

Product Update:

**adalimumab 40mg solution for injection in pre-filled syringe or pen,
40mg/0.8mL solution for injection vial for paediatric use (Humira®)**

SMC No. (1050/15)

AbbVie Ltd

10 April 2015

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: for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

SMC restriction: use within specialist rheumatology services (including those working within the network for paediatric rheumatology).

Treatment of paediatric patients with adalimumab resulted in clinically relevant improvements in the number of active joints with arthritis compared with placebo at 12 weeks.

Adalimumab has previously been accepted for restricted use within NHS Scotland in combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 2 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).

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 05 January 2015.

**Chairman
Scottish Medicines Consortium**

Published 11 May 2015