British Thoracic Society

Standards & Audit

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British Thoracic Society: Response to NICE MTA - Asthma (severe, persistent, patients aged 6+, adults) - omalizumab (rev TA133, TA201)
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The British Thoracic Society is the professional society for those working in respiratory medicine in the UK. The Society's statutory objectives are "the relief of sickness and the preservation and protection of public health by promoting the best standards of care for patients with respiratory and associated disorders, advancing knowledge about their causes, prevention and treatment and promoting the prevention of respiratory disorders".

The evidence-based British Guideline on the Management of Asthma, produced by the British Thoracic Society and Scottish Intercollegiate Guidelines Network recommends Omalizumab for use only in specialist centres, among people whose asthma remains uncontrolled despite high doses of other treatments. BTS supports the recommendation that that this treatment should be made available to children and adults with severe allergic asthma on that basis.

BTS response

Most of the available data on the use of Omalizumab derives from studies in North America where the management of asthma has traditionally been very different to that in Northern Europe. The use of both oral and inhaled steroids and long acting beta-agonists has always been much less in north America than in our population and this is likely to contribute to the significant increase in mortality from asthma in North America.

This drug is only appropriate for use in genuinely severe asthma in patients who require either continuous systemic corticosteroids, usually daily oral prednisolone, or else very frequent "bursts" of systemic corticosteroids (probably 4 - 6 courses per annum), despite maximal inhaled steroid therapy (± other treatments).

The only alternative to Omalizumab in this small group of patients with genuinely severe asthma is continuation of long term oral corticosteroids. Other agents such as methotrexate and cyclosporin are only appropriate for a small subgroup of patients and these drugs are toxic and frequently ineffective.

Thus, for this group of patients, the most important primary outcome measure is oral corticosteroid sparing. This has not been investigated as a primary outcome in any randomised trial to date and has only been investigated as a secondary outcome in small numbers of patients. However, there are now a number of 'real-life' studies in larger groups of patients with severe asthma, including data from the UK, which supports a substantial steroid sparing effect in these patients [we understand that the UK data is being made available to NICE in separate submissions].

A great deal of emphasis has been placed on death from asthma in the economic analysis – however, this is an inappropriate measure to use in assessing paediatric and adult asthma as the mortality rate, relative to disease prevalence, is small and the excess reliance on using death as an outcome measure totally distorts the analysis.

Oral corticosteroids are cheap medications, but they are associated with very considerable adverse effects in the medium to long term including hypertension, osteoporosis, obesity, hyperlipidaemia, cardiovascular disease, diabetes etc. Omalizumab has a significant impact on morbidity and quality of life by decreasing oral steroid requirements in this population, and this is unlikely to be included in the QALY calculation based on the available randomised clinical trials, as the numbers of patients in this category was small.

The long term economic consequences of treating iatrogenic steroid induced conditions is substantial and needs to be seriously considered in any analyses. We accept that precise economic data on the lifetime morbidity cost of systemic steroid exposure is not currently available in a cohort of severe asthmatics, but believe this to be significant.

Patients and parents of children with severe asthma invariably hate being placed on long term oral corticosteroids and many patients simply refuse to take them in a regular and consistent manner.

In summary, Omalizumab is a step change for a small percentage of patients with severe atopic asthma with emerging evidence of its ability to act as an oral steroid sparing agent in this patient group. We strongly support its continued availability for use only in specialist centres, among people whose asthma remains uncontrolled despite high doses of other treatments.

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