NICE National Institute for Health and Care Excellence

# Professional organisation submission

## Pembrolizumab for adjuvant treatment of resected melanoma with high risk of recurrence

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on the technology in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

**Information on completing this submission**

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 13 pages.

| **About you** | |
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| 1. Your name | **Dr Pamela McHenry and Dr Louise Fearfield, on behalf of the Therapy & Guidelines sub-committee** |
| 2. Name of organisation | **British Association of Dermatologists (BAD)** |

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| 3. Job title or position | **Consultant Dermatologists** |
| 4. Are you (please tick all that apply): | ☒ an employee or representative of a healthcare professional organisation that represents clinicians?<br>☐ a specialist in the treatment of people with this condition?<br>☐ a specialist in the clinical evidence base for this condition or technology?<br>☐ other (please specify): |
| 5a. Brief description of the organisation (including who funds it). | The BAD's charitable objectives are the practice, teaching, training and research of Dermatology. It works with the Department of Health, patient bodies and commissioners across the UK, advising on best practice and the provision of Dermatology services across all service settings. It is funded by the activities of its Members. |
| 5b. Do you have any direct or indirect links with, or funding from, the tobacco industry? | No. |
| **The aim of treatment for this condition** | |
| 6. What is the main aim of treatment? (For example, to stop progression, to improve mobility, to cure the condition, | To stop progression in this context i.e. as an adjuvant treatment |

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| or prevent progression or disability.) | |
| 7. What do you consider a clinically significant treatment response? (For example, a reduction in tumour size by x cm, or a reduction in disease activity by a certain amount.) | Progression free survival |
| 8. In your view, is there an unmet need for patients and healthcare professionals in this condition? | Yes as there is no adjuvant therapy available for earlier stage of Melanoma |
| **What is the expected place of the technology in current practice?** | |
| 9. How is the condition currently treated in the NHS? | Surgery<br>Interferon has been used but is not currently generally used due to side effects and lack of effectiveness<br>(Of note there are other adjuvant studies in melanoma that have also been published recently looking at Nivolumab, Ipilumumab and Dabrafenib combined with Trametinib as adjuvant treatments but these are not currently available outside trials) |
| • Are any clinical guidelines used in the | NICE melanoma guidelines |

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| treatment of the condition, and if so, which? | |
| • Is the pathway of care well defined? Does it vary or are there differences of opinion between professionals across the NHS? (Please state if your experience is from outside England.) | Pathway of care is generally well defined |
| • What impact would the technology have on the current pathway of care? | From the results of the recently published trial: Eggermont et al N Engl J Med 2018; 378:1789-1801 there was a significant increased progression free survival in these patients on pembrolizumab compared to placebo |
| 10. Will the technology be used (or is it already used) in the same way as current care in NHS clinical practice? | It will be a new addition to treatment of Stage III melanoma as it is adjuvant therapy but it is currently used for Stage IV metastatic melanoma.<br>It will only be given for 12 months and will still be given every 3 weeks as per the metastatic regime |
| • How does healthcare resource use differ between the technology and current care? | Not currently available as adjuvant therapy |

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| • In what clinical setting should the technology be used? (For example, primary or secondary care, specialist clinics.) | Secondary care specialist clonics |
| • What investment is needed to introduce the technology? (For example, for facilities, equipment, or training.) | As it is currently used already for metastatic melanoma the facilities, equipment and training are in place however it will now include Stage III patients so more resources will be required however as it leads to increased progression free survival less resources will be required for more advanced melanoma if patients are not progressing also the number of surgical interventions should decrease |
| 11. Do you expect the technology to provide clinically meaningful benefits compared with current care? | Yes |
| • Do you expect the technology to increase length of life more than current care? | Yes |
| • Do you expect the technology to increase health-related quality of life more than current care? | Yes |

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| 12. Are there any groups of people for whom the technology would be more or less effective (or appropriate) than the general population? | No |
| **The use of the technology** | |
| 13. Will the technology be easier or more difficult to use for patients or healthcare professionals than current care? Are there any practical implications for its use (for example, any concomitant treatments needed, additional clinical requirements, factors affecting patient acceptability or ease of use or additional tests or monitoring needed.) | As it is already being used for metastatic the answer is basically no<br><br>The adjuvant study showed no differences in terms of toxicity and patients will generally be fitter with earlier stage melanoma |

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| 14. Will any rules (informal or formal) be used to start or stop treatment with the technology? Do these include any additional testing? | Yes – toxicity and likely be given only for 12 months as per trial |
| 15. Do you consider that the use of the technology will result in any substantial health-related benefits that are unlikely to be included in the quality-adjusted life year (QALY) calculation? | It is likely to if patients don't progress<br><br>Patients with metastatic melanoma will need further treatments including targeted treatments and immunotherapy, and may also require in patient treatment and palliative care<br><br>It would be difficult to calculate for these benefits at this stage |
| 16. Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how might it | Yes |

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| improve the way that current need is met? | |
| • Is the technology a 'step-change' in the management of the condition? | Yes |
| • Does the use of the technology address any particular unmet need of the patient population? | Yes there has been no effective adjuvant treatment available for Stage III melanoma |
| 17. How do any side effects or adverse effects of the technology affect the management of the condition and the patient's quality of life? | There have been reported significant side effects with this medication that can in some instances have long term consequences such as endocrine and neurological side effects<br><br>In this study adverse events of grades 3 to 5 that were related to the trial regimen were reported in 14.7% however a significant number of these are likely to be reversible on stopping the medication |
| **Sources of evidence** | |
| 18. Do the clinical trials on the technology reflect current UK clinical practice? | Yes |

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| • If not, how could the results be extrapolated to the UK setting? | |
| • What, in your view, are the most important outcomes, and were they measured in the trials? | For adjuvant studies progression free survival and ultimately overall survival need to be measured |
| • If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes? | |
| • Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently? | Some adverse events are seen after discontinuation of immunotherapies but these are often similar to those seen in the trials however as it effects the immune system it is possible that adverse events may occur subsequently that wont be reported specifically in trials but this is likely to be rare |
| 19. Are you aware of any relevant evidence that might not be found by a systematic review of the trial evidence? | no |

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| 20. Are you aware of any new evidence for the comparator treatment(s) since the publication of NICE technology appraisal guidance [TAXXX]? [delete if there is no NICE guidance for the comparator(s) and renumber subsequent sections] | There are other comparators including Nivolumab, Ipilumumab, Dbarafenib and trametinib but I think NICE are aware of these comparators as a lot are also going through NICE appraisals |
| 21. How do data on real-world experience compare with the trial data? | |
| **Equality** | |
| 22a. Are there any potential equality issues that should be taken into account when considering this treatment? | |

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| 22b. Consider whether these issues are different from issues with current care and why. | |
| **Topic-specific questions** | |
| 23 [To be added by technical team at scope sign off. Note that topic-specific questions will be added only if the treatment pathway or likely use of the technology remains uncertain after scoping consultation, for example if there were differences in opinion; this is not expected to be required for every appraisal.] | |

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| **if there are none delete highlighted rows and renumber below** | |

| **Key messages** |
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| 24. In up to 5 bullet points, please summarise the key messages of your submission.<br>• Step change in treatment of Stage III melanoma<br>• Significantly improved progression free survival<br>• Generally well tolerated<br>• Defined period of treatment i.e. 12 months<br>• Potentially will decrease need for surgery that will have long term consequences for e.g. lympoedema secondary to lymph node dissections |

Thank you for your time.

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