NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Cemiplimab for adjuvant treatment of high-risk cutaneous squamous cell carcinoma after surgery and radiotherapy ID6659

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of cemiplimab as an adjuvant therapy within its marketing authorisation for treating high-risk cutaneous squamous cell carcinoma after surgery and radiotherapy.

Background

Cutaneous squamous cell carcinoma (SCC) is a non-melanoma form of skin cancer that starts in the cells lining the top of the epidermis (the outer layer of the skin), their role is to produce keratin which protects the outer layer of the skin. The skin constantly sheds these cells.[1] Cutaneous SCC presents itself on the surface of the skin as a firm pink lump with a rough surface and are tender to touch.[1] There is a small risk (up to 5%) for cutaneous SCC lesions to spread but if they do, then they spread deeper into layers of the skin as well as metastasise across the body.[2]

Cutaneous SCC accounts for about 20% of skin cancers and 23% of non-melanoma skin cancers.[3] Cutaneous SCC is the second most common cancer in the UK, with over 50,000 people diagnosed every year.[4] 155,985 new cases of non-melanoma skin cancer were reported in the UK, from 2016 to 2018.[4] Deaths from cutaneous SCC are rare, however the prognosis for metastatic cutaneous SCC is poor, with a median overall survival of less than 2 years.[5]

High-risk cutaneous SCC is defined by stage node-negative (no regional lymph node metastasis) and has high-risk features associated with sub-clinical metastasis (cancer that has spread from the primary tumour to other sites but are not detectable by clinical examination or standard imaging). These features include the tumour extending beyond the basement membrane with a depth of invasion greater than 2 mm, exhibiting poor histological differentiation, and occurring in anatomically high-risk areas of the body.[6] People who have cutaneous SCC with these high-risk features are at risk for recurrence after definitive local therapy.[7]

Surgery is the main treatment for non-melanoma skin cancer. For cutaneous SCC tumours that recur, further surgery, with or without radiotherapy, may be used.[8] There are currently no NICE-recommended adjuvant treatment options for people with high-risk cutaneous SCC after surgery and radiation therapy.

For locally advanced and metastatic disease, the European consensus-based interdisciplinary guideline suggests alternative treatment options if surgery is not feasible such as radiotherapy and chemotherapy.[5] NICE technology appraisal guidance TA802 recommends cemiplimab as an option for treating metastatic or locally advanced cutaneous squamous cell carcinoma in adults when curative surgery or curative radiotherapy is not suitable.

The technology

Cemiplimab (Libtayo; Regeneron Pharmaceuticals) does not have a marketing authorisation for the treatment of high-risk cutaneous squamous cell carcinoma after surgery and radiotherapy. It does have a marketing authorisation for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation.

Intervention(s)	Cemiplimab (as an adjuvant treatment)
Population(s)	Adults with high-risk cutaneous SCC who have had surgery and radiation therapy
Comparators	Established clinical management without cemiplimab, which may include: • radiation therapy
Outcomes	The outcome measures to be considered include: • disease-free survival • overall survival • response rate • duration of response • 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:** Cemiplimab for treating advanced cutaneous squamous cell carcinoma (2022) NICE technology appraisal guidance 802.

	Related technology appraisals in development: Pembrolizumab for adjuvant treatment of locally advanced cutaneous squamous cell carcinoma after surgery and radiotherapy. NICE technology appraisal guidance [ID6473] Publication date to be confirmed. **Related NICE guidelines:** Improving outcomes for people with skin tumours including melanoma (2006) NICE cancer service guideline CSG8. Last reviewed: May 2019. **Related interventional procedures:** Electrochemotherapy for primary basal cell carcinoma and primary squamous cell carcinoma (2014) NICE interventional procedures guidance IPG478. Photodynamic therapy for non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions) (2006) NICE interventional procedures guidance IPG155. **Related quality standards:** Skin cancer (2016) NICE quality standard QS130. Last updated January 2024.

Questions for consultation

Where do you consider cemiplimab will fit into the existing care pathway for high-risk cutaneous squamous cell carcinoma after surgery and radiotherapy?

Is it anticipated that cemiplimab would be used alongside radiation therapy for high-risk cutaneous squamous cell carcinoma?

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

Do you consider that the use of cemiplimab 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 cemiplimab 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

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2. Dema Reading (2025) Symptoms of Squamous Cell Carcinomas (SCC) [Accessed 8 December 2025]
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4. Cancer research UK (2025) Non-melanoma skin cancer statistics [Accessed 10 December 2025]
5. International trends in the incidence of cutaneous squamous cell carcinoma and melanoma, British Journal of Dermatology, Volume 190, Issue 4, April 2024, Page e40, https://doi.org/10.1093/bjd/ljae072
6. Burton, K.A., Ashack, K.A. & Khachemoune, A. Cutaneous Squamous Cell Carcinoma: A Review of High-Risk and Metastatic Disease. *Am J Clin Dermatol* 17, 491–508 (2016). https://doi.org/10.1007/s40257-016-0207-3
7. Rischin D, Porceddu S, Day F, et al. Adjuvant Cemiplimab or Placebo in High-Risk Cutaneous Squamous-Cell Carcinoma. *N Engl J Med*. 2025;393(8):774-785. doi:10.1056/NEJMoa2502449

8. Stratigos A, Garbe C, Lebbe C et al. ‘Diagnosis and treatment of invasive squamous cell carcinoma of the skin: European consensus-based interdisciplinary guideline’. Eur J Cancer. (2015) Volume 51, Issue 14, Pages 1989–2007. 2. Cancer Research UK (2017) Skin cancer