

### Comments on the ACD Received from the Public through the NICE Website

<b>Name</b>	██████████
<b>Role</b>	NHS Professional
<b>Other role</b>	
<b>Location</b>	England
<b>Conflict</b>	Yes
<b>Notes</b>	Roche drugs are used in various clinical trials in which I am involved
<b>Comments on individual sections of the ACD:</b>	
<b>Section 1</b> (Appraisal Committee's preliminary recommendations)	Maintenance rituximab is used second line and there is first line data. I havent given it personally but understand it is being given via the ICDF. To stop would be a retrograde step.
<b>Section 2</b> (The technology)	
<b>Section 3</b> (The manufacturer's submission)	
<b>Section 4</b> ( Consideration of the evidence)	
<b>Section 5</b> ( Implementation)	
<b>Section 6</b> (Proposed recommendations for further research)	
<b>Section 7</b> ( Related NICE guidance)	
<b>Section 8</b> (Proposed date of review of guidance)	
<b>Date</b>	22/03/2011 16:39

<b>Name</b>	██████████
<b>Role</b>	NHS Professional
<b>Other role</b>	
<b>Location</b>	England
<b>Conflict</b>	yes
<b>Notes</b>	Honoraria medical advisor for Roche
<b>Comments on individual sections of the ACD:</b>	
<b>Section 1</b> (Appraisal Committee's preliminary recommendations)	The committee should recommend first-line maintenance treatment for patients with Follicular Lymphoma. The recommendation fails to take account of patient choice - there are many situations where it may be extremely valuable for a patient to delay the time to relapse. It will be hard for patients who have completed their first course of chemotherapy (R-CVP) then to be told that they will not have access to maintenance therapy knowing that there is strong trial data to support this intervention. I am concerned that improved PFS has been used to approve other technologies by NICE. I am also concerned that this intervention is widely available in Europe, the US and other parts of the UK
<b>Section 2</b> (The technology)	

<b>Section 3</b> (The manufacturer's submission)	
<b>Section 4</b> ( Consideration of the evidence)	
<b>Section 5</b> ( Implementation)	
<b>Section 6</b> (Proposed recommendations for further research)	
<b>Section 7</b> ( Related NICE guidance)	
<b>Section 8</b> (Proposed date of review of guidance)	
<b>Date</b>	17/03/2011 14:03

<b>Name</b>	
<b>Role</b>	NHS Professional
<b>Other role</b>	
<b>Location</b>	England
<b>Conflict</b>	no
<b>Notes</b>	
<b>Comments on individual sections of the ACD:</b>	
<b>Section 1</b> (Appraisal Committee's preliminary recommendations)	At NICE's request, the manufacturer has already conducted health economic analyses based on a number of assumptions. These demonstrated ICER values between £15,000 and £30,000 implying cost-effective use of NHS resources. However there are fundamental issues about how much weight can be attributed to the manufacturer's projections of benefits up to 6 years, which is considerably beyond the period of observation (the median follow up was 38 months). These factors were highlighted in the previous PCT and CSAS submission to NICE. It is expected that the manufacturer will produce further analyses for consideration at the next Appraisal Committee. the assumptions put forward in the manufacturers model do not seem plausible. Any model must be considered in the context of failure to demonstrate improvements in overall survival, and uncertainties about the use of salvage chemotherapy following disease progression. The manufacturer's model was based over a 6 year time period, despite only 4 years' follow up in the PRIMA study.
<b>Section 2</b> (The technology)	Were NICE to reverse this minded no, a positive recommendations could increase the use and therefore the overall cost of this drug for a PCT population. According to the manufacturer's estimates, the cost of treating a person with an average body surface area of 1.8m2 with rituximab maintenance treatment for 2 years is £14,669. Implementing this guidance could carry additional annual drug costs of approximately £380,000 for the average PCT of 300,000 people with an estimated 52 people receiving maintenance treated with rituximab for this indication per year. PCTs would need to give consideration to which haematology services would not receive investment to make way for a requirement to fund this indication.
<b>Section 3</b> (The manufacturer's submission)	l amounts of data were redacted in the original ERG report. The most relevant study was the the PRIMA trial and this forms the basis of the manufacturer's submission. Data from the post-study observational follow-up period, which had a median follow-up of 38

	months, were submitted to the ERG as 'academic in confidence' and will become more generally available when and if they are published. We note that the ERG cautioned that the data were immature and that the early closure of the trial might have led to an overestimation of the clinical benefits of rituximab maintenance treatment. with the level of redaction (presumably on grounds of commercial sensitivity) it makes it hard to form a balanced view.
<b>Section 4</b> ( Consideration of the evidence)	In the manufacturer's base case analysis, rituximab maintenance was cost effective compared with observation when the benefits of rituximab are assumed to last for 6 years (ICER £15,978/QALY). In sensitivity analyses undertaken by the ERG, ICERs ranged from £21,000 to £26,000 per QALY when the benefit was assumed to be sustained for the first 3 to 4 years. given our view that the manufacturers assumptions are "somewhat optimistic" we do not view the manufacturers model as a reliable estimate, and would place more emphasis on the (worst case) assumptions in the sensitivity analysis to be more reflective of a true base case.
<b>Section 5</b> ( Implementation)	
<b>Section 6</b> (Proposed recommendations for further research)	
<b>Section 7</b> ( Related NICE guidance)	
<b>Section 8</b> (Proposed date of review of guidance)	
<b>Date</b>	16/03/2011 22:03

<b>Name</b>	NHS Nottingham City
<b>Role</b>	PCT
<b>Other role</b>	
<b>Location</b>	
<b>Conflict</b>	
<b>Notes</b>	
<b>Comments on individual sections of the ACD:</b>	
<b>Section 1</b> (Appraisal Committee's preliminary recommendations)	After reviewing the available information, and consulting with our regional East Midlands cancer commissioners, I can confirm that NHS Nottingham City is supportive of the provisional recommendation outlined within NICE's second Appraisal Consultation Document for the Technology Appraisal of Rituximab for the maintenance treatment of follicular non-Hodgkin's lymphoma following response to first-line chemotherapy. This is to not recommend Rituximab for the maintenance treatment of follicular non-Hodgkin's lymphoma following response to first line chemotherapy.
<b>Section 2</b> (The technology)	
<b>Section 3</b> (The manufacturer's submission)	
<b>Section 4</b> ( Consideration of the evidence)	
<b>Section 5</b>	

( Implementation)	
<b>Section 6</b> (Proposed recommendations for further research)	
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