Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Final Appraisal Recommendation

Advice No: 3916 – December 2016

Adalilumab (Humira®) 40 mg solution for injection (pre-filled pen, pre-filled syringe and vial)

Limited submission by AbbVie Ltd

Recommendation of AWMSG

Adalimumab (Humira®) is recommended as an option for use within NHS Wales for the treatment of moderately to severely 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.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.
- This advice incorporates and replaces the existing AWMSG recommendation on adalimumab for the treatment of severely active Crohn's disease in paediatric patients (Advice number 2013, originally published August 2013).

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 3118), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	AbbVie Ltd
Date of first issue	December 2016
Last reviewed	August 2020