Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
www.scottishmedicines.org.uk
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Product Update:

adalimumab 40mg solution for injection in a single-use pre-filled syringe, pre-filled pen and a 40mg/0.8mL paediatric vial (Humira®) (No: 880/13)
AbbVie Ltd

07 June 2013

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

adalimumab (Humira®) is accepted for restricted use within NHS Scotland.

Indication under review: is indicated for the treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies.

SMC restriction: prescribing by specialists in paediatric gastroenterology.

Treatment of paediatric patients with adalimumab resulted in similar clinical remission and response rates at weeks 26 and 52 to that achieved with adalimumab in severe active Crohn's disease in adults.

Adalimumab has previously been accepted for use for this indication in adults with severe active Crohn's disease in NHS Scotland as NHS Healthcare Improvement Scotland advised that NICE Multiple Technology Appraisal No 187 was valid for Scotland.

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 2013.

Chairman,
Scottish Medicines Consortium

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