

**Skin Cancer sub-committee,  
British Association of Dermatologists**

**Comments on the NICE appraisal consultation document (ACD) for the Single  
Technology Appraisal (STA) on ipilimumab for previously treated advanced  
(unresectable or metastatic) malignant melanoma**

The British Association of Dermatologists Skin Cancer sub-committee supports the decision by NICE not to recommend ipilimumab at this point for the treatment of patients with previously treated advanced (unresectable or metastatic) malignant melanoma.

The committee acknowledges that ipilimumab shows some potential to improve the median survival of patients with advanced melanoma and feels that the technology had been fairly appraised. The committee accepts the following factors that may have contributed to the decision by NICE, despite the promising results of the MDX010-20 trial:

- the toxicity levels, adverse events (including deaths on treatment) and side effects
- absence of patient characteristics or biomarkers
- reported delayed response in patients
- the high cost of the drug

The committee agrees that the drug requires further research to identify:

- the group of patients who will most benefit from it . identification of the small group who have long-term benefit should form the basis for future reconsideration
- the optimal dosage
- any achievable reduction in adverse events and side-effects

The committee would like to echo the ACD and point out that this decision by NICE does not preclude patients from applying on an individual patient basis, at local level, for funding for the drug.

Addressing the questions laid out in the ACD:

1. Has all of the relevant evidence been taken into account?  
→ The process by which NICE assesses potential improvements in healthcare is thorough, rigorous and evidence-based, with a complete review by experts of current evidence.
2. Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?  
→ The detailed analysis appears balanced and the re-analysis of the manufacturers data relating to QALYs appears reasonable.
3. Are the provisional recommendations sound and a suitable basis for guidance to the NHS?  
→ While the current decision does not support the routine provision of ipilimumab for advanced melanoma, trials should be continued. If evidence emerges demonstrating significant benefit in the future, particularly to certain sub-categories of people with melanoma, NICE will review their decision, as has been

done before with other modalities. It is important that a) there is further study to clarify if there is a definable sub-group of patients who demonstrates much better outcomes with ipilimumab, and b) the NICE guidelines are promptly reviewed if such information is available.

4. Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?
  - ➔ The decision has no bearing on individual patients of gender, race, disability, age, sexual orientation, religion or belief.

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