

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of nivolumab within its marketing authorisation for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy.

Background

Head and neck cancer is a heterogeneous group of malignant tumours that arise in the head and neck at the following sites: skin and lip, oral cavity, oropharynx, larynx, hypopharynx, nasopharynx, salivary glands, nasal cavity and paranasal sinuses, and external auditory meatus and middle ear. The most common histological type of head and neck cancer is squamous cell carcinoma (approximately 90%),¹ particularly that affecting the oral cavity, oropharynx and larynx. Although local metastases of head and neck cancer occur frequently (usually spreading through the lymphatic system in the neck), distant metastases are less common.

The annual incidence of head and neck cancer is estimated to be 0.022% and 0.009% for males and females, respectively, equating to approximately 8,000 cases in England each year.² Approximately 60% of patients present with locally advanced disease at diagnosis, and most of these develop local or regional recurrence, with approximately 20–30% developing distant metastases.³ Survival depends on several factors, mainly the origin of the cancer and the stage of the disease at diagnosis. In 2012, there were 3,300 deaths in the UK.⁴

Treatment options for squamous head and neck cancer vary according to the specific sites involved. In some people with recurrent disease, the tumour may be amenable to surgery or radiotherapy with curative intent. In people with metastatic disease or who have previously received radiotherapy, palliative chemotherapy is normally given to control the disease and improve quality of life. Platinum-based chemotherapy is commonly used for recurrent or metastatic head and neck cancer. There is no established pathway of care when platinum-based therapy is not clinically appropriate.

The technology

Nivolumab (Opdivo, Bristol-Myers Squibb) is a humanised monoclonal antibody that targets and blocks a receptor on the surface of lymphocytes known as PD-1. This receptor is part of the immune checkpoint pathway, and

blocking its activity may promote an anti-tumour immune response. Nivolumab is administered by IV infusion.

Nivolumab does not currently have a marketing authorisation in the UK for treating squamous-cell carcinoma of the head and neck after platinum-based therapy. It has been studied in a randomised controlled trial compared with investigator's choice of therapy of cetuximab, methotrexate or docetaxel in people with recurrent or metastatic platinum-refractory squamous cell carcinoma of the head and neck.

Intervention(s)	Nivolumab
Population(s)	Adults with recurrent or metastatic squamous-cell carcinoma of the head and neck who have previously received platinum-based chemotherapy
Comparators	<ul style="list-style-type: none"> • docetaxel • paclitaxel • methotrexate
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • overall survival • progression-free survival • 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>
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	<p>Related Guidelines:</p> <p>'Cancer of the upper aerodigestive tract: assessment</p>

<p>and NICE Pathways</p>	<p>and management in people aged 16 and over'. Published February 2016.</p> <p>Related Quality Standards: 'Head and neck cancer'. NICE quality standard in development. Publication date February 2017.</p> <p>Related NICE Pathways: Head and neck cancer NICE pathway</p>
<p>Related National Policy</p>	<p>NHS England</p> <p>NHS England (2014) Manual for prescribed specialised services 13/14. Specialist cancer services (adults) 105 (page 235)</p> <p>NHS England. National Programmes of care and clinical reference groups. B16. Complex Head & Neck (accessed 14 10 2015)</p> <p>National Service Frameworks</p> <p>Cancer</p> <p>Other policies</p> <p>Department of Health, NHS Outcomes Framework 2015-2016, Dec 2014. Domains 2, 4 and 5. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/385749/NHS_Outcomes_Framework.pdf</p>

References

1. Cancer of the head and neck. Patient.co.uk [accessed April 2016].
2. National Institute for Health and Care Excellence (2008) Cetuximab for the treatment of locally advanced squamous cell cancer of the head and neck: costing template and report.
3. Vermorken JB and Specenier P (2010) Optimal treatment for recurrent/metastatic head and neck cancer. *Annals of Oncology* 21: vii252–vii261.
4. The Rich Picture. People with Head and Neck cancer. Macmillan cancer support.
<http://www.macmillan.org.uk/documents/aboutus/research/richpictures/update/rp-people-with-head-and-neck-cancer.pdf> [accessed April 2016].