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

Final scope

Final 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.[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 is the second most common cancer in the UK, with over 50,000 people diagnosed every year.[3, 4] Whilst most cutaneous squamous cell carcinomas are well managed and do not spread, a small proportion metastasise and have a poor prognosis with a median overall survival of less than 2 years.[5]

There is no standard definition of high-risk cutaneous SCC. High-risk cutaneous SCC is commonly identified in clinical guidelines by the presence of nodal features (like nodal disease with extracapsular extension) and non-nodal features (such as perineural invasion), sub-clinical metastases (defined as cancer that has spread from the primary tumour to other sites but are not detectable by clinical examination or standard imaging) and advanced primary tumours (T4).[6,7] People who have cutaneous SCC with these high-risk features are at risk for recurrence after definitive local therapy.

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. Following completion of surgery and radiotherapy, cutaneous SCC is usually managed with routine clinical surveillance. Additional active anti-cancer treatment is not offered unless there is evidence of disease recurrence.[6]

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) has a marketing authorisation as a monotherapy for the adjuvant treatment of adult patients with cutaneous squamous cell carcinoma at high risk of recurrence after surgery and 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: • routine clinical surveillance
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.

References

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6. Keohane SG, Botting J, Budny PG, et al. British Association of Dermatologists guidelines for the management of people with cutaneous squamous cell carcinoma (2020). Br J Dermatol. 2021;184(3):401-14.

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