The Royal College of Pathologists
Celebrating 50 years 1962–2012

Response to NICE 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)

This appraisal examines the clinical and cost-effectiveness of omalizumab in severe asthma.

It is disappointing that despite evidence of clinical effectiveness in individuals with severe asthma, particularly those on long-term oral steroids, the cost-effectiveness of omalizumab with regard to cost per QALY obtained, results in the conclusion that the drug is not a cost-effective use of NHS resources. There are concerns that evidence available does not reflect current UK practice where a small group of individuals with unstable asthma, often therapy-resistant, gain significant clinical benefit from therapy, although it is acknowledged that this experience has not been collated into published evidence and therefore remains anecdotal.

Has all of the relevant evidence been taken into account?
Relevant published evidence and appropriate modeling have been undertaken. Limitations of the available data have been highlighted in both the report and the previous Assessment Report

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
Yes, given the limitations of data outlined above.

Are the provisional recommendations sound and a suitable basis for guidance to the NHS?
There are concerns over the recommendation that those currently on therapy can continue this until patient and clinician consider that treatment can be stopped, whereas following publication of these recommendations new patients with the same clinical phenotype will no longer be able access the treatment.
With such unequivocal recommendations commissioning groups are highly unlikely to agree to fund treatment of severe asthma with omalizumab, even on grounds of exceptionality. This will cause clear inequality within patient groups. If final conclusions recommend that omalizumab should not be offered to patients with severe asthma, onsideration should be given to the recommendation of a definite time-limit for cessation of therapy in existing patients – 12 months is suggested as evidence presented suggests declining benefit of therapy after this time.

Omalizumab is being used in an unlicensed manner for treatment of chronic urticarial and angioedema. Published small-scale studies indicate that the therapy can be effective in treatment-resistant patients. Availability of the drug for this indication, usually funded on an individual funding request basis, is likely to be adversely effected by these recommendations.

Equality Issues
None identified.