

NICE TA 278 Omalizumab for treating severe persistent allergic asthma (review of technology appraisal guidance 133 and 2010)

1	Summary of NICE TA 278
1.1	<p>NICE has recommended omalizumab 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 and</p> <ul style="list-style-type: none"> • require 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.
1.2	<p>Optimised standard therapy is defined as a full trial of and, if tolerated, documents compliance with inhaled high-dose corticosteroids, long-acting beta₂ agonists, leukotriene receptor antagonists theophyllines, oral corticosteroids, and smoking cessation if clinically appropriate.</p>
1.3	<p>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.</p>
2	<p>Number of people in Northern Ireland expected to take up service/therapy (new cases per year)</p> <p>Based on local clinical data it is estimated currently 27 patients (20 adults and 7 children) on treatment with omalizumab for severe asthma in Northern Ireland.</p> <p>Local clinicians have advised that the additional number of patients projected to commence treatment with omalizumab in line with NICE TA 278 will be:</p> <ul style="list-style-type: none"> • 8 children; • 30 adult new patients waiting to be seen; and, • 30 adult review patients. <p>Given the number of adult new patients waiting to be seen there is some uncertainty regarding the number of new referrals per year. HSCB/PHA will wish to monitor this.</p> <p>In the first instance patients will commence treatment with omalizumab for a trial period of 16 weeks. Approximately 60% will respond to treatment with omalizumab and continue treatment (Table 1)</p>

Table 1

	Number of patients currently on treatment with omalizumab	Drug cost per patient per year	Additional number of patients projected to commence treatment in line with NICE TA 278	Additional number of patients projected to continue treatment after the 16 week trial period (60%)
Children	7	£8455*	8	5
Adults	20	£8056*	30	18
Adults (review patients)	-	£8056*	30	18
Total			68	41

* From costing statement accompanying TA 278

3 Costs

3.1 Cost per patient per annum

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) given every 2 weeks.

Local clinical advice has indicated that patients will commence treatment for a trial period of 16 weeks after which 60% of patients will continue treatment.

In the costing statement accompanying TA 278, an estimated average annual cost of treatment with omalizumab per patient is given as:

- Adults and adolescents - £8056
- Children aged 6-11 - £8455

The costing statement also builds in assumptions regarding nursing admin costs (see Table 2).

The NICE Costing Statement for England that accompanies TA 278 indicates that implementation of this guidance is unlikely to result in resource uses in the NHS. However, there is currently a backlog of 80 patients of whom it is estimated 30 will be eligible to commence treatment with omalizumab.

Table 2

	Projected no. patients	Drug cost per patient per year	Total cost per year
Children	5	£8,455	£42,275
Adults	18	£8,056	£145,008
Adults (review patients)	18	£8,056	£145,008
Drugs cost			£332,291
Nurse admin costs			£6,245
Total costs			£338,536

There is some uncertainty regarding the number of new referrals per year. HSCB/PHA will wish to monitor this and fund further patients if they arise.

3.2 In year cost per patient per annum (for new and prevalent cases)

The manufacturer of this product has agreed a patient access scheme which makes this product available at a discount. The size of the discount is commercial in confidence. Belfast Trust will be expected to avail of this scheme. The additional in year cost before the patient access scheme is estimated at £85k. The PAS will reduce this significantly.

The HSCB/PHA will closely monitor uptake of this regime and expenditure in this regard in the context of the overall expenditure on the treatment of people with severe asthma.

3.3 Cost savings and how these will be secured

Omaliuzumab 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.

The costs of managing severe uncontrolled allergic asthma are substantial, and many patients with the condition are currently managed in severe asthma clinics. The manufacturer's submission to NICE reported that the average cost of a hospitalisation for asthma is estimated to be £785 and that the average cost of an exacerbation is around £300.

<p>3.4</p>	<p>Recurrent overall cost</p> <p>The manufacturer of this product has agreed a patient access scheme which makes this product available at a discount. The size of the discount is commercial in confidence. Belfast Trust will be expected to avail of this scheme. The additional cost before the patient access scheme is estimated at £338k. The PAS will reduce this significantly.</p> <p>There is some uncertainty regarding the number of new referrals per year. HSCB/PHA will wish to monitor this and fund further patients if they arise.</p> <p>The HSCB/PHA will closely monitor uptake of this regime and expenditure in this regard in the context of the overall expenditure on the treatment of people with severe asthma.</p>
<p>4</p>	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients.</p>
<p>5</p>	<p>Commissioning arrangements</p> <p>This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team.</p>
<p>6</p>	<p>Monitoring arrangements</p> <p>Belfast Trust will be required to provide Specialist Services Commissioning Team on a quarterly basis commencing 2013/14 with details of patients commencing treatment to include:</p> <ul style="list-style-type: none"> • the number of patients that have been given the drug and the cost of the drug per patient; • the number of patients who have ceased treatment following the 16 week trial; and, • confirmation that each patient complies with the NICE requirements for this treatment.
<p>7</p>	<p>DHSSPS Legislative/Policy Caveats</p> <p>This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.</p>