lowest part of the oesophagus, which goes across the gastro-oesophageal junction. The aim of treatment in advanced or metastatic gastric, gastro-oesophageal junction cancer or oesophageal adenocarcinoma is primarily palliative; to prevent progression, extend survival and relieve symptoms with minimal adverse effects

For people who have untreated HER2-positive metastatic gastric or gastrooesophageal junction adenocarcinoma, that express high levels of HER2 as defined by a positive immunohistochemistry score of 3 (IHC3 positive), [NICE](#)

Draft scope for the evaluation trastuzumab deruxtecan for treating HER2-positive advanced gastric or gastro-oesophageal junction adenocarcinoma after trastuzumab-based treatment (review of TA879) ID6680

[technology appraisal 208 recommends](#) trastuzumab in combination with cisplatin and capecitabine or fluorouracil.

[NICE technology appraisal 191](#) recommends capecitabine in combination with a platinum-containing agent as an option for inoperable untreated advanced gastric cancer.

[NICE clinical guideline 83](#) recommends chemotherapy combination regimens for people who have a performance status 0 to 2 and no significant comorbidities. Chemotherapy regimens include doublet treatment with fluorouracil or capecitabine in combination with cisplatin or oxaliplatin or triplet treatment with fluorouracil or capecitabine in combination with cisplatin or oxaliplatin plus epirubicin.

The technology

Trastuzumab deruxtecan (Enhertu, Daiichi Sankyo) is indicated for the treatment of adult with advanced HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen.

Intervention(s)	Trastuzumab deruxtecan
Population(s)	Adults with advanced HER2-positive gastric or gastroesophageal junction adenocarcinoma who had a prior trastuzumab-based regimen
Subgroups	<p>If the evidence allows, the following subgroups will be considered:</p> <ul style="list-style-type: none"> • HER2 status by IHC score • Line of treatment • ECOG performance status
Comparators	<ul style="list-style-type: none"> • Palliative chemotherapy • Best supportive care • Trifluridine–tipiracil (for people at third line treatment or beyond)
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • overall survival • progression-free survival • response rates • adverse effects of treatment • health-related quality of life.

Draft scope for the evaluation trastuzumab deruxtecan for treating HER2-positive advanced gastric or gastro-oesophageal junction adenocarcinoma after trastuzumab-based treatment (review of TA879) ID6680

<p>Economic analysis</p>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
<p>Other considerations</p>	<p>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.</p>
<p>Related NICE recommendations</p>	<p>Related technology appraisals:</p> <p>Pembrolizumab with trastuzumab and chemotherapy for untreated locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma (2024). NICE technology appraisal TA983</p> <p>Trifluridine–tipiracil for treating metastatic gastric cancer or gastro-oesophageal junction adenocarcinoma after 2 or more treatments (2022). NICE technology appraisal 852</p> <p>Trastuzumab for the treatment of HER-2 positive metastatic gastric cancer (2010). NICE technology appraisal 208</p> <p>Capecitabine for the treatment of advanced gastric cancer (2010). NICE technology appraisal 191</p> <p>Related technology appraisals in development:</p> <p>None.</p> <p>Related NICE guidelines:</p> <p>‘Oesophago-gastric cancer: assessment and management in adults’ (2018). NICE guideline 83. Last reviewed August 2022.</p> <p>Related Interventional Procedures:</p> <p>‘Laparoscopic gastrectomy for cancer’ (2008). NICE interventional procedures guidance 269.</p>

Draft scope for the evaluation trastuzumab deruxtecan for treating HER2-positive advanced gastric or gastro-oesophageal junction adenocarcinoma after trastuzumab-based treatment (review of TA879) ID6680

	Related Quality Standards: Oesophago-gastric cancer (2018) NICE quality standard 176
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Questions for consultation

Where do you consider trastuzumab deruxtecan will fit into the existing care pathway HER2-positive advanced gastric or gastro-oesophageal junction cancer?

Have all relevant comparators been included in the draft scope?

What treatment regimens might palliative chemotherapy include?

Could you estimate what proportions of people whose cancer has progressed after prior trastuzumab treatment would have the various listed comparators (or any other comparators not listed)?

Which ICD codes would most accurately capture the population for this appraisal (please give ICD-O-3 codes if this would help better reflect the specific population)?

Do you consider that any real-world evidence (for example SACT data) could help inform this appraisal? If yes, please give details.

Please select from the following, will trastuzumab deruxtecan 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 trastuzumab deruxtecan be a candidate for managed access?

Do you consider that the use of trastuzumab deruxtecan 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.

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 trastuzumab deruxtecan will be licensed;

Draft scope for the evaluation trastuzumab deruxtecan for treating HER2-positive advanced gastric or gastro-oesophageal junction adenocarcinoma after trastuzumab-based treatment (review of TA879) ID6680

- 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. NHS Digital. [Cancer Registration Statistics, England, 2023](#). Accessed: February 2026
2. Cancer Research UK. [Stomach cancer incidence statistics](#). Accessed February 2026.
3. Cancer Research UK. [Oesophageal cancer incidence statistics](#). Accessed February 2026
4. NHS England. Digital [Cancer Survival in England, cancers diagnosed 2016 to 2020, followed up to 2021](#). Accessed February 2026.

Draft scope for the evaluation trastuzumab deruxtecan for treating HER2-positive advanced gastric or gastro-oesophageal junction adenocarcinoma after trastuzumab-based treatment (review of TA879) ID6680