British Thoracic Society

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Registered as a charity in England and Wales No. 285174
Scottish Charity No. SC041209
Company Registration No. 1645201

British Thoracic Society
NICE MTA - Asthma - Omalizumab (rev TA133, TA201) [ID482]- ACD
Deadline 30 November 2012

The British Thoracic Society notes the provisional recommendation that:

1.1 Omalizumab is not recommended within its marketing authorisation for treating severe persistent allergic asthma.

1.2 People currently taking Omalizumab should be able to continue treatment until they and their clinician consider it appropriate to stop. For children and adolescents, this decision should be made jointly by the clinician, the child or adolescent, and their parents or carers.

It is the experience of clinicians working with those who have severe asthma that in the small number of patients for whom it is suitable and effective, it is life transforming.

* **Has all of the relevant evidence been taken into account?**

We note that the manufacturer did not perform studies in the population for whom the drug was made available by NICE.

* **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?**

We note the different assumptions made by the NICE Assessment Group in their model compared to that of the Manufacturer. We agree with some of their changes, for example in using a lower mortality rate than the perhaps unrealistically high figure derived from the Watson paper. However, we would like clarification around the assumption that "people in the state of day-to-day asthma symptoms (and not only the state of clinically significant severe exacerbation) have an elevated risk of asthma-related death compared with people without asthma and could die because of asthma" (para 4.2.18). It is true that people with asthma do not always recognise or act on a deterioration in symptoms and may therefore appear to die suddenly "out of the blue", but asthma mortality studies show that in the majority of deaths there is a discernible period of time in which action might have been taken i.e. in a large majority of cases, death is preceded by clinically severe exacerbation. This is important in terms of translating Omalizumab's effect on reducing exacerbations into a mortality benefit in the cost-effectiveness analysis.

We are not convinced that the manufacturers were wrong in their model to use AQLQ data mapped to EQ-5D. AQLQ is a disease specific QOL measure with well validated responsiveness to change data, and the AQLQ data used by Novartis was taken from a superior study (INNOVATE) whilst the

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Assessment Group used EQ-5D data from the open-label EXALT study. In this instance we think the manufacturer made a better choice than the NICE Assessment group.

We note that the Scottish Medicines Consortium, in reviewing the same data, approved Omalizumab and made the drug available to patients who were dependent on oral steroids. This would be the substantial majority of patients in the UK for whom the drug is used and the current NICE position will introduce significant inequity in this severe asthma population within the UK, where therapeutic options are extremely limited.

We also note that the NICE models assess only direct costs, which excludes any indirect cost such as lost work days and potentially more significantly, the cost of systemic steroid induced morbidity. While there may be no good reliable data at this point, there are almost certainly longer term economic benefits in reducing steroid burden.

We do not feel that the impact of oral corticosteroids has been taken into account sufficiently when deciding on cost effectiveness of Omalizumab. This clinically effective treatment should not be withheld due to the inability of health economists to accurately cost the undoubted morbidity attached to long term oral corticosteroid use. Using the ICER per QALY is inappropriate in a patient population with life long severe disease, but an overall low mortality.

* **Are the provisional recommendations sound and a suitable basis for guidance to the NHS?**

The provisional guidelines are not sound, nor suitable. Omalizumab is a well established treatment for severe asthma across Europe and the USA.

The loss of this effective therapy, which is steroid sparing in this population, would be a significant backward step in severe asthma care and is significantly out of step with established best practice for severe asthma.

The document is long and complicated and would benefit from being simplified.

BTS 28 Nov 2012

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The Primary Care Respiratory Society joins the British Thoracic Society in objecting to the provisional decision not to recommend further use of omalizumab.

We have seen the high levels of effectiveness achieved with this product for patients who have struggled to control their asthma on a wide variety of combinations of therapy until omalizumab became available. It has genuinely transformed the lives of this small group of patients.

We agree that considering only the direct costs fails to acknowledge the full extent of the impact of severe asthma on the lives of people with asthma and their families, friends, employers and colleagues.

We also agree that the negative effects of high dose steroids are considerable in patients' lives and removal of omalizumab from the armamentarium will result in omalizumab patients returning to a life dominated by the difficulties and side effects associated with high dose inhaled and oral steroids. To remove a medication that is genuinely steroid sparing in this highly complex but small group of patients is a retrograde step.

We urge NICE to consider carefully the content of the submission from the British Thoracic Society, and to reconsider the proposal not to recommend omalizumab.

The Primary Care Respiratory Society has also reviewed and supported the submission made by Asthma UK.

November 28 2012