Everolimus: for treatment of Renal Cell Carcinoma (mRCC -second line metastatic)

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Patient Group response to the Appraisal Consultation
Document issued on 9th February 2010

The James Whale Fund for Kidney Cancer on behalf of its membership disagrees fundamentally with the preliminary NICE decision (ACD) that Everolimus is not a cost effective use of NHS resources and will not be recommended as 2nd line treatment for advanced and/or metastatic Renal Cell Carcinoma (mRCC)

Prepared by [redacted] at James Whale Fund for Kidney Cancer. Date - 1st March 2010

nb. The kidney cancer patients, carers, families and supporters of the James Whale Fund for Kidney Cancer have given permission for their experience, opinion and patient perspective to be used in the preparation of this document.
THE NHS CONSTITUTION

1st paragraph - The NHS belongs to the people.

“It is there to improve our health and well-being, supporting us to keep mentally and physically well, to get better when we are ill and, when we cannot fully recover, to stay as well as we can to the end of our lives. It works at the limits of science – bringing the highest levels of human knowledge and skill to save lives and improve health. It touches our lives at times of basic human need, when care and compassion are what matter most.”

HIGH QUALITY CARE FOR ALL - OUR JOURNEY SO FAR.

Foreword - Secretary of State Rt Hon Mr Andy Burnham

“From the cradle to the grave, the NHS is there for all of us. It supports people at those moments in life when they find themselves at their most vulnerable, providing a service to everyone that is free at the point of need. It is not just an organisation, but a cherished and ingrained part of life in our country.”

INTRODUCTION.

The James Whale Fund for Kidney Cancer is the UK’s leading specialist kidney cancer charity (Registered Charity No.1120146). We seek to reduce the harm caused by kidney cancer by increasing knowledge and raising awareness. We provide accurate and up-to-date patient information and we support kidney cancer patients, carers and their families by offering practical support, advocacy & friendship through a network of local Support Groups across the UK and an active online patient forum. The Fund actively promotes and facilitates research into the causes, prevention and treatment of Kidney Cancer.

- In this document The James Whale Fund is responding to the Appraisal Consultation Document (ACD) set out on 9th February 2010 on www.nice.org and the preliminary decision of the Appraisal Committee that Everolimus is not a cost effective use of NHS resources and is NOT recommended for the second-line treatment of advanced and/or metastatic Renal Cell Carcinoma (RCC).
- We believe that the preliminary decision not to recommend Everolimus for kidney cancer patients reaching the end of their life, fails to take account of the unmet
clinical needs for this Group of vulnerable patients for whom there are no alternative treatment options. The Fund believes it is clinically and ethically unjust to refuse rarer cancer patients active treatment which is proven to be clinically effective and proven to extend life.

- We believe the drug Everolimus, meets the criteria as an “end of life” drug as set out in the NICE supplementary advice to be taken into account when appraising new & innovative treatments for small numbers of patients with incurable illnesses. We ask the Appraisal committee to reconsider their decision to refuse NHS funding for Everolimus and to attach the proper weight to the patient experience.

- We would ask the Appraisal Committee to take into account the following points at the second committee meeting on the 9th March 2010. These views have been collated from patient correspondence, patient surveys, notes taken during telephone conversations and online forum posts from patients, carers and survivors of kidney cancer.

Has all of the relevant evidence been taken into account?

It is our assertion that meaningful patient input is missing from the ACD. The James Whale Fund feel the evidence should be revisited and the patient perspective must be included and given due weight if NICE wish to present a balanced and rounded appraisal.

- The spend on cancer drugs is higher in other EU Countries. A recent report from Policy Exchange states that spending on cancer medicines in England is only 60% of that spent by other advanced EU countries and our cancer death rate is 6% higher than the EU average, it would be naïve not to see the connection between those two figures. Cancer patients in England are hugely disadvantaged by this process of rationing by cost.

- The last 10 years has seen much research into innovative anti-cancer drugs come to fruition. In the case of Kidney Cancer, NICE has reviewed 5 such new drugs and has only approved one 1st line new drug (Sunitinib) and refused all 2nd line sequential treatments. The drugs refused by NICE are widely available in all western countries and NICE’s justification for denying access to innovative new cancer drugs to NHS patients are based on esoteric cost calculations and statistics which are incomprehensible to patients and the general public. Denying treatment to terminally ill cancer patients has been hugely controversial and the Department of Health, through NICE, has been forced to react to public criticism by introducing an “End of Life” criteria to ensure that modern and comparably costly drugs, are not automatically refused when they fail the notorious and arbitrary NICE QALY. There is no evidence that the EOL criteria have been applied to this application for Everolimus even though Everolimus fits the criteria perfectly. The consequence of this unfair approach is that mRCC patients have only 1 drug for 1st line treatment (accepting there maybe some limited use for 20 year old immunotherapy treatments such as interferon alfa), none at all for sequential 2nd line treatment leaving only, as a last resort, best supportive care. Once again kidney cancer patients in the UK are disadvantaged by the NICE model of cost analysis.
• The figure of the £30,000 Q A L Y has not been updated since its inception - one can imagine the furore if other cost areas in the NHS i.e. salaries and expenses had remained unchanged for 9 years. A simple calculation shows if the QALY had been adjusted in line with other NHS costs, a £50/55,000 Q A L Y would be the norm and taking the figure of 1.4 quoted recently by Professor Stevens as the multiplier, the EOL Q A L Y should now be £70/75,000. N I C E appears to exist in a time warp for this one area of their work. Today’s treatments for today’s patients should not be judged against a set of “rules” which are nearly 10 years old.
• (patient quote) “Cancer survival rates are much higher in other EU countries especially when sequential treatment is available.”

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

It is apparent to us from talking and listening to patients and the general public that the majority of people do not understand the pseudo-science of mathematical models, ICER’s and QALY’s. Patients do not understand how an actual invoice cost of £31,000 pa can, following an appraisal by N I C E, be transformed into a cost to the NHS of £75,000 pa. If N I C E cannot find a way to explain their processes to patients denied access to clinically effective treatments that Clinicians wish to prescribe, then we suggest it is out of touch with the NHS patients it is meant to be serving.

• (patient quote) “It’s so difficult to understand what they are saying, with all that gobblygook, when Sutent stops working for me, can I really expect to live another 11 or 12 months without any proper cancer treatment at all. That’s not what I read on the patients forums. Do other stage 4 patients and the Oncologists agree with that I wonder?”
• NICE should take into account the wider societal benefits of access to end of life drugs for cancer patients when assessing cost effectiveness. If patients on active treatment can continue to work and support their families, is that worth nothing?
• (patient quote) “The NHS has a forecast underspend against budget this year of £1.4 billion - is it a cost effective use of NHS resources to keep that money sitting in NHS bank accounts rather than spend it on front line services like cancer treatments for patients who desperately need them.”
• If this decision is not changed, NICE will have recently rejected all five 2nd line kidney cancer treatments despite promised greater flexibility from NICE for EOL drugs
• Is there a figure being used as the benchmark for “end of life” drugs? How do patients or the public know whether that figure is “reasonable”? How can we comment when the information is not made available? What is a cost effective use of resources when keeping any patient alive? Is it the cost of kidney dialysis per year; is it the cost of an organ transplant operation and ongoing drugs for life?
• (Patient quote)”Our drugs will always be more expensive as there are far fewer of us and pharmaceutical companies have to recoup R & D costs. Drugs
must cost the same to get a license whether they are prescribed to 1000 rarer cancer patients or 40,000 patients.”
• (patient quote) “Everolimus is cost effective - it works, it does what it says on the tin. I know what it is worth because I’m taking the drug.”
• (patient quote) “NICE is just rationing treatments based on money, but rarer cancer patients obviously are still coming off worse”.

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

The general feeling from the kidney cancer community is that they are passionate defenders of the NHS and the principle of universal care, but do not understand why a committee set up to appraise cancer drugs would do so without a leading Oncologist on the panel and without the added value and experience of a cancer patient. To exclude both viewpoints from membership of the Appraisal committee in favour of multiple commissioning and health economics input seems perverse.

• (patient quote) “Rarer cancer patients are discriminated against & feel disenfranchised by the NICE process”
• (patient quote) “Kidney cancer patients have paid into the NHS; I've paid a lifetime of taxes - we have paid into the system now all we want is to have treatment options like other cancer patients”
• (patient quote) “This QALY figure is arbitrary, it is out of date and based on goodness knows what? Was it guesswork?”

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?

• Do kidney cancer patients just have the “wrong type of cancer” Patients are dying prematurely because they simply have the bad luck to have been diagnosed with a rare cancer, through no fault of their own. Nothing will change until the NHS accepts that rarer cancer patients need a separate process of appraisal. A one size HTA does not fit all.
• (patient quote) “Everolimus is available in other EU countries as 2nd line treatment for mRCC, why not in Great Britain?”
• (patient quote) “KC patients have limited treatment options unlike more common cancers (chemotherapy & radiotherapy do not work for kidney cancer) Why can’t similar amounts of money that other cancer patients have access to for their treatments be given to us to help pay for drugs we need. If patients with rarer cancers can’t get treatment because they are in a minority surely this is a form of discrimination.”
The James Whale Fund for Kidney Cancer ask the Appraisal Committee to take account of the following general points from the perspective of the hundreds of kidney cancer patients who will be affected by their ultimate decision.

We feel the principle of cost effectiveness is applied randomly - NICE asserts it is the guardian of NHS resources by applying clinical effective evidence in a rigorous manner. It tells us that NHS funded treatments must be evidence based. Despite this assertion cancer patients know there is striking evidence this principle is not consistent across the NHS. It is difficult for kidney cancer patients to reconcile the control NICE exerts over clinically effective and proven cancer drugs and yet fails to apply to other NHS funded treatments -

1. Homeopathy, which is available on the NHS at huge cost and yet is unproven and felt by many to be no better than placebo.
2. Acupuncture, which is available on the NHS with very little peer reviewed evidence.
3. Alternative medicines available on the NHS and not subject to NICE scrutiny.
4. The swine flu panic now agreed to have led to the waste of huge NHS resources.
5. The winter flu jab for the over 65’s, now seen as failing to deliver measurable benefit.

These examples are proof to patients the NHS is not consistent and NICE is a questionable guardian of precious NHS resources and yet NICE persist in denying treatments to fulfill an unmet clinical need for a 2nd line treatment for terminally ill kidney cancer patients.

Patients tell us they are actively encouraged to enter clinical trials for new cancer drugs. They do so for a number of reasons; it may be the only route to active treatment, they feel they are “doing a good thing” helping to further medical knowledge and they feel their involvement may help future generations of cancer patients. Each time that NICE deny access to effective drugs, the effect on those patients who took part on the clinical trials is immediate and diminishes their contribution; they feel let down and some feel hoodwinked. Their hopes of enabling effective treatment to be used to help other cancer patients are dashed. The knock on effect for further research and trials in the UK must be recognized as must the effect on patients whose hopes are raised when they hear first hand in their Clinics, about good results and evidence, but then discover NICE will not allow these new compounds to be funded by the NHS.

We urge the committee on the 9th March to acknowledge the value of the patient experience, we have asked that our expert patient Mr Bill Savage should be available for
your committee to talk to about the points we have raised in our submission and we would like your agreement to that request.

In conclusion we will share with your committee the words of a stage 4 kidney cancer patient who, until disease progression 3 months ago, was taking a kidney cancer drug refused by NICE, a cancer drug that has given him 3 years of extra life - not a few weeks as we hear quoted in the media, but 3 years during which time he has continued to work and play a full role in his family ..................

“Being told you have terminal kidney cancer is not the worst thing in the world to happen to you - far worse is knowing there are proven drugs that can help you, but you can’t have them.”

Patients in this situation now need sequential 2nd line treatment: who is going to sit this patient down and say to him..........

“It has become too expensive for us to keep you alive.”

- Patient Advocate
The James Whale Fund for Kidney Cancer