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Subject: NICE appraisal of rituximab in relapsed/refractory CLL  
Importance: High

Dear [REDACTED]

I am emailing you in my capacity as Chairman of the UK CLL Forum to appeal against the FAD for rituximab in relapsed/refractory CLL. I apologise that my appeal is a little late. However, I hope that you will be able to take it into account.

My main objection is that the FAD precludes the use of rituximab in combination with fludarabine and cyclophosphamide (R-FC) in patients who have previously received rituximab. The grounds for my appeal are as follows:

1. CLL is a chronic relapsing disease that requires multiple treatment episodes. According to national and international guidelines, treatments that have produced more than 2 years of remission are considered worthy of giving a second time round provided there are no toxicity issues.
2. In the MD Anderson phase II trial of R-FC as second line therapy, CR and PR rates were no worse in patients who had received prior rituximab.
3. The FAD in its current form discriminates against patients who have already received rituximab as part of their first-line treatment with chlorambucil as part of the Roche phase II trial, which may or may not show a benefit of rituximab in this setting. Paradoxically, this consideration does not apply to patients who have received ofatumumab (a similar CD20 antibody) plus chlormabucil in the GSK phase III trial. I think you will agree that this is a rather perverse situation.
4. Second-line rituxumab-containing regimens have been approved by NICE in follicular lymphoma under very similar circumstances.

I hope that NICE can be persuaded to change its mind about this particular issue. The other elements of the FAD are less controversial.

I am copying this to [REDACTED] Chairman of the CLL Support Association, for [REDACTED] information.

Best wishes

[REDACTED]