



Final Appraisal Recommendation

Advice No: 1621 – November 2021

Ustekinumab (Stelara®) 45 mg and 90 mg solution for injection

Submission by Janssen-Cilag Ltd

Recommendation of AWMSG

Ustekinumab (Stelara®) is recommended as an option for restricted use within NHS Wales.

Ustekinumab (Stelara®) is licensed for the treatment of moderate to severe plaque psoriasis in children from the age of 6 to 11 years, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

Ustekinumab (Stelara®) is restricted for use for the treatment of severe plaque psoriasis (as defined by a total Psoriasis Area Severity Index [PASI] of 10 or more) in children from the age of 6 to 11 years, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

Additional note(s):

- See NICE guidance for ustekinumab for the treatment of adults with moderate to severe plaque psoriasis (TA180, originally published September 2009).
- See NICE guidance for adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people (TA455, originally published July 2017).

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 3687), which includes the All Wales Therapeutics and Toxicology Centre (AWTTC) assessment, 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.

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All Wales Medicines Strategy Group Final Appraisal Recommendation – 1621:
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