

**NATIONAL INSTITUTE FOR HEALTH AND CARE  
EXCELLENCE**

**Final draft guidance**

**Pembrolizumab for neoadjuvant and adjuvant  
treatment of resectable locally advanced head  
and neck squamous cell carcinoma**

**1 Recommendation**

1.1 Pembrolizumab can be used, within its marketing authorisation, as an option to treat resectable locally advanced head and neck squamous cell carcinoma in adults whose tumours express PD-L1 with a combined positive score of 1 or more:

- as neoadjuvant treatment
- then as adjuvant treatment with radiotherapy, with or without cisplatin
- then as monotherapy.

Pembrolizumab can only be used if the company provides it according to the commercial arrangement (see [section 2](#)).

**What this means in practice**

Pembrolizumab must be funded in the NHS in England for the condition and population in the recommendations, if it is considered the most suitable treatment option. Pembrolizumab must be funded in England within 90 days of final publication of this guidance.

There is enough evidence to show that pembrolizumab provides benefits and value for money, so it can be used routinely across the NHS in this population.

### **Why this recommendation was made**

Usual treatment for resectable locally advanced head and neck squamous cell carcinoma is surgery. After surgery (known as adjuvant treatment) people can have radiotherapy with or without cisplatin. There are no treatments available before surgery (known as neoadjuvant treatment).

Clinical trial evidence shows that neoadjuvant and adjuvant pembrolizumab increases how long people have before their condition gets worse. The evidence also suggests that it may increase how long people live compared with usual treatment.

The most likely cost-effectiveness estimates for neoadjuvant and adjuvant pembrolizumab are within the range that NICE considers an acceptable use of NHS resources. So, it can be used.

For all the evidence, see the [committee papers](#). For more information on streamlined evaluations, see [NICE's technology appraisal and highly specialised technologies guidance manual](#).

## **2 Information about pembrolizumab**

### **Marketing authorisation indication**

- 2.1 Pembrolizumab (Keytruda, MSD) as monotherapy is indicated 'for the treatment of resectable locally advanced head and neck squamous cell carcinoma as neoadjuvant treatment, continued as adjuvant treatment in combination with radiation therapy with or without concomitant cisplatin and then as monotherapy in adults whose tumours express PD-L1 with a CPS  $\geq$  1'.

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## Dosage in the marketing authorisation

- 2.2 The dosage schedule is available in the [summary of product characteristics for pembrolizumab](#).

## Price

- 2.3 The list price is £2,630.00 for a 25 mg per 1-ml concentrate for solution for infusion vial (excluding VAT; BNF online accessed February 2026).
- 2.4 The company has a commercial arrangement (commercial access agreement). This makes pembrolizumab available to the NHS with a discount. The size of the discount is commercial in confidence.

## Sustainability

- 2.5 Information on the Carbon Reduction Plan for UK carbon emissions for MSD will be included here when guidance is published.

## 3 Implementation

- 3.1 Section 7 of the [National Institute for Health and Care Excellence \(Constitution and Functions\) and the Health and Social Care Information Centre \(Functions\) Regulations 2013](#) requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 90 days of its date of publication.
- 3.2 Chapter 2 of [Appraisal and funding of cancer drugs from July 2016 \(including the new Cancer Drugs Fund\) – A new deal for patients, taxpayers and industry](#) states that for those drugs with a draft recommendation for routine commissioning, interim funding will be available (from the overall Cancer Drugs Fund budget) from the point of marketing authorisation, or from release of positive draft guidance, whichever is later. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early

Access to Medicines Scheme designation or cost comparison evaluation), at which point funding will switch to routine commissioning budgets. The [NHS England Cancer Drugs Fund list](#) provides up-to-date information on all cancer treatments recommended by NICE since 2016. This includes whether they have received a marketing authorisation and been launched in the UK.

- 3.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 60 days of the first publication of the final draft guidance.
- 3.4 When NICE recommends a treatment ‘as an option’, the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has resectable, locally advanced, head and neck squamous cell carcinoma and the healthcare professional responsible for their care thinks that pembrolizumab is the right treatment, it should be available for use, in line with NICE’s recommendations.

## **4 Evaluation committee members and NICE project team**

### **Evaluation committee members**

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered as a streamlined evaluation by the lead team of [committee D](#), and the committee C chair.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

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## **Chair**

**James Fotheringham**

Chair, technology appraisal committee C

## **NICE project team**

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager, and an associate director or principal technical adviser.

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