

**KIDNEY CANCER UK
(KCUK)**

**COMMENTS ON THE NICE APPRAISAL
CONSULTATION DOCUMENT (ACD) FOR
THE DRUG AXITINIB IN THE TREATMENT
OF ADVANCED RENAL CELL
CARCINOMA (RCC) AFTER FAILURE OF
PRIOR SYSTEMIC TREATMENT**

January, 2013

KCUK is most disappointed with the provisional conclusion of the ACD indicating that NICE is minded *not* to recommend axitinib for second-line treatment of RCC. In response to this, KCUK wishes to make the following points.

Availability of second-line treatments

If the ACD recommendation is enshrined in the Final Appraisal Determination (FAD) this would mean that NICE has failed to find in favour of *any* of the three drugs put forward for second-line treatment: sunitinib, everolimus and, now, axitinib. Such a situation compares unfavourably against the positions adopted in many other countries in which second-line treatment is routinely available in corresponding national health services.

Alternative drugs for second-line treatment

In the course of this appraisal there has been some discussion over the relation between axitinib and everolimus, given that the latter is sometimes funded through the Cancer Drugs Fund (CDF). KCUK considers it important for drugs of this kind to be recognised as eligible for NHS funding, rather than just the CDF, which is both temporary and only available in England (and not in other countries of the UK). But KCUK has

two further points on this. First, as attested to by the oncology consultees, it is valuable to have a number of drugs available for patients, since some patients often respond better to one drug than to the others. This is especially important where there are serious genomic factors involved. Specialist opinion is strongly behind having both a TKI (such as axitinib) and an mTOR inhibitor (such as everolimus) as second-line options. One suggestion is that patients who have benefited for less than 6 months from the first-line TKI (indicating that their diseases were not very sensitive to the modality of that treatment) should be considered for an mTOR inhibitor (everolimus) for their second-line treatment, whilst those who have benefited more significantly from the first-line TKI (ie for more than 6 months) should be offered a further TKI (axitinib) for their second-line treatment. Thus, in this context, the two drugs can be viewed more as complements to each other rather than as substitutes. When either of these drugs is not recognised for funding, some patients could be said to be discriminated against, in only being offered sub-optimal second-line treatment.

A second point is that, however many different drugs there are, the total cost burden upon the NHS will remain broadly the same. On page 42 of the ACD (paragraph 4.17) it is noted that the estimated population for whom axitinib is licensed (1580 people in year 1 and up to 1743 people in year 5) represents a rather small number of patients overall. Recognising axitinib together with everolimus would not make any significant difference to these numbers and consequently no material difference to the total costs borne by the NHS.

Post-progression survival (P-PS)

In paragraph 3.45 on ACD page 31, the length of P-PS is taken as being the same for axitinib plus best supportive care as it is for patient just receiving first-line treatment plus best supportive care. But is this a reasonable assumption to make?

We understand that, in clinical practice, most patients survive on best supportive care for longer if they have had the second-line drug than if their active drug treatment finished with the first-line drug. In other words, there is a residual benefit here; and allowing for this would have the effect of reducing the calculated ICER, or cost per QALY, down from the figure of £62 000 in the direction of the lower estimate of £41 000.