

# WILL YOU?

**Campaign for patients with advanced melanoma to  
access treatment**

**Patient and Professional Groups**

**A 'how to' guide for NICE registered commentators, consultees and  
non-registered stakeholders to respond by 4 November**





Friday 14 October 2011

Dear colleagues,

**Campaign for patients with advanced melanoma to access treatment**

As you will be aware, on 14 October the National Institute for Health and Clinical Excellence (NICE) issued draft guidance which, if not quickly overturned, will prove to be a devastating blow to patients with advanced melanoma. In its provisional recommendations in the ACD (Appraisal Consultation Document) it said that the use of the drug Yervoy (Ipilimumab) for patients in England and Wales, has been denied. The ACD recommendations are now out for consultation for 20 days.

The provisional decision by the NICE Appraisal Committee is extremely disappointing as it will deny to many patients across England and Wales the long-awaited arrival of a new and effective treatment option. It could mean that patients will continue to have limited treatment options beyond the current standard of care, a chemotherapy that was first licensed in the 1970s.

National skin cancer charity Skcin – who administer the group Skin Cancer UK – and patient support group Factor50 have joined forces to campaign to ensure that patients with advanced malignant melanoma are able to access this innovative new drug. We are passionate in our campaign for access to this treatment given that the incidence of malignant melanoma is on the rise and, at the moment, there are few treatment options available for people with advanced disease.

As interested stakeholders in this process, **we urge you to ensure that you also respond to the NICE ACD and encourage your supporters/members to do the same.** Given the inevitable pressures on your time, we have provided more information on this process below, with guidance for both official commentators/consultees and individuals/stakeholders who are not registered with NICE.

We have until **4 November to respond to this decision**, after which the NICE Appraisal Committee will meet again to consider these responses (on 16<sup>th</sup> November 2011).

In addition, we would welcome your support in **signing our open letter to NICE** (by 24 October) and/or attending **our Parliamentary Stakeholder Investigation** in Westminster hosted by Pauline Latham MP (on 8 November). More details on this can be found below.

Yours sincerely,

**Richard Clifford**

Founder & Trustee, SKCIN / Chairman, Skin Cancer UK

**Gill Nuttall**

Founder, Factor50

# WILL YOU?

## What you can do:

- 1) Respond to the ACD by 4 November
- 2) Encourage your members/supporters to respond to the ACD by 4 November
- 3) Sign our open letter to be sent to NICE
- 4) Attend the Parliamentary Stakeholder Investigation hosted by Pauline Latham MP

“Ipilimumab represents a real advance in the treatment of patients with advanced melanoma. This is the first treatment for 30 years in the UK to extend patients’ life expectancy”

Dr Paul Lorigan,  
Christie NHS Foundation Trust

“Your comments on the Appraisal Consultation Document (ACD) are very important. Please comment at this stage even if you will be unable to take part at any other stage”

NICE, ‘Contributing to a Technology Appraisal’ - guide

“As a 40 year old, otherwise fit, father of 3 young children, Ipilimumab offers me the best chance to “win” my war with Melanoma. It has the possibility to return me to a normal life made of the things most people take for granted and that I, and my family, can now value every single day”

Taron. Age 40

“I need to live. I **have** to live for my children. I just want a few more years so that my boys will remember me”

Joanne. Age 30

# How to...

## 1) Respond to the ACD

### If you are a consultee or commentator:

You will have been sent a document by NICE containing the provisional recommendation made by the Appraisal Committee and you will have been asked to comment on its contents.

NICE advise consultees and commentators to submit their comments in writing, preferably via email.

#### **NICE would like to know:**

- 1) If you agree/disagree with the provisional recommendations
- 2) Why you think that the Committee has reached an inappropriate or incorrect decision
- 3) If there are any inaccuracies in the document
- 4) If you think the Committee has failed to take into account of evidence in the Evaluation Report
- 5) Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence

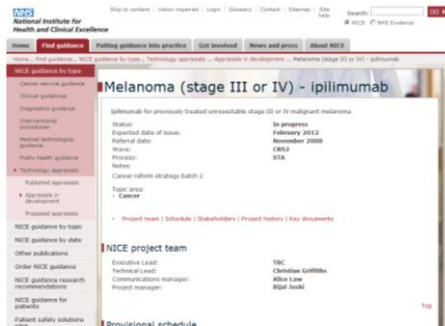
#### Suggested comments:

- That you disagree with the provisional ACD.
- That this treatment is the first drug licensed since the 1970s for the treatment for advanced melanoma and NICE themselves have acknowledged that this is a step change in the treatment for advanced melanoma.
- That this drug addresses an unmet need. There will be a huge impact on patients if this drug is rejected by NICE. For example, this is the only therapy that has been shown to increase the 1 year survival rate compared to its comparator in a Phase 3 clinical trial.
- That the incidence of melanoma is increasing. Over the last 25 years, the rate of malignant melanoma in the UK has risen faster than any other of the top 10 cancers in the UK. It is the second most common cancer in the 15-34 age group. More than 11,700 people in the UK are diagnosed with malignant melanoma each year.
- Please also add your perspective as a professional/patient group and why this decision will affect you and the people you care for.

The ACD deadline for consultees and commentators is 4 November 2011.

## If you are a non-official consultee or commentator:

If you/ or your organisation are not a registered stakeholder you can still respond either individually or on behalf of your organisation.



Please encourage your members/supporters to respond as well.

NICE has published the ACD with an electronic comment facility for non-consultees and commentators to respond.

NICE will then send the comments received from this consultation to the Appraisal Committee for consideration so please ensure that you respond.

Every voice counts.

Please complete the consultation on the NICE website by 4 November and ask that **NICE re-think this decision**.

The link can be found here:

<http://guidance.nice.org.uk/TA/WaveCRS2/48/Consultation/DraftGuidance>

We advise that you make your comments under the heading '**1) Appraisal Committee's preliminary recommendations**' and be sure to fill out the box at the top of the page 'click here to you identify yourself.' NICE require this information as they need to know if you are a health professional, carer etc.

In your response you may wish to highlight:

- That you disagree with the provisional ACD.
- That this treatment is the first drug licensed since the 1970s for the treatment for advanced melanoma and NICE themselves have acknowledged that this is a step change in the treatment for advanced melanoma.
- That this drug addresses an unmet need. There will be a huge impact on patients if this drug is rejected by NICE. For example, this is the only therapy that has been shown to increase the 1 year survival rate compared to its comparator in a Phase 3 clinical trial.
- That the incidence of melanoma is increasing. Over the last 25 years, the rate of malignant melanoma in the UK has risen faster than any other of the top 10 cancers in the UK. It is the second most common cancer in the 15-34 age group. More than 11,700 people in the UK are diagnosed with malignant melanoma each year.
- Please also add your perspective as a professional/individual/patient group and why this decision will affect you and the people you care for.

The deadline is 4 November.

The consultation can be viewed at

<http://guidance.nice.org.uk/TA/WaveCRS2/48/Consultation/Latest>

The ACD deadline for non consultees and commentators is 4 November 2011.

## How to...

### **2) Sign our open letter to be sent to NICE**

We hope to send an open letter to NICE with signatories from patient and professional groups. This will demonstrate the strength of feeling behind this provisional decision and we hope it will ensure that NICE re-considers its decision.

The draft text of the open letter is below.

Should you wish to be a signatory, please email Charlotte Fionda (Skcin) on [charlotte.fionda@skcin.org](mailto:charlotte.fionda@skcin.org) or Gill Nuttall (Factor50) on [factor50enquiries@googlemail.com](mailto:factor50enquiries@googlemail.com). Please state your name, job title and organisation.

The deadline for this is **MONDAY 24 OCTOBER**.

#### **OPEN LETTER TO PROFESSOR SIR MIKE RAWLINS, CHAIR, NICE**

cc Lord Howe (Parliamentary Under Secretary of State for Health)  
cc Professor Sir Mike Richards CBE (National Clinical Director for Cancer)  
cc Professor Sir Andrew Dillon (CE, NICE)  
cc Dr Jane Adam MB BS, MRCP, FRCR (Chair, Appraisal Committee A)

As representatives of leading professional associations and patient groups involved in working with, and on behalf of, patients with advanced melanoma we are writing to urge you to rethink your preliminary decision not to recommend Ipilimumab (Yervoy). This is a shocking decision and one that will be a devastating blow to people with advanced melanoma.

Clinicians and patients across the UK have been waiting for three decades for a treatment breakthrough in advanced melanoma and we believe that this treatment fulfils a real unmet need for this patient group. We are extremely concerned that if the draft NICE guidance on Ipilimumab, published 14 October, is not overturned it will mean that patients will continue to have limited treatment options beyond the current standard of care, a treatment that was first licensed in the 1970's.

This decision is even more devastating because, as you will be aware, the incidence of melanoma is on the rise in the UK. Over the last 25 years, the rate of malignant of melanoma has risen faster than any of the top 10 cancers in the UK and it is the second most common cancer in the 15-34 age group. More than 11,700 people are diagnosed with malignant melanoma each year. While the majority of skin cancers are treatable, malignant melanoma kills over 2,000 people each year with an average 22 years of life lost from each melanoma death, more than most other cancers.

We urge NICE to reconsider its draft guidance at the Appraisal Committee meeting on 16 November and issue a positive response to patients across the NHS, many of whom are devastated by this decision especially in light of the Cancer Drugs Fund coming to an end in 2014. We ask you to re-examine the clinical evidence and also give extra consideration for the fact that this aggressive disease disproportionately affects young people – many of whom have young families. As NICE has acknowledged itself, this treatment fulfils a real unmet need. It is vital that NICE consider the innovation behind this treatment and the subsequent substantive benefit to patients.

If not approved, the hopes of many of our patients and supporters will be dashed.

Please tell us that you'd like to be a signatory of the open letter by Monday 24 October.

## How to...

### 3) Attend the Parliamentary Stakeholder Investigation

A high profile meeting in Parliament will be held on **Tuesday 8 November, 5.30 - 7pm.**

Please inform us if you'd like to attend the Parliamentary Stakeholder Investigation by Tuesday 1 November.

Hosted by Pauline Latham MP, this meeting will enable patients, clinicians and professional groups to vocalise their concerns about the guidance, discuss the innovation behind Yervoy and also highlight how this drug will address an unmet need.

For more details and to RSVP, please email [melanoma.investigation@gmail.com](mailto:melanoma.investigation@gmail.com) or telephone 020 7824 1852.

## WILL YOU?

### Background information

NHS Choices: <http://www.nhs.uk/news/2011/08August/Pages/new-skincancer-drug-yervoy-ipilimumab.aspx>.

#### 1. Timings

25 July 2011	Yervoy (Ipilimumab) launched in the UK with a license approved by the European Medicine Agency.
20 September 2011	Yervoy (Ipilimumab) considered by NICE Appraisal Committee A. Patient groups, patients, professional associations, the manufacturer and an Academic Expert Reference Group presented written and verbal evidence to the committee. After considering the evidence, the Committee behind closed doors agreed that Yervoy (Ipilimumab) is not recommended for the treatment of advanced melanoma.
14 October 2011	NICE published on their website the draft guidance (ACD) to patients in England and Wales.
4 November 2011	The 20-day consultation period closes at 5pm on 4 November.
16 November 2010	The NICE Appraisal Committee will meet to consider the submissions it receives during the consultation process.  After considering the submissions and representations, the Appraisal Committee may publish final guidance (Final Appraisal Determination).  Alternatively, the Appraisal Committee may agree to reconsider evidence, or request further analysis and economic modelling. In this situation the publication of the final guidance (Final Appraisal Determination), will be delayed until the New Year.

## 2. Who is making the decision?

The Appraisal Committee considering Yervoy (Ipilimumab) is NICE Appraisal Committee A. Members of the Committee are listed on the NICE website at:

[http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalcommittee/members/committee\\_a\\_members.jsp](http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalcommittee/members/committee_a_members.jsp)

## 3. Information on the appraisal of Yervoy (Ipilimumab)

Further information and all historical documents relating to the appraisal can be seen at:

<http://guidance.nice.org.uk/TA/WaveCRS2/48>

The draft guidance can be viewed at:

<http://guidance.nice.org.uk/TA/WaveCRS2/48/Consultation/Latest>

## 4. Is Yervoy (Ipilimumab) available for patients to access at the present time?

Yervoy (Ipilimumab) received its UK license from the European Medicine Agency in July 2011. It is currently undergoing a NICE Technology Appraisal which, if approved, will see it being available to patients across England and Wales in 2012. In Scotland the Scottish Medicines Consortium is due to appraise Yervoy in early 2012. In Northern Ireland, the Department of Health, Social Services and Public Safety (HPSS) will make a local decision on access to Yervoy (Ipilimumab) following the NICE decision for England and Wales.

At present however, in England access to the treatment is possible through the Cancer Drugs Fund (CDF) or via local PCTs. Although demand for treatment via the Cancer Drugs Fund has been widespread there still remains inconsistency in patient access across the UK.

Whilst the CDF is available in England, there are no such schemes for Scotland, Wales and Northern Ireland.

In order to ensure equitable access, NICE and the SMC must approve the use of Yervoy (Ipilimumab).

**Thank you for your help.**

**For more information, please do not hesitate to contact us:**

Charlotte Fionda, Skcin. [charlotte.fionda@skcin.org](mailto:charlotte.fionda@skcin.org) or 07834 450 671.

Gill Nuttall, Factor50. [factor50enquiries@googlegmail.com](mailto:factor50enquiries@googlegmail.com) or 07930 375 360.

**About Skcin:** National skin cancer charity Skcin (the Karen Clifford Skin Cancer Charity) was founded by Richard Clifford after his wife Karen passed away on New Year's Eve 2005, after a courageous battle against skin cancer. Skcin campaigns to raise awareness of skin cancer, with the emphasis on sun safety education for behavioural change and skin cancer awareness resulting in early detection of the disease. The charity is also passionate about improving patient care and access to treatment for all affected by skin cancer.



### About Skin Cancer UK

Skcin co-ordinates Skin Cancer UK, a coalition of organisations which campaigns for action regarding the alarming increase in the incidence of the disease.



**About Factor50:** Factor50 is a patient support group working with The Christie. It campaigns for greater awareness and the dangers of malignant melanoma, the skin cancer which kills over 2000 people a year in the UK. Factor50 also raises money to conduct research into Malignant Melanoma.

