

WILL YOU?

Campaign for patients with advanced melanoma to access treatment

Patients, supporters, friends, carers, and individuals

**A 'how to' guide – how you can respond and make your voice heard by
4 November**





Friday 14 October 2011

Dear friends and supporters,

It is with regret that we are writing to inform you that on 14 October the National Institute for Health and Clinical Excellence (NICE) issued a statement which is a devastating blow to patients with advanced melanoma. In the statement it said that the use of the drug Yervoy (Ipilimumab) for patients in England and Wales, has been denied.

Yervoy (Ipilimumab) is the first drug licensed since the 1970s for the treatment for advanced melanoma. It works in a new way by stimulating the body's own immune system to fight cancer (known as immunotherapy).

Patients with this aggressive disease are expected to have a median overall survival of 6-9 months but in trials, 46% of patients taking Yervoy (Ipilimumab) were still alive after a year and in some cases, some patients live even longer.

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

However, **there is hope**. The NICE Appraisal Committee has acknowledged that Yervoy (Ipilimumab) is a step change in the treatment of advanced melanoma and that there is a significant unmet need for effective treatment in this patient population. We therefore need your help to **tell the NICE Committee it needs to review its decision**. That way, Yervoy (Ipilimumab) will be available on the NHS to all those patients across England and Wales who require it.

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 November 2011).

We urgently need your support in making representations to your MP, NICE and the Department of Health. **It is important that they understand the scale of the opposition to this guidance**. We need as many patients, carers, friends, supporters, and health professionals as possible to write to NICE and respond to the consultation, as well as tell their local MPs about their concerns. Please use our simple 'how to' guide so we can work together to tell NICE of our disappointment in its decision.

Yours sincerely,

Handwritten signature of Richard Clifford in black ink.

Richard Clifford

Founder & Trustee, SKCIN / Chairman, Skin Cancer UK

Handwritten signature of Gill Nuttall in black ink.

Gill Nuttall

Founder, Factor50

I WILL...

There are three ways in which you can help:

- **Write to your Member of Parliament (MP)**
- **Respond to the consultation on the NICE website**
- **Attend the Parliamentary Stakeholder Investigation in the House of Commons, hosted by Pauline Latham MP**

Please, if you can even take just ONE ACTION, you will be helping us in our campaign to enable patients to receive the treatment they need for advanced melanoma.

“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

“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

“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

Accessing Yervoy before NICE makes a decision:

NICE issues guidance for the NHS in England and Wales. In Scotland the SMC (Scottish Medicines Consortium) will produce its final guidance for Yervoy in early 2012.

The Cancer Drugs Fund (CDF) in England has been set up to ensure that drugs such as Yervoy (Ipilimumab) can be made available to patients ahead of the lengthy decision-making process by NICE. Should you wish to explore whether you can access Yervoy (Ipilimumab) at the present time please speak to your clinician and discuss the local options available for you.

There is currently no such fund in Wales, Scotland and Northern Ireland.

HOW TO...

You can:

- Write to your MP
- Respond to NICE
- Attend a seminar at the House of Commons

1) Write to your Member of Parliament

Supporters of Factor50, Skcin and people affected by malignant melanoma should contact their local Members of Parliament (MP). We hope that MPs will then write to NICE and the Department of Health on your behalf.



Please remember NICE's short consultation timeframe and write as soon as you can!

You can identify your MP by entering your postcode at this link: <http://www.parliament.uk/mps-lords-and-offices/mps/>. This website will then provide contact details for your MP. Once you have found this, you can write to them at:

Your MP's name, House of Commons, London, SW1A 0AA.

In order to maximise awareness of the appraisal of Yervoy (Ipilimumab) and the effect that denying access to the treatment will have on patients with melanoma, we urge you to also post a copy of your letter to:

Professor Sir Mike Rawlins
Chair
NICE
Mid City Place
71 High Holborn
London
WC1V 6NA

Rt Hon Andrew Lansley CBE MP
Secretary of State for Health
Department of Health
Richmond House
79 Whitehall
London
SW1A 2NL

Your letter should be personal and include your reasons as to why you are writing to your MP. A suggested template is overleaf.

The NICE consultation deadline is 4 November so please write as soon as you can!

As a guide, you may wish to include:

Your address -

Please include your postcode

so your MP can see you are a constituent

XXXXXX MP

House of Commons

London

SW1A 0AA

- *That you are the MP's constituent and are a melanoma patient/carer/nurse etc.*
- *That you are writing to your MP to see if they can make representations to NICE on your behalf in order to ensure that Yervoy (Ipilimumab) is approved when NICE review it in November.*
- *That you are disappointed to hear that Yervoy has so far been declined by NICE. This is a shocking decision as clinicians and patients have been waiting for three decades for a treatment breakthrough in advanced melanoma.*
- *Your personal story and why you are writing to them (e.g. you have been diagnosed with advanced melanoma)*
- *That you understand that Yervoy has the backing of a number of clinicians and patient groups.*
- *That Yervoy is the first treatment to be licensed in the UK which demonstrates an overall survival benefit for people with advanced melanoma.*
- *That if this drug is not available on the NHS, patients will continue to have limited treatment options beyond the current standard of care that was first licensed in the 1970s.*
- *In addition you may wish to highlight the growing incidence of melanoma. For example, over the last 25 years, the rate of malignant melanoma in the UK has risen faster than any of the top 10 cancers in the UK.*
- *That malignant melanoma kills over 2000 people in the UK each year, with an average 22 years of more life lost from each melanoma death than many other cancers.*
- *That you are copying this letter to the Secretary of State and the Chair of NICE.*
- *That you look forward to hearing from them.*

Yours sincerely,

cc Professor Sir Mike Rawlins, NICE and Andrew Lansley MP, Secretary of State for Health

HOW TO...

2) Respond to the consultation on the NICE website

NICE unfortunately has a very bureaucratic and formal process to take comments on the draft guidance.

Non-official consultees such as individual patients, carers and friends wishing to officially respond to NICE must do so via their website.

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 comment 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 patient, health professional etc.



In your response you should state:

- That you are disappointed to hear of NICE's decision that this new drug – Yervoy – for people with advanced melanoma has been denied.
- This is a shocking decision by NICE and a devastating blow to people with advanced melanoma.
- If this preliminary decision is not overturned then patients will continue to have limited treatment options beyond the standard of care.
- This issue is important to you because XXXXXX
(Please state why you are writing to NICE and why you are concerned about this decision. For example, are you a patient, a carer? Please add your story)
- Patient's hopes have been dashed. It is devastating that many patients have been left with little hope. You urge NICE to review its decision.

The consultation can be viewed at

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

The deadline is **4 November 2011**

Use this 'how to' guide to post your comments on the NICE website by 4 November 2011

HOW TO...

3) Attend the Parliamentary Stakeholder Investigation

A high profile meeting in Parliament will be held on **Tuesday 8 November, 5.30 -7pm**. 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. A transcript of the proceedings will be submitted to NICE as evidence.

Space is extremely limited, but we are keen for patients to explain the strength of feeling about this matter. Please let us know if you wish to attend by **calling Gill Nuttall at Factor50** on 07930 375 360, email factor50enquiries@googlemail.com or call Laura Burley who is helping to organise the event on 020 7824 1852. Places (two invitations per person) will be allocated on a ballot basis and we will be able to reimburse reasonable travel expenses.

WILL YOU?

Background information

For more information on Yervoy, please visit NHS Choices at <http://www.nhs.uk/news/2011/08August/Pages/new-skincancer-drug-yervoy-ipilimumab.aspx>.

NICE

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, manufacturer and Academic Expert Reference Group presented written and verbal evidence to committee. After considering the evidence, the Committee behind closed doors agreed to that Yervoy (Ipilimumab) is not recommended for the treatment of advanced melanoma.
14 October 2011	NICE published on its website the draft guidance (ACD) to patients in England and Wales. It asks for comments on its decision.
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

3. NICE Background on the appraisal

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 at all at the moment?

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 in the NHS to patients across England and Wales (in 2012). In Scotland the Scottish Medicines Consortium (SMC) is due to appraise Yervoy (Ipilimumab) 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, access to the treatment in England 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.

We believe that, 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 or 07834 450 671.

Gill Nuttall, Factor50. factor50enquiries@googlemail.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.

