

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Cemiplimab for treating cutaneous squamous cell carcinoma

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of cemiplimab within its marketing authorisation for treating cutaneous squamous cell carcinoma.

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 cancers² and 23% of non-melanoma skin cancers³. Around 122,000 cases of non-melanoma skin cancer were registered in 2015 in England.² 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.⁴

Surgery is the main treatment for non-melanoma skin cancer. For locally advanced and metastatic disease, the European consensus-based interdisciplinary guideline⁴ suggests alternative treatment options if surgery is not feasible such as radiotherapy and chemotherapy (e.g. cisplatin, carboplatin, 5-fluorouracil and bleomycin). In addition, electrochemotherapy can be used for locally advanced lesions and EGFR inhibitors (e.g. cetuximab) can be considered as second line treatments after chemotherapy.⁴ The treatment used will depend on the type, size and location of the non-melanoma skin cancer.¹

The technology

Cemiplimab (Libtayo; Sanofi) is a fully human monoclonal antibody that blocks the programmed cell death-1 receptor (PD-1). This receptor is part of the immune checkpoint pathway, and blocking its activity may promote an anti-tumour immune response. It is administered intravenously.

Cemiplimab does not currently have a marketing authorisation in the UK for treating locally advanced or metastatic cutaneous squamous cell carcinoma (SCC). It has been studied in two clinical trials as monotherapy without an active comparator in adults with metastatic cutaneous SCC or with locally

advanced cutaneous squamous cell carcinoma who are not candidates for surgery.

Intervention	Cemiplimab
Population	People with metastatic cutaneous squamous cell carcinoma or locally advanced cutaneous squamous cell carcinoma in whom there is no curative local therapy.
Comparators	<ul style="list-style-type: none"> • Best supportive care • Chemotherapy (such as platinum based chemotherapy and fluorouracil)
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • progression-free survival • overall survival • response rate • duration of response • adverse effects of treatment • health-related quality of life.
Economic analysis	<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>Other considerations</p>	<p>If the evidence allows the following subgroups will be considered. These include:</p> <ul style="list-style-type: none"> • people with metastatic cutaneous squamous cell carcinoma, and • people with locally advanced cutaneous squamous cell carcinoma for whom there is no curative local therapy. <p>Guidance will only be issued in accordance with the marketing authorisation.</p> <p>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 and NICE Pathways</p>	<p>Related Guidelines: Improving outcomes for people with skin tumours including melanoma (2006) NICE cancer service guideline CSG8 Review date: March 2018</p> <p>Related Diagnostics guidance: VivaScope 1500 and 3000 imaging systems for detecting skin cancer lesions (2015) NICE diagnosticsguidance DG19</p> <p>Related Medical Technologies guidance: Ambulight PDT for the treatment of non-melanoma skin cancer (2011) NICE medical technologies guidance MTG6</p> <p>Related Interventional Procedures: Electrochemotherapy for primary basal cell carcinoma and primary squamous cell carcinoma (2014) NICE interventional procedures guidance IPG478</p> <p>Photodynamic therapy for non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions) (2006) NICE interventional procedures guidance IPG155</p> <p>Related Public Health Guidelines: Skin cancer prevention (2011) NICE guideline PH32 Last updated: February 2016</p> <p>Related Quality Standards: Skin cancer (2016) NICE quality standard QS130 http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp</p> <p>Related NICE Pathways:</p>

	<p>Skin cancer (2017) NICE Pathway</p> <p>Suspected cancer recognition and referral (2017) NICE Pathway</p>
Related National Policy	<p>NHS England (2017) Manual for Prescribed Specialised Services 2017/18. Chapter 105: Specialist cancer services (adults)</p> <p>Independent Cancer Taskforce (2015) Achieving world-class cancer outcomes: a strategy for England 2015-2020</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017 (published 2016): Domains 1, 4–5.</p>

References

1. NHS Choices (2017) Non-melanoma skin cancer [accessed at 05/02/2018] <https://www.nhs.uk/conditions/non-melanoma-skin-cancer/>
2. Cancer Research UK (2017) Skin cancer
3. National cancer Intelligence Network (2013) Non-melanoma skin cancer in England, Scotland, Northern Ireland, and Ireland
4. 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.
<http://www.eado.org/medias/Content/Files/2015-Stratigos-EurGuidelineSCC-EJC.pdf> [Accessed at 24/08/2018]