NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Nanoparticle albumin bound paclitaxel for the first-line treatment of metastatic malignant melanoma

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of nanoparticle albumin bound paclitaxel within its licensed indication for the first-line treatment of metastatic malignant melanoma.

Background

Malignant melanoma is a cancer of the skin which in its early stages is normally asymptomatic and, if detected early, before it has spread, can be curable. When the cancer cells spread to other parts of the body it is known as metastatic (stage IV). The most common places to spread to are the lung, liver, brain, distant lymph nodes or other distant areas of the skin. At presentation, 10% of malignant melanomas will have metastasised. It occurs more frequently in fair-skinned people and there is strong evidence of a causal link with ultra violet exposure. People with an above-average mole count, sun-sensitive skin, or a strong family history of melanoma are at greatly increased risk.

The incidence of malignant melanoma is increasing in England and Wales with rates doubling approximately every 10-20 years. There were 10,656 new diagnoses of malignant melanoma and 1825 related deaths in England in 2010. In the UK, melanoma is diagnosed at a mean age of around 50 years but approximately 13% of cases occur in young adults aged between 15 and 39 years old.

A very small minority of people with advanced disease at presentation can still have their tumours removed. People with metastatic malignant melanoma can be treated with biological therapies, chemotherapies, radiotherapies or surgery. First line treatment normally involves the administration of dacarbazine. Some new drugs target the person's BRAF gene mutation status. NICE technology appraisal 269 recommends vemurafenib as an option for treating locally advanced or metastatic BRAF V600 mutation-positive unresectable or metastatic melanoma.

The technology

Nanoparticle albumin bound –'nab'- paclitaxel (Abraxane, Celgene) is an albumin-bound formulation of paclitaxel. It uses albumin binding proteins to achieve high intratumoral paclitaxel accumulation. It is administered intravenously.

Nab-paclitaxel does not have a UK marketing authorisation for the treatment of malignant metastatic melanoma. It is being studied in a randomised clinical trial in comparison with dacarbazine in adults with previously untreated metastatic malignant melanoma.

Intervention(s)	Nanoparticle albumin bound paclitaxel
Population(s)	People with previously untreated metastatic malignant melanoma
Comparators	dacarbazine
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. The availability of any patient access scheme for the intervention or comparator technologies should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation

Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No. 269, December 2012 'Vemurafenib for treating locally advanced or metastatic BRAF V600 mutation-positive malignant melanoma'. Review Proposal Date November 2014. Technology Appraisal in Preparation, 'Ipilimumab for previously untreated unresectable stage III or IV malignant melanoma' Earliest anticipated date of publication June 2014. Technology Appraisal in Preparation, 'Dabrafenib for the treatment of unresectable, advanced or metastatic BRAF V600 mutation-positive melanoma' Earliest anticipated date of publication April 2014. Related Guidelines: Clinical Guideline in Preparation, 'Malignant melanoma: assessment and management of malignant melanoma' Earliest anticipated date of publication April 2015. Related Public Health Guidance: Public Health Guidance No. 32, January 2011, 'Skin cancer prevention: information, resources and environmental changes' Review Proposal Date January 2014. Related Pathways: http://pathways.nice.org.uk/pathways/preventing-skin-cancer Other guidance: Cancer Service Guidance CSGSTIM, May 2010, 'Improving outcomes for people with skin tumours including melanoma'

Questions for consultation

Should the population be separated by BRAF gene mutation status?

Have the most appropriate comparators for nab-paclitaxel for the treatment of malignant metastatic melanoma been included in the scope? In particular:

- Should the comparators be separated by BRAF gene mutation status? If so, should vemurafenib be included as a comparator?
- Are there any other comparators which should be included?

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

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 nab-paclitaxel 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 the technology 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 the technology 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

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/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)