

**omalizumab 150 mg powder and solvent for solution for injection (Xolair®)** **(No: 611/10)**

**Novartis Pharmaceuticals UK Ltd.**

**Product Update**

05 March 2010

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

**ADVICE:** following an abbreviated submission

**omalizumab (Xolair®)** is accepted for restricted use within NHS Scotland.

**Licensed indication under review:** add-on therapy to improve asthma control in children (6 to <12 years of age) with severe persistent allergic asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Omalizumab treatment should only be considered for patients with convincing IgE (immunoglobulin E) mediated asthma.

**SMC restriction:** Use is restricted to patients who are prescribed chronic systemic steroids and in whom all other treatments have failed. The response to omalizumab treatment should be assessed in all patients at 16 weeks and treatment should be discontinued in patients who have not shown a marked improvement in overall asthma control.

The Scottish Medicines Consortium has previously accepted this product for restricted use in adults and adolescents (12 years of age and above). Omalizumab is listed in the British National Formulary for Children for the prophylaxis of allergic asthma.

**Advice context:**

*No part of this advice may be used without the whole of the advice being quoted in full.*

*This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.*

*This assessment is based on data submitted by the applicant company up to and including 13 January 2010.*

**Chairman,  
Scottish Medicines Consortium**

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