NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Cemiplimab for treating cutaneous squamous cell carcinoma

Draft scope

Draft remit/appraisal objective

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

Background

Cutaneous 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[2] and 23% of non-melanoma skin cancers[3]. 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. It involves removing the cancerous tumour and some of the surrounding skin. Other treatments for non-melanoma skin cancer include freezing (cryotherapy), anti-cancer creams (fluorouracil[5], imiquimod[2]), radiotherapy and a form of light treatment called photodynamic therapy (PDT). The treatment used will depend on the type, size and location of the non-melanoma skin cancer.[1]

The technology

Cemiplimab (REGN2810; Regeneron Pharmaceuticals and 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 a clinical trial as monotherapy without an active comparator in adults with untreated metastatic cutaneous SCC or with unresectable locally advanced cutaneous SCC.

Intervention	Cemiplimab
Population	People with: • untreated metastatic cutaneous squamous cell carcinoma or • locally advanced cutaneous squamous cell carcinoma in whom surgery is not appropriate
Comparators	• Best supportive care
Outcomes	The outcome measures to be considered include: • progression-free survival • overall survival • response rate • 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.
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 and NICE Pathways	Related Guidelines: 'Improving outcomes for people with skin tumours including melanoma' (2006) NICE guideline CSG8 Review date: March 2018 Related Diagnostics guidance: 'VivaScope 1500 and 3000 imaging systems for detecting skin cancer lesions' (2015) NICE diagnostics

	guidance 19 Related Medical Technologies guidance: 'Ambulight PDT for the treatment of non-melanoma skin cancer' (2011) NICE medical technologies guidance 6 Related Interventional Procedures: 'Electrochemotherapy for primary basal cell carcinoma and primary squamous cell carcinoma' (2014) NICE interventional procedures 478 'Photodynamic therapy for non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions)' (2006) NICE interventional procedures 155 Related Public Health Guidelines: Skin cancer prevention (2011) NICE guideline PH32 Last updated: February 2016 Related Quality Standards: Skin cancer (2016) NICE quality standard 130 http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp Related NICE Pathways: Skin cancer (2017) NICE Pathway Suspected cancer recognition and referral (2017) NICE Pathway http://pathways.nice.org.uk/
Related National Policy	NHS England (2017) Manual for Prescribed Specialised Services 2017/18. https://www.england.nhs.uk/wp-content/uploads/2017/10/prescribed-specialised-services-manual-2.pdf NHS England (2017) Manual for prescribed specialised services 2017/18 Chapter 105: Specialist cancer services (adults) Department of Health (2016) NHS outcomes framework 2016 to 2017 Independent Cancer Taskforce (2015) Achieving world-class cancer outcomes: a strategy for England 2015-2020 Department of Health, NHS Outcomes Framework 2016-2017 (published 2016): Domains 1, 4–5. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

Questions for consultation

Which treatments are considered to be established clinical practice in the NHS for unresectable locally advanced cutaneous squamous cell carcinoma (SCC)? Which treatments are considered to be established clinical practice in the NHS for metastatic cutaneous SCC?

How should best supportive care be defined?

Are there any active treatments with which cemiplimab should be compared?

Are the outcomes listed appropriate?

Are there any subgroups of people in whom cemiplimab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider cemiplimab will fit into the existing NICE pathway, Skin cancer?

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.

Do you consider cemiplimab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of cemiplimab can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

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 06/02/2018]

5. Patient (2016) Squamous cell carcinoma of skin https://patient.info/doctor/squamous-cell-carcinoma-of-skin [Accessed at 12/02/2018]