



AWMSG Secretariat Assessment Report – Limited submission

Ustekinumab (Stelara[®]) 45 mg solution for injection, 45 mg and 90 mg solution for injection in pre-filled syringe

Company: Janssen-Cilag Ltd

Licensed indication under consideration:

Ustekinumab (Stelara[®]) is indicated for the treatment of chronic moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

Marketing authorisation date: 22 June 2015

Comparator(s):

The comparators included in the company submission were best supportive care (BSC) and etanercept (Enbrel[®]) (budget impact only).

Etanercept is not currently recommended by the All Wales Medicines Strategy Group but the company considered it appropriate to include it as a comparator for budget impact information as this has been the only biological therapy available in Wales via an alternative funding route for patients who do not respond to other systemic therapies or phototherapies up until the time of this submission. The All Wales Medicines Strategy Group has however subsequently recommended adalimumab (Humira[®]) for the same indication in children and adolescents.

Limited submission details:

The limited submission criteria were met as this is a minor license extension for use in adolescent patients from the age of 12 years and older, and the anticipated usage of ustekinumab is considered to be of minimal budgetary impact.

Clinical effectiveness:

- The National Institute for Health and Care Excellence (NICE) Technology Appraisal (TA) 180 recommends ustekinumab (Stelara[®]) as a treatment option for adults with moderate to severe plaque psoriasis. The licence extension under appraisal in this report allows the use of ustekinumab from the age of 12 years.
- Evidence submitted by the company includes a phase III, multi-centre, randomised, double-blind, placebo controlled study (CADMUS), which investigated the use of half dosage and standard dosage of ustekinumab versus placebo in 110 patients ≥ 12 to < 18 years of age with moderate to severe plaque-type psoriasis over a 60 week period.
- The primary outcome demonstrated a significantly greater proportion of subjects randomised to either dosages of ustekinumab achieved a Physician's Global Assessment (PGA) score of cleared (0) or minimal (1) compared to placebo ($p < 0.001$) with a trend towards generally higher and better sustained efficacy in the standard dosage groups after 12 weeks.

Furthermore, improvements in health-related quality of life were demonstrated in this patient group.

- No comparative evidence against etanercept (Enbrel®) for clinical effectiveness was provided.
- The European Medicines Agency (EMA) concluded that the safety profile in the paediatric study was generally comparable with that observed in the two adult psoriasis studies and no other new adverse events or safety issues were identified.

Budget impact:

- The company estimate that the prevalence of psoriasis is 0.73% across all ages; among them a small proportion of the patients (1.10%) are eligible for biological treatment and that a maximum of 14 patients annually may therefore be considered eligible for ustekinumab for this indication within NHS Wales.
- The company has assumed that patients moving from the paediatric to adult indication will offset new patients and therefore, the number of eligible patients is assumed to remain constant at 14.
- The number of injections in year one is five with an annual cost of £10,735 per patient; in year two and onwards the average number of injections per year is 4.3 with an annual cost of £9,306.
- Comparatively, the company estimate the annual cost of BSC per patient to be between £4,417 and £11,029 and the annual treatment cost of etanercept as £9,296.
- The company has assumed that ustekinumab will increase gradually its market share at a rate of 10% per year up to a maximum of 50% market share at year five. The number of patients on ustekinumab is calculated based on total number of patients eligible for biologics and the market share of the given year.
- With regards to the budget impact the company has provided two scenarios. The cost of ustekinumab compared to equal treatment with either etanercept or BSC, gives an incremental budget impact ranging from £3,879 in year one to £18,577 in year five. When all patients are treated with etanercept, this gives an incremental budget impact ranging from £1,439 in year one to £1,502 in year five. The company has estimated budget impact on the lowest BSC annual cost, and has therefore, presented worst case scenarios.
- The company estimates of the proportion of patients receiving BSC and etanercept are however subject to uncertainty. Any increase in BSC would result in a larger incremental cost.
- The company has suggested that vial sharing is unlikely due to the low anticipated number of patients eligible for therapy, and that at least three quarters of the vial will be needed for a dose in the majority of patients. The cost of the wastage is therefore included in the annual cost of ustekinumab and also the cost of the comparator therapies.

Additional information:

- AWTTTC is of the opinion that, if recommended, ustekinumab (Stelara®) is appropriate for specialist only prescribing within NHS Wales for the indication under consideration.
- The company anticipate that ustekinumab (Stelara®) will be supplied by a home healthcare provider.

Evidence search:

Date of evidence search: 16 October 2015.

Date of range of evidence search: No date limits were applied to database searches.

Further information:

This assessment report will be considered for review every three years.

References are available on request. Please email AWTTTC at AWTTTC@Wales.nhs.uk for further information.

This report should be cited as:

All Wales Therapeutics and Toxicology Centre. AWMSG Secretariat Assessment Report. Ustekinumab (Stelara[®]) 45 mg solution for injection, 45 mg and 90 mg solution for injection in pre-filled syringe. Reference number: 2068. January 2016.