Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
www.scottishmedicines.org.uk
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NHS SCOTLAND

Product Update

omalizumab (Xolair®) 75mg, 150mg solution for injection as prefilled syringe (No: 708/11)

Novartis Pharmaceuticals UK Ltd.

06 May 2011

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 75mg, 150mg (Xolair ®) solution for injection is accepted for restricted use within NHS Scotland.

Indication under review: omalizumab is indicated in adults, adolescents (12 years of age and older) and children (6 to <12 years of age) 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.

SMC has previously accepted omalizumab (Xolair ®) 150mg powder and solvent for injection for restricted use in adults, adolescents and children. This submission is for a new solution for injection formulation that will replace the existing formulation. The 150mg solution for injection formulation is bioequivalent to the 150mg powder and solvent for injection formulation and costs the same. The new 75mg strength is half the cost of the 150mg injection and should eliminate wastage that occurred previously with certain doses.

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 **15 April 2011.***

Chairman
Scottish Medicine Consortium

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