Patient/carer organisation consultee template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

STA Ipilimumab for previously untreated 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: [redacted]

Name of your organisation: The Karen Clifford Skin Cancer Charity (Skcin)

At Skcin, we consider ourselves to be the UK's only skin cancer specific charity with national status, raising awareness of the UK's most common cancer. We focus on promoting the prevention and early detection of the disease and supporting patients. A large part of our work concerns the promotion of sun safety initiatives to halt the rising incidence of the disease in years to come. We also campaign for cultural and educational change and for patient rights.

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)

  TICK – Title: Development Director

- other? (please specify)

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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.

Improved prospect of quality long-term survival:

There is evidence of improved patient outcomes and experience, which is based on second line use of Yervoy to date, and now strong first line trial data. The primary outcome observed in trials relates to the increased potential for improved quality survival, with secondary outcomes relating to increased time to disease progression and improved health-related quality of life.

We believe that a significant number of additional patients could benefit more profoundly from Yervoy as a first line treatment, based upon evidence that that those patients treated earlier with Yervoy will be more likely to receive the full treatment course and therefore experience the full benefit.

A highly innovative advance in treatment:

Yervoy is one of the most innovative treatments in recent years, a highly effective immuno-therapy, the benefits of which could be significantly enhanced by extending the treatment to patients at an earlier stage in the pathway.

Targets an area of high unmet need:

The incidence of melanoma is rising significantly in the UK, and this trend is set to continue. This is referenced in the British Journal of Cancer (Oct 2011), which revealed that melanoma has the largest projected rate of increase of the cancers studied. Rates are set to rise by an estimated 52% over the next 20 years. It is also worth mentioning that the disease has a relatively young profile, the average age of diagnosis is 50, but melanoma is now the second most common cancer in the 15-34 age group. Having a younger profile means patients are often of a working age and many have young families, which makes any possible life extension and the speed of intervention invaluable. Treatments that can improve outcomes in terms of life expectancy and the ability to continue a more normal family and working life can obviously have a huge impact socially, emotionally and economically.

Furthermore, clinicians the charity has contact with have expressed a desire to be able to offer Yervoy at an earlier stage in the patient pathway, particularly to non-BRAF+ patients.

(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

Prognosis for advanced melanoma is very poor, without the hope offered by new innovative treatments patients; families and carers understandably hit rock bottom and have very low morale. Thus early (first line) treatment with Yervoy has the ability to have positive benefit in all of the inclusions listed above – outcome, physical symptoms, pain, level of disability and impact on mental health – leading to enhanced quality of life for patients, family and friends.

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 thier family (for example cost of travel needed to access the technology, or the cost of paying a carer)

Noted common adverse reactions to Yervoy include, nausea, vomiting, diarrhoea, skin rash, pruritus, decreased appetite and abdominal pain. These need to be proactively managed, but are generally medically manageable. Patients are more positive and willing to tolerate to gain potential survival benefits.

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

None noted

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?

Individuals who are not BRAFV600 positive who do not have the option of the targeted treatment provided by Vemurafenib should benefit more from Yervoy as a first line treatment. Conversely BRAFV600 positive patients may benefit less, although they will still benefit from the option to be treated with Yervoy if they were not responding to Vemurafenib.

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.

Dacarbazine has been, until recently, the standard treatment of care for this patient group. The survival prognosis for patients with advanced melanoma treated with dacarbazine chemotherapy alone is an average of 9 months, with only a very small percentage experiencing any tumour shrinkage. Patients on chemotherapy experience side effects resulting from its high toxicity and their quality of life is significantly lowered.

Vemurafenib is indicated only for patients who are BRAF V600 positive, which present in under half of patients with inoperable metastatic melanoma. Thus a significant portion of the patient population would not be recommended for this treatment.

Yervoy is an effective second line option, but the full treatment benefits are not always realised when it is given following dacarbazine or vemurafenib. Yervoy will be a more effective first line option, based upon evidence that those patients treated earlier with Yervoy will be more likely to receive the full treatment course and therefore experience the fill benefit.

(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 of 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)

Innovative treatments for advanced melanoma like Yervoy have the ability to increase the range of effective treatment options available to all patients for whom it is clinically appropriate and thus provide patients with greater choice and hope!

(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).

Not compared with current standard practice no.

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.

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

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.

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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?

For patients and their family/friends it is torture going through months of first line treatment when they know there are second line treatments that can make a real difference. Having the potential to extend life and to provide a longer period of time in which the patient can enjoy better health, enabling better quality of life, more time with family and friends and even the ability to continue their working lives. Although not a cure, approving Yervoy as a first line treatment can and has provided lifelines to patients. It gives hope and may enable them to 'hang on' for new advances in treatment that could further prolong their lives, or eventually for a cure to the disease.

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

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

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.

N/A

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

Patient reported outcomes are a very important consideration in the evaluation of this treatment, extension of life, hope and morale boost to patients their family and friends should be a value that is also taken into consideration alongside the monetary cost of the drug and its clinical effectiveness.

REFERENCES:

Cancer Research UK, Skin Cancer key facts. Available from: http://www.cancerresearchuk.org/cancer-info/cancerstats/keyfacts/skin-cancer/cancerstats-key-facts-on-skin-cancer