

## Statement of Advice:

**adalimumab (Humira<sup>®</sup>) 40mg/0.4ml Pre-filled Syringe and Pre-filled Pen**  
**adalimumab (Humira<sup>®</sup>) 40mg/0.8ml Pre-filled Syringe and Pre-filled Pen**  
**adalimumab (Humira<sup>®</sup>) 40mg/0.8ml vial for paediatric use**

**(No: 1208/16)**

**AbbVie Limited**

07 October 2016

**ADVICE:** in the absence of a submission from the holder of the marketing authorisation

**adalimumab (Humira<sup>®</sup>)** is not recommended for use within NHS Scotland.

**Indication under review:** Treatment of moderately active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator, or who are intolerant to or have contraindications for such therapies.

The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.

SMC has previously accepted adalimumab for restricted use 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 880/13). This advice remains valid.

### **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. 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.*

**Chairman,  
Scottish Medicines Consortium**

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