

Sent: 06 November 2006 12:51
To: Christopher Feinmann
Subject: Comments on ACD

I give below my comments on the ACD on Fludarabine :-

(i) Whether you consider that all of the relevant evidence has been taken into account

We do not consider that the evidence relating to the use of Fludarabine in combination with Cyclophosphamide has been fairly considered. Restricting the Appraisal Committee's guidance to Fludarabine alone is blinkered and short sighted. It ignores the submissions of both Clinical Experts and both Patient Experts to NICE who support the use of Fludarabine in combination therapy with Cyclophosphamide as it produces a higher response rate and longer remissions. It also ignores the fact that on a worldwide basis Fludarabine in combination with Cyclophosphamide ,and often also with Rituximab, is increasingly seen as the gold standard for treatment of CLL. In other words other countries have analyzed the same data available to NICE on Fludarabine and reached a diametrically opposed conclusion !!

(ii) Whether you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate

Again these summaries are flawed as they focus on Fludarabine monotherapy. However given the opportunity that this review provides we strongly recommend that all available evidence is collected to enable full consideration now of ICER's for a comparison of Fludarabine/Cyclophosphamide treatment versus Chlorambucil. Failure to do this now would represent a major lost opportunity and deny many UK CLL patients a treatment which demonstrably gives better responses and longer remissions.

(iii) Whether you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS.

As is clear from our comments above we do not consider that the ACD recommendations are sound and if confirmed would represent a major lost opportunity for CLL patients in the UK. There would continue to be a postcode lottery in the provision of Fludarabine in the UK and many patients would be denied a better treatment. We agree with the AC recommendation that prognostic marker tests should be used to better identify sub groups of patients who would benefit from Fludarabine. There has already been extensive research on this and several tests are now widely available but are not generally offered on the NHS. We would like to see ALL CLL patients benefiting from these prognostic tests as a matter of routine and Fludarabine being approved as a treatment option for suitable patients.

Regards,

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