



Ipilimumab for previously treated advanced (unresectable or metastatic) malignant melanoma:

Joint response from Skcin, Factor50 and the Myfanwy Townsend Melanoma Research Fund on the NICE Appraisal Consultation Document

4 November 2011

About Skcin:

National skin cancer charity Skcin (the Karen Clifford Skin Cancer Charity) was founded by Richard Clifford after his wife 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 Factor50:

Factor50 is a patient support group working with The Christie. It campaigns for greater awareness about the dangers of malignant melanoma, and also raises money to conduct research into malignant melanoma. It works closely with patients themselves, offering support and guidance to those coping with this aggressive and destructive cancer. Factor50 was formed following the realisation that there were very limited options for advanced melanoma patients other than standard treatments, which were clearly inadequate.

About the Myfanwy Townsend Melanoma Research Fund:

After Myfanwy Townsend died from melanoma on October 20th 1999, husband Harry and their three sons set up the Charity in her name to raise awareness, educate, publicise, make diagnosis more available (e.g. holding free Walk-In Mole Check Clinics, mobile displays etc.) and help to fund practical research to strive to find a cure. We also publicise nationally Melanoma Awareness Week annually in June.

Consultation Response:

Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

We would like to thank the NICE Appraisal Committee (Appraisal Committee A) for their report on Ipilimumab for previously treated advanced (unresectable or metastatic) malignant melanoma. All three of our organisations work closely with, and for, patients affected by this terrible and aggressive disease and are deeply passionate about any new treatment that comes to the market that may benefit patients with advanced melanoma. This is because we are acutely aware that there have been no new licensed treatments for this group of patients since the 1970s and many patients and clinicians tell us about their frustrations about the lack of treatment options available to them.

The introduction of Ipilimumab is an exciting development and breakthrough in the market for patients with advanced melanoma. Therefore, we are extremely disappointed by the provisional decision from NICE to deny many patients across England and Wales access to this new and innovative treatment option, and we do not believe that the provisional recommendations are a sound and suitable basis for guidance to the NHS. We feel that this is a particularly short-sighted decision that the Cancer Drugs Fund in England, which currently allows patients access to this treatment in many areas across the country, is to come to an end by 2013.

Our concern about this draft guidance is threefold. Firstly, the incidence of melanoma in the UK is rising and new evidence in the British Journal of Cancer suggests that incidence rates will rise even faster than any other cancer; secondly, we are also concerned because this drug fulfils a real unmet need and gap in the market; and finally, we are disappointed as we believe that this treatment is truly innovative and thus more weight needs to be added by the Committee to this element of the decision. We therefore believe it is imperative that NICE re-evaluates this decision and works with all parties involved to find a solution to ensure that patients will benefit from this new treatment for people with advanced melanoma.

Rising incidence:

The incidence of melanoma is rising significantly in the UK, and this trend is only set to continue. A recent study published in the British Journal of Cancer (October 2011) revealed that malignant melanoma had the largest projected rate of increase of the cancers studied. It showed that rates are set to rise by an estimated 52% over the next 20 years. The study projects the disease will become the fourth most common cancer in men and the fifth most common in women over the period. This is extremely concerning and we believe that is even more important that an expanding group of patients are able to access established and effective treatments for advanced melanoma in the coming years.

We also believe that NICE has failed to apportion enough weight to the fact that this is a disease that affects the young as well as the old. The average age of diagnosis is 50 years and melanoma is the second most common cancer in the 15-34 age group. Melanoma is an aggressive disease. We know from our experiences – both personally and professionally – the value of having extra months and years with loved ones. Any extension of life for these

sufferers is invaluable, particularly given the aggressive nature of the disease with sometimes just months between diagnosis to death. It is therefore encouraging that, in trials, 44 – 46% of those given Ipilimumab were still alive after a year compared with 25% given other treatments. This disease disproportionately affects people of a working age and a number of these patients have young families. We urge NICE to look at the social value of the drug and add appropriate weight to this element of its decision.

Unmet need:

There has been no licensed treatment brought to the market for this patient group since the 1970's. Currently, the standard treatment of care is Dacarbazine and this provides limited treatment options for both clinicians and patients. We believe that Ipilimumab fulfils a real gap and unmet need. We are pleased to read that the Committee understands that Ipilimumab addresses a "significant unmet need for effective therapies in this patient population," and we urge the Committee to add further weight to its consideration of the draft evidence by considering the lack of other treatment options that are available to patients with advanced melanoma.

Innovation:

We also believe that this treatment is innovative. We understand that Ipilimumab is a form of immunotherapy that works by encouraging the immune system to produce more cancer-killing cells, something that has not previously been available to patients before.

We therefore believe that there is a real need to reconsider the clinical evidence and add further weight to the innovation behind Ipilimumab. This, combined with the fact this disease disproportionately affects young people, should be a key feature of discussion when the Appraisal Committee meets again to discuss this draft guidance on 16 November.

Over the last 20 days, since the draft guidance was issued by NICE on 14 October, we have continued to work alongside and engage with our supporters about the negative draft guidance issued by the Appraisal Committee. Not only have patients been struck by the innovation behind this treatment but also by the cost. Whilst we feel that we cannot necessarily comment on the cost of Ipilimumab, we hope that the manufacturer, NICE and the Department of Health can work together to do all they can to ensure that the innovation behind this therapy is fully considered so this treatment is made available to these patients who need it the most.

Reconsidering the decision:

We urge that Appraisal Committee A take into consideration all representations it has received in the last 20 days as part of the consultation process. It is important that the jump in rising incidence is taken into account, as well as the unmet need in this disease area. We are extremely concerned that without a positive decision on Ipilimumab for previously treated advanced (unresectable or metastatic) malignant melanoma, patients will lose out on

the chance of a lifeline to have extra months or even years with their loved ones. Many people have told us of their fears and hopes about this treatment being available on the NHS in England and Wales and we hope that the Committee recognise the serious ramifications for choice for patients – and indeed clinicians – if this treatment is not recommended.