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Dear Sir

I am replying to the NICE evaluation report of Rituximab for recurrent or refractory stage 3 or 4 follicular non-Hodgkin's lymphoma (review of TA37). This is a joint response from the British Society for Haematology and the Royal College of Physicians/Royal College of Pathologists Intercollegiate Committee in Haematology

Thank you for asking us to comment on the appraisal consultation document on Rituximab. I do believe all the appropriate evidence has been reviewed in this document and I am pleased that the original recommendation of Rituximab mono-therapy for patients when all alternative treatment options have been exhausted, remains. This is a small group of patients but nonetheless in those with no chemotherapy options or particularly those without the haematological reserve to continue with chemotherapy, this is an extremely useful and active treatment modality.

I would like to address recommendation 1.3 first which is that the ACD does not recommend the use of Rituximab in combination with chemotherapy for induction of remission of patients with relapsed stage 3 or 4 follicular non-Hodgkin's lymphoma. This seems a somewhat strange decision as the evidence for the combination of Rituximab with chemotherapy in the two trials that you have reviewed extensively, shows a significant increase in response rates in those patients receiving the combination and those response rates translate into significant improvements in progression free survival. There is every likelihood that these improvements will translate into overall survival benefits as is being seen with the similar trials for newly diagnosed patients. There is an assumption through this document that patients at relapse will have received Rituximab as part of induction therapy following on from the recent recommendation to Rituximab in combination with CVP chemotherapy for newly diagnosed patients requiring therapy. The vast majority of patients requiring treatment for relapse over the next few years are going to be Rituximab naive and so this cohort of patients is going to be refused access to this drug as a consequence of when they were diagnosed. It is also clear, although in a limited number of patients, that the addition of Rituximab to chemotherapy derives an equal benefit with regards response, whether those patients relapse following chemotherapy or following immuno-chemotherapy.

With regards recommendation 1.2, the use of Rituximab mono-therapy as maintenance. The addition of Rituximab to chemotherapy for follicular lymphoma produces significant increases in overall response rates thereby limiting Rituximab maintenance to those patients that have had a response (which I assume you define as a complete remission together with a partial remission) will mean that significantly fewer patients will be eligible to receive Rituximab. Using CHOP as an example approximately 13% of patients will not get a response by failing to have the addition of Rituximab to the chemotherapy and these patients will then not be eligible for Rituximab by way of maintenance. So what you have done here is reduce the likelihood of people getting response by limiting access to Rituximab with chemotherapy and those patients then fail a second time because they will not be eligible for Rituximab in a maintenance setting.

Kind regards