NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA269; Vemurafenib for treating locally advanced or metastatic BRAF V600 mutation-positive malignant melanoma

Final recommendation post consultation
The guidance should be incorporated into an on-going clinical guideline on the assessment and management of malignant melanoma. The current Patient Access Scheme for vemurafenib will remain in place.

1. Background

This guidance was issued in December 2012.

At the GE meeting of 4 November 2014 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

2. Proposal put to consultees and commentators

The guidance should be incorporated into an on-going clinical guideline. The current Patient Access Scheme for vemurafenib will remain in place.

3. Rationale for selecting this proposal

Further follow-up data from the studies originally included in the appraisal have been published. These additional data are not inconsistent with the results used for the appraisal and would not be expected to change the decision.

4. Summary of consultee and commentator responses

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent: British Association of Dermatologists **Response to proposal:** Agree Please note that the British Association of Dermatologists agrees with the proposal to incorporate TA269 in the upcoming NICE clinical guidelines for the assessment and management of melanoma.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: British Association of Skin Cancer Specialist Nurses **Response to proposal:** Agree We are in continued support of the NICE Technology Appraisal Guidance No. 269 and are pleased to be able to continue to support patients prescribed with the BRAF inhibitor drug Vemurafenib.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: Bristol-Myers Squibb **Response to proposal:** No objection We do not object to NICE's plans to incorporate the TA269 guidance into the Melanoma Clinical Guideline.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: Royal College of Nursing **Response to proposal:** No comment Nurses working within this area of health have reviewed the above review proposal and have no comments to submit at this present time.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: National Cancer Research Institute; Royal College of Physicians; Royal College of Radiologists; Association of Cancer Physicians **Response to proposal:** Agree The NCRI/RCP/RCR/ACP are in agreement with the NICE proposal for the above consultation.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: Royal College of Pathologists **Response to proposal:** No comment The Royal College of Pathologists does not have any comments and is agreeing for TA269 to be moved to the static list.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: Roche Products **Response to proposal:** Agree We are happy with this proposal, and are not aware of any additional and relevant evidence and have no comments on the provisional matrix of consultees and commentators. We are also pleased to note that your proposal will maintain funding for this important medicine.	**Comment from Technology Appraisals** Comment noted. No action required.

Paper signed off by: Janet Robertson, 19 December 2014

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