Appendix G - professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Dabrafenib for treating unresectable, advanced or metastatic BRAFV600 mutation-positive melanoma [ID605]

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name[redacted] *(on behalf of the Therapy & Guidelines and Skin Cancer sub-committees)*

Name of your organisation: ***British Association of Dermatologists***

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? ***Yes***
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? ***Yes***
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc)? ***Yes, Consultant Dermatologist***
- other? (please specify)

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What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Patients with metastatic melanoma with a BRAFV600 mutation may be treated with vemurafenib (BRAF inhibitor). Single agent dacarbazine is not commonly used now for BRAF mutation positive metastatic melanoma. Patients may be entered into a trial depending on their mutational status. At present, dabrafenib is generally only available in centres participating in clinical trials. Other treatments available are ipilimumab as second line, and all other agents such as MEK inhibitors and anti-PD1 are generally only available as part of clinical trials. Geographical differences are generally due to the availability of centres with clinical trials.

Vemurafenib is the current BRAF inhibitor licensed for the treatment of metastatic melanoma. The alternative BRAF inhibitor is Dabrafenib and this has a similar toxicity profile except that it does not cause significant photosensitivity but is linked to development of pyrexia and Grovers. No combination treatment of a BRAF plus MEK inhibitor is licensed and available at present for treatment of metastatic melanoma. There are some important advantages of using combination therapies as side effects, especially skin toxicity and development of secondary cancers such as cutaneous squamous cell carcinoma, are reduced.

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient?
No

Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

Dabrafenib side effect profile is similar to Vemurafenib in that it can cause development of second malignancies such as cutaneous squamous cell carcinomas but these are generally easily managed by prompt surgical excision. Dabrafenib has the advantage that it is not associated with phototoxicity but is linked to development of Pyrexia and Grovers in a small proportion of patients.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics?

Secondary care or specialist melanoma clinics, in a multi-disciplinary setting with oncologists and dermatologists involved.

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Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

Specialist cancer nurses will be needed to support the patients. Dermatologists will also be required to support skin toxicity. Ophthalmologists will need to screen for eye toxicity and gynaecologists will be needed to screen for cervical pathology.

If the technology is already available, is there variation in how it is being used in the NHS?
Only single agent vemurafenib is currently available.

Is it always used within its licensed indications?

Yes

If not, under what circumstances does this occur?

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

No national guidelines available at present.

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

The medication is taken orally. Screening will be required as listed above.

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

A BRAFV600 mutation will have to be identified as a pre-requisite of the treatment. Stopping the medication is usually due to side effects.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice.

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The medication is only available at present in a clinical trial setting and therefore reflects that observed in clinical practice.

Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting?

Trials conducted multi-centre including the UK.

What, in your view, are the most important outcomes, and were they measured in the trials?

Overall survival, disease-free intervals and side effect profile.

If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions?

Side effects are very similar to Vemurafenib but there are differences as noted above. Also in clinical practice patients who get a rash with one BRAF inhibitor do not necessarily get it with the other and therefore having two potential BRAF inhibitors available is important if one isn't tolerated then you can switch to the other.

In what ways do these affect the management of the condition and the patient's quality of life?

Treatment may not be tolerated if the side effects are moderate or severe.

Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

Medication not available in routine practice.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

Implementation issues

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The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition?

Availability to more patients.

Would NHS staff need extra education and training?

No, as similar drugs are already in use.

Would any additional resources be required (for example, facilities or equipment)?

No.

Equality
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 this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/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 lead to recommendations that 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.

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