NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
Health Technology Evaluation

Tislelizumab with chemotherapy for untreated advanced oesophageal squamous cell cancer

Final scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of tislelizumab within its marketing authorisation for treating unresectable, locally advanced or metastatic oesophageal squamous cell cancer that has not been previously treated.

Background

Oesophageal cancer is a malignant tumour arising from cells lining the oesophagus (gullet), which is the muscular tube through which food passes from the throat to the stomach. The two main types of oesophageal cancer are squamous cell carcinoma and adenocarcinoma. Cancers in the upper or middle oesophagus are usually squamous cell cancer, whereas cancers in the lower oesophagus including where the oesophagus joins the stomach, are usually adenocarcinomas. The most common symptom of oesophageal cancer is difficulty swallowing. Other symptoms include food regurgitation, nausea or vomiting, unexplained weight loss, pain in the chest, back or throat, and persistent indigestion or cough.

Oesophageal cancer is more common in men than women. In 2017-19, there were 2,900 new diagnoses in women and 6,500 in men (a total of 9,400 new cases) in the UK. The risk of developing oesophageal cancer increases with age. Around 41% of all new cases in the UK are diagnosed in people aged 75 and over (2017-2019).[1] Because of the nature of symptoms, oesophageal cancer is often diagnosed at an advanced stage. On average, 70-80% are diagnosed at stage 3 (locally advanced) or 4 (metastatic). For adults diagnosed between 2013 and 2017 in England, the 1-year survival rate for people with oesophageal cancer is around 47% and 5-year survival rate is 18%.[2]

The aim of treatment in advanced or metastatic oesophageal cancer is primarily palliative. NICE clinical guideline (NG83) 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.

NICE technology appraisal 737 recommends pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy as an option for untreated locally advanced unresectable or metastatic carcinoma of the oesophagus whose tumours express PD-L1 with a combined positive score (CPS) of 10 or more. NICE technology appraisal 865 recommends nivolumab with fluoropyrimidine-based and platinum-based combination chemotherapy as an option for untreated unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma in adults whose

tumours express PD-L1 at a level of 1% or more only if pembrolizumab plus chemotherapy is not suitable.

The technology

Tislelizumab (Tevimbra, BeiGene) in combination with chemotherapy does not currently have a marketing authorisation in the UK for the treatment of adult patients with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma. It was studied in a clinical trial in people with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma.

Intervention(s)	Tislelizumab with chemotherapy
Population(s)	Adults with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma
Comparators	• chemotherapy alone, which includes doublet treatment with fluorouracil or capecitabine plus cisplatin or oxaplatin For people whose tumours express PD-L1 • nivolumab with platinum- and fluoropyrimidine-based chemotherapy • pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rate • adverse effects of treatment • health-related quality of life.
Economic analysis	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.

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:** Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced HER2-negative gastric or gastro-oesophageal junction adenocarcinoma. NICE Technology appraisal guidance 997 Nivolumab with fluoropyrimidine- and platinum-based chemotherapy for untreated unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma (2023). NICE Technology appraisal guidance 865. Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced oesophageal and gastro-oesophageal junction cancer (2021). NICE Technology appraisal guidance 737. Nivolumab for previously treated unresectable advanced or recurrent oesophageal cancer (2021). NICE Technology appraisal guidance 707. **Related appraisals in development:** Tislelizumab for treating unresectable advanced oesophageal squamous cell cancer after platinum-based chemotherapy. NICE technology appraisal guidance [ID4070]. Expected publication date: TBC **Related NICE guidelines:** Oesophago-gastric cancer: assessment and management in adults (2018). NICE guideline 83. Suspected cancer: recognition and referral (2015, updated 2021). NICE guideline 12. Barrett's oesophagus: ablative therapy (2010). NICE clinical guideline 106
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 105 – Specialist cancer services (adults). NHS England commissions upper gastrointestinal cancers, page 275. NHS England (2018) 2013/14 NHS standard contract for cancer: oesophageal and gastric (adult) Department of Health and Social Care (2016) NHS outcomes framework 2016 to 2017

	NHS Digital (2022) NHS Outcomes Framework England, March 2022 Annual Publication

Questions for consultation

Where do you consider tislelizumab will fit into the existing care pathway untreated advanced oesophageal squamous cell cancer?

Please select from the following, will tislelizumab 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.

Should any other comparators for tislelizumab be included in scope?

Would tislelizumab be a candidate for managed access?

Do you consider that the use of tislelizumab 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 tislelizumab 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. Cancer Research UK. Oesophageal cancer incidence statistics. Accessed February 2025

2. NHS England. Digital, Cancer Survival in England, cancers diagnosed 2016 to 2020, followed up to 2021. Accessed February 2025.