Omalizumab for treating severe persistent allergic asthma (review of technology appraisal guidance 133 and 201)

Published: April 2013
NICE Technology Appraisal Guidance 278
1 Introduction

1.1 The guidance on omalizumab for treating severe persistent allergic asthma in people aged 6 years and over (NICE technology appraisal 278) is unlikely to result in a significant change in resource use in the NHS.

1.2 The guidance is a review of NICE technology appraisal 133 ‘Omalizumab for severe persistent allergic asthma’ and NICE technology appraisal 201 ‘Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 to 11 years’, and replaces this previous guidance. The eligible population in this guidance may be slightly higher than the eligible population identified in the previous NICE guidance for omalizumab. The recommendations are still directed at those people whose condition is severe, though it is defined differently. The number of people actually receiving omalizumab is not estimated by clinicians to increase significantly, and because a patient access scheme has been agreed, a significant change in resource use is not anticipated.

1.3 The guidance states that:

- Omalizumab is recommended as an option for treating severe persistent confirmed allergic IgE-mediated asthma as an add-on to optimised standard therapy in people aged 6 years and older
  - who need continuous or frequent treatment with oral corticosteroids (defined as 4 or more courses in the previous year), and
  - only if the manufacturer makes omalizumab available with the discount agreed in the patient access scheme.
- Optimised standard therapy is defined as a full trial of and, if tolerated, documented compliance with inhaled high-dose
corticosteroids, long-acting beta_2_ agonists, leukotriene receptor antagonists, theophyllines, oral corticosteroids, and smoking cessation if clinically appropriate.

- People currently receiving omalizumab whose disease does not meet the criteria in 1.1 should be able to continue treatment until they and their clinician consider it appropriate to stop.

2 **Patient numbers affected**

2.1 There are approximately 3.5 million people aged 6 years and over in England who are affected by asthma.¹

2.2 It is estimated that there are around 67,000 emergency hospital admissions in England each year. With good asthma management and routine care, 75% of all hospital admissions for asthma are avoidable.²

2.3 The costing template for NICE technology appraisal 133 estimated that around 1600 people in England aged 12 years and over would be receiving omalizumab in 2011. This is based on a range identified during sensitivity analysis of between 550 and 3600 eligible people. Data obtained by the manufacturer suggest that the current uptake for this age group in England is approximately 1400. This uptake figure corresponds to around 3 people in a population of 100,000.

2.4 The number of people aged 6 years and over who will receive omalizumab following implementation of the new guidance is not anticipated to be significantly different to current practice. The new guidance extends the recommended age range to include children aged from 6 to 11 years. The manufacturer estimates that uptake in this age range may be up to 150 children in England, which is less than 1 per 100,000 population. Clinical opinion is in line with this.

---

¹ Based on the manufacturer’s submission, which states that there are 3,744,174 people aged 6 years and over with asthma in England and Wales. A proportion of 94% has been used to obtain an estimate for England only, in line with costing procedures.

² Reported by [Asthma UK](http://www.asthma.org.uk)

National costing statement: Omalizumab for treating severe persistent allergic asthma (review of TA133 and TA201) (April 2013)
3 Resource impact

3.1 The list price of omalizumab is £256.15 for a 150 mg vial and £128.07 for a 75 mg vial. Omalizumab is administered as a subcutaneous injection every 2 to 4 weeks and the exact dose depends on the patient’s serum IgE and weight. The cost of omalizumab ranges from approximately £1665 per patient per year for a 75 mg dose given every 4 weeks to approximately £26,640 per patient per year for a 600 mg dose (the maximum recommended dose in the summary of product characteristics) given every 2 weeks. Table 1 below shows the estimated average annual cost of treatment with omalizumab per patient. This includes the cost of: the drug itself (based on the list price); an initial appointment; administration; and monitoring. These costs may be subject to local variation and do not include the initial costs associated with diagnosing severe persistent allergic asthma.

<table>
<thead>
<tr>
<th>Patient group</th>
<th>Average drug cost of omalizumab (based on list price)</th>
<th>Initial appointment cost</th>
<th>Annual administration and monitoring costs4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First year</td>
<td>Second year and thereafter</td>
<td></td>
</tr>
<tr>
<td>Adults and adolescents</td>
<td>£80561</td>
<td>£1892</td>
<td>£260</td>
</tr>
<tr>
<td>Children aged 6–11 years</td>
<td>£84553</td>
<td>£2913</td>
<td>£268</td>
</tr>
</tbody>
</table>

Table 1 Estimated average annual cost of treatment per patient

1 Average costs provided in the Technology Assessment Report ‘Omalizumab for the treatment of severe persistent allergic asthma: a systematic review and economic evaluation’ (CRD/CHE Technology Assessment Group [Centre for Reviews and Dissemination/Centre for Health Economics], University of York). These are based on the distribution of doses used by patients in the trials. The average annual cost was found to be similar for adults and children.
2 Payment by Results Tariff 2013-2014 for outpatient appointments (treatment function 340 – Respiratory Medicine, Consultant Led: First attendance single professional).
3 Payment by Results Tariff 2013-2014 for outpatient appointments (treatment function 258 Paediatric Respiratory Medicine, Consultant Led: First attendance single professional).
4 Costs of administration were estimated by assuming 10 minutes of administration time using the hourly cost of a specialist asthma nurse at £47/hour. Monitoring costs for anaphylaxis were included up to and including an assessment of response at 16 weeks. For the first 3 administrations, monitoring was assumed to take 2 hours while, from the fourth administration up to the 16-week assessment, monitoring was assumed to take only 1 hour. From 16 weeks onwards, no monitoring costs are incurred.

3 Unit costs of omalizumab are taken from the Dictionary of Medicines and Devices.
4 Costs per patient per year are taken from the Technology Appraisal 278 guidance. These are in line with the costs included in the costing tools for Technology Appraisal 133 and Technology Appraisal 201.

National costing statement: Omalizumab for treating severe persistent allergic asthma (review of TA133 and TA201) (April 2013)
3.2 The Department of Health and the manufacturer have agreed that omalizumab will be available to the NHS with a patient access scheme that makes omalizumab available with a discount. The size of the discount is commercial in confidence. It is the responsibility of the manufacturer to communicate details of the discount to the relevant NHS organisations. Any enquiries from NHS organisations about the patient access scheme should be directed to the Commercial Operations Team at Novartis Pharmaceuticals UK on 01276 698717 or via email to commercial.team@novartis.com.

4 Savings and benefits

4.1 Omalizumab treatment has the potential to improve asthma control and management from a reduction in the number of exacerbations and improvements in health related quality of life. There may be a reduced need for maintenance oral corticosteroid use, which is associated with long-term adverse effects. There may also be a reduction in requirements for other maintenance therapies, and in hospital attendances and admissions.

4.2 The cost of difficult-to-treat asthma to the NHS is estimated to be more than £680 million per year. The costs of severe uncontrolled allergic asthma are substantial, and many patients with the condition are currently managed in severe asthma clinics. The manufacturer’s submission reported that the average cost of a hospitalisation for asthma is estimated to be £785\(^5\) and that the average cost of an exacerbation is around £300\(^6\).

5 Conclusion

5.1 The guidance on omalizumab for treating severe persistent allergic asthma in people aged 6 years and over (NICE technology

---

\(^5\) Based on NHS Reference Costs (2009/10). Calculated as the weighted average of all asthma inpatient Healthcare Resource Group codes DZ15A-F and PA12Z.

\(^6\) Based on NHS Reference Costs (2009/10).
appraisal 278) is unlikely to result in a significant change in resource use in the NHS.