

<b>NICE Health Technology Appraisal On Omalizumab for severe, persistent asthma (Review of TA133 and TA201) Appraisal Consultation Document</b>	
<b>TO: NICE</b>	<b>FROM: Healthcare Improvement Scotland</b>  <b>16 November 2012</b>

1. Do you consider that all the relevant evidence has been taken into account? *If not, what evidence do you consider has been omitted, and what are the implications of this omission on the results?* Yes
2. Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence? *If not, in which areas do you consider that the summaries are not reasonable interpretations?* Yes
3. Are the provisional recommendations of the Appraisal Committee sound and do they constitute a suitable basis for the preparation of guidance to the NHS? *If not, why do you consider that the recommendations are not sound? There is a definite unmet need for patients with severe persistent allergic asthma despite currently available treatment options .I still have some concerns about the overall main recommendation in severe persistent allergic asthma , because there is no such thing as an average patient, and there are clearly individual responders where there may be marked benefits which can be identified from an initial 4 month trial ,using pragmatic metrics such as ACQ,AQLQ and steroid sparing .*
4. Are the patient pathways and treatment options described in the assessment applicable to NHSScotland? *If not, how do they differ in Scotland?* Yes
5. Would the provisional recommendations change the patient pathways and/or patient numbers in NHSScotland? *If so, please describe what these changes would be.* No

6. Do you think there is any reason why this provisional guidance would not be as valid in Scotland as it is in England and Wales? *If yes, please explain why this is the case.* No
7. Please add any other information which you think would be useful to NICE or helpful in guiding the Scottish response to this assessment  
None

***Above comment provided to Healthcare Improvement Scotland by:***

1. Do you consider that all the relevant evidence has been taken into account? *If not, what evidence do you consider has been omitted, and what are the implications of this omission on the results?*  
*The review seems very comprehensive and thorough*
2. Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence? *If not, in which areas do you consider that the summaries are not reasonable interpretations?*  
*I concur with the Assessment Group's conclusion that the mortality rates for acute asthma used by the manufacturer are too high (sections 4.2.2, 4.2.15). The notion that mortality for patients >45 is 2.478% per exacerbation is not born out clinically. If this were the case we would be seeing large numbers of asthma deaths in admitted patients, this is simply not the case, I cannot remember the last time I saw an asthma death in an admitted patient.*
3. Are the provisional recommendations of the Appraisal Committee sound and do they constitute a suitable basis for the preparation of guidance to the NHS? *If not, why do you consider that the recommendations are not sound?*  
*This is dependent on the Appraisal Committee's judgement as to the cost per QALY that is acceptable to the NHS. As the health economic analysis is highly specialised and somewhat difficult to follow (it might as well have been written in hieroglyphics) I really can't comment on the validity of the recommendations.*
4. Are the patient pathways and treatment options described in the assessment applicable to NHSScotland? *If not, how do they differ in Scotland?*  
*The pathways and treatment options are applicable to Scotland, having worked both sides of the border there are minimal differences in asthma or asthma care between England and Scotland*

5. Would the provisional recommendations change the patient pathways and/or patient numbers in NHSScotland? *If so, please describe what these changes would be.*

*I suspect that all of the patients in Scotland who will benefit from Omalizumab are currently prescribed the medication. This would continue based on the provisional recommendation. However, if applied the recommendation would prevent the use of Omalizumab in the patients who develop severe asthma in the future, this would impact children first.*

6. Do you think there is any reason why this provisional guidance would not be as valid in Scotland as it is in England and Wales? *If yes, please explain why this is the case.*

*Presumably this depends on the cost per QALY deemed acceptable to NHS Scotland/SMC, I do not know this. In the first instance the guidance should be valid in Scotland*

7. Please add any other information which you think would be useful to NICE or helpful in guiding the Scottish response to this assessment  
*Nothing to add.*

***Above comment provided to Healthcare Improvement Scotland by:***

**[REDACTED]**