NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Review Proposal Project (RPP) decision paper

Review of TA321; Dabrafenib for treating advanced unresectable or metastatic BRAFV600 mutation-positive melanoma.

Final recommendation post consultation
The guidance should be transferred to the 'static guidance list'

1. Background

This guidance was issued in October 2014.

At the Guidance Executive meeting of 24 October 2017 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 transferred to the 'static guidance list'. That we consult on this proposal.

3. Rationale for selecting this proposal

There are no new cost or clinical effectiveness data for dabrafenib, which would warrant reconsideration of the existing recommendations. Since technology appraisal 321 was issued, dabrafenib has been recommended in combination with trametinib for the same indication (technology appraisal 396). Because the combination therapy has been demonstrated to be more clinically effective than dabrafenib monotherapy it is anticipated that in clinical practice, combination therapy will replace monotherapy in the majority of cases. However, there will be some people for whom dabrafenib monotherapy, but not combination therapy, will be suitable. As such NICE technology appraisal guidance on dabrafenib monotherapy remains relevant. Technology appraisal 321 has been incorporated in NICE guideline 14 Melanoma: assessment and management (2015).

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 The British Association of Dermatologists agrees with the proposal to move guidance TA321: dabrafenib for treating advanced unresectable or metastatic BRAFV600 mutation-positive melanoma to the static list.	**Comment from Technology Appraisals** Agreement noted

Respondent: NCRI-ACP-RCP **Response to proposal:** Agree The NCRI-ACP-RCP is grateful for the opportunity to respond to the above consultation. We confirm full support for this proposal.	**Comment from Technology Appraisals** Agreement noted

Respondent: Novartis Pharmaceuticals UK Limited **Response to proposal:** No comment	**Comment from Technology Appraisals** Noted

Paper signed off by: Jenniffer Prescott, 18 December 2017

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