All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

AWMSG ADVICE SUPERSEDED BY NICE GUIDANCE (TA497)

NICE GUIDANCE ISSUED JANUARY 2018

(Refer to NICE website for full guidance on NICE recommendations, including any specific restrictions on the use of the technology)

Final Appraisal Recommendation

Advice No: 2316 – September 2016

Golimumab (Simponi®) 50 mg solution for injection in prefilled pen, 50 mg solution for injection in prefilled syringe and 100 mg solution for injection in prefilled pen

Submission by Merck Sharp & Dohme Ltd

Recommendation of AWMSG

Golimumab (Simponi®) is recommended as an option for use within NHS Wales for the treatment of adults with severe, active non radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.

This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 1562), 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 the Minister for Health and Social Services and will be considered for review every three years.