

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**Single Technology Appraisal (STA)**

**Ipilimumab for previously treated unresectable malignant melanoma**

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

**About you**

**Your name:** Michael Tidman

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

**Are you (tick all that apply):**

- a patient with the condition for which NICE is considering this technology?
- a carer of a patient with the condition for which NICE is considering this technology?
- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc)
- X other? (please specify) Chair of the Therapy & Guidelines subcommittee of the British Association of Dermatologists

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**What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?**

**1. Advantages**

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

Ipilimumab is the first technology that has been shown to have the potential to improve the median survival of patients with advanced (unresectable stage III and IV) melanoma. By reducing tumour load, ipilimumab may also reduce symptoms.

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above.

The potential benefit of ipilimumab relates to an improved median survival time in patients with advanced melanoma. Reduction of tumour load may also improve symptoms.

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**What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)**

**2. Disadvantages**

Please list any problems with or concerns you have about the technology.

Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse.
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

Ipilimumab is associated with a variety of side effects, including fatigue, diarrhoea, rashes, pruritus, endocrine deficiencies and colitis. Fatalities due to side effects have been recorded.

Furthermore, trials to date suggest that only a minority of patients are likely to respond to this technology.

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

We are not aware of differences in opinion between patients as to the usefulness of this technology.

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

This technology is directed at patients with unresectable or metastatic melanoma. It is likely that its use in less advanced melanoma would be contraindicated by its side effect profile.

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**Comparing the technology with alternative available treatments or technologies**

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

Unresectable stage III or stage IV (metastatic) melanoma patients are usually treated with dacarbazine. Radiotherapy, immunotherapy and combination chemotherapy are alternative options.

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

- improvement in the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

Ipilimumab has been confirmed to enhance median survival in advanced melanoma.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:

- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

The potential for serious, and possibly fatal, side effects is a disadvantage.

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**Research evidence on patient or carer views of the technology**

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

Ipilimumab does not yet have a marketing authorisation in the UK and so is not in routine NHS use.

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

Not yet in routine NHS use.

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

No

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**Availability of this technology to patients in the NHS**

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

Ipilimumab has the potential for increasing median survival time in patients with advanced melanoma.

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

If ipilimumab was not made available to NHS patients, they would be denied a therapy that might prolong survival.

Are there groups of patients that have difficulties using the technology?

Not that we are aware of.

**Equality**

Are there any issues that require special attention in light of the NICE's duties to have due regard to the need to eliminate unlawful discrimination and promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others?

None that we are aware of.

**Other Issues**

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

We are not aware of other issues that might affect the appraisal process.