National Institute for Health and Clinical Excellence

Multiple Technology Appraisal

Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 and over and adults (review of TA133 and TA201)

Royal College of Nursing

Introduction

The Royal College of Nursing (RCN) was invited to review the Appraisal Consultation Document (ACD) for Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 and over and adults (review of TA133 and TA201).

Nurses caring for people with asthma were invited to review this consultation document on behalf of the RCN.

Appraisal Consultation Document – RCN Response

The Royal College of Nursing welcomes the opportunity to review the Appraisal Consultation Document (ACD) of the technology appraisal of Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 and over and adults (review of TA133 and TA201). The RCN's response to the questions on which comments were requested is set out below:

i) **Has the relevant evidence been taken into account?**

This seems reasonable.

ii) **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence, and are the preliminary views on the resource impact and implications for the NHS appropriate?**

In summary and in response to the Appraisal Committee, we consider that from a professional and clinical perspective, the Committee has made the wrong decision in not recommending omalizumab for the treatment of severe persistent allergic asthma.

Our clinical expert gave her opinion based on the evidence and clinical effectiveness of the drug submitted to the Appraisal Committee and clinical experience of using omalizumab in children attending a demanding asthma service in Leicester over the last 4 years. In this trust, they initiated treatment with this health technology in eight children. Over this time frame; after careful consideration and assessment they deduced that these children were suitable candidates for this treatment and where all other licensed medications had been tried. To date seven out of the eight children continued with the treatment past the sixteen week assessment and there has been considerable improvement not only in their asthma control but also in theirs and their family's quality of life.

The feedback from these children and their families is that treatment with omalizumab has been life changing in not only reducing exacerbations and hospital admissions but also in allowing them to reduce or stop their oral steroid treatment which is of extreme importance considering the potential and actual side-effects of corticosteroids.

We note that that this concern was recognized by the Committee who concluded 'that some adverse effects of oral corticosteroid use, such as obesity, hypertension, mood changes, depression, psychosis, thinning skin, delayed wound healing, reduced growth in children, and increased risk of infection were additional important factors' but that these 'had not been captured when calculating the QALY'. (4.4.13)

As healthcare professionals involved in the care and management of children with severe allergic asthma, reducing the actual and potential risk of the corticosteroids and reducing the risk of acute and potentially life threatening asthma attacks is paramount.

The feedback from the families and children also showed improvements to their quality of life based on the Juniper Paediatric Quality of Life Questionnaire (PAQLQ) scores, and carers' quality of life questionnaire score. Again, this is in line with the Committee's view that there could be additional health-related benefits conferred to carers as a result of omalizumab use 'but that these were currently not quantifiable.' (4.4.17)

iii) **Are the provisional recommendations of the Appraisal Committee sound and suitable basis for the preparation of guidance to the NHS?**

In summary, we consider that the decision not to support the use of omalizumab is going to deny a small but important and vulnerable group of children and adults the opportunity to have treatment with a drug that has been shown to be clinically effective and has undoubtedly changed and improved the quality of lives for those that have had the opportunity to have this treatment in the last four years.

iv) **Are there any aspects of the recommendations that need particular consideration to ensure avoidance of unlawful discrimination against any group of people on grounds of gender, race, disability, age, sexual orientation, religion or belief?**

None that we are specifically aware of at this stage.

v) **Are there any equality related issues that need special consideration that are not covered in the ACD?**

This health technology has a positive impact on a vulnerable group of children and adults. We would ask that any guidance issued should show that equality issues have been considered and that the guidance demonstrates an understanding of issues concerning patients' age, faith, race, gender, disability, cultural and sexuality where appropriate.