All Wales Therapeutics and Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

AWMSG Secretariat Assessment Report – Limited submission

Adalimumab (Humira®) 40mg/0.8ml solution for injection for paediatric use

Company: AbbVie Ltd

Licensed indication under consideration:

Adalimumab (Humira®) for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies

Refer to the Summary of Product Characteristics (SPC) for the full licensed indication.

Marketing authorisation date: 26 March 2015

Comparator(s)

The applicant company suggest there are no suitable comparators as there are no other biologic treatments currently available in Wales for use in the treatment of paediatric psoriasis.

Limited submission details

The limited submission criteria were met as this is a minor licence extension and the anticipated usage of adalimumab (Humira®) in NHS Wales is considered to be of minimal budgetary impact.

Clinical effectiveness

- The phase III paediatric study (M04-717), which compared adalimumab 0.4 mg/kg and adalimumab 0.8 mg/kg with methotrexate showed that, for the first primary endpoint, a statistically significantly higher proportion of patients randomised to adalimumab 0.8 mg/kg achieved a Psoriasis Area Severity Index [PASI] 75 response than patients randomised to adalimumab 0.4 mg/kg or methotrexate at 16 weeks. The second primary endpoint, the response at Week 16 of Physician Global Assessment [PGA]) 0,1 (cleared, minimal), did not reach statistical significance. However, a tendency for clinical efficacy was demonstrated. Taken together, the Committee for Medicinal Products for Human Use (CHMP) stated that a fairly convincing efficacy of adalimumab 0.8 mg/kg had been demonstrated in children and adolescents.
- In the open label period of the study, PASI 75 and PGA (clear, minimal) responses were maintained for up to an additional 52 weeks with no new safety findings.
- CHMP concluded that no new safety concerns emerged from the M04-717 study performed in paediatric patients with psoriasis. Those noted, reflect the adverse events seen in both adult patients with psoriasis and paediatric patients in clinical trials using adalimumab for other indications. The safety profile in younger children with plaque psoriasis (lower age limit of 4 years) would be consistent with the safety profile in younger patients with polyarticular juvenile idiopathic arthritis (JIA); it is on this basis that the proposed lower age limit between 4–6 years, has been justified.

- National Institute for Health and Care Excellence (NICE) Technology Appraisal 146 recommends adalimumab as a treatment option for adults with severe plaque psoriasis for whom anti-tumour necrosis factor (TNF) treatment is being considered where the disease has not responded to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant of, or has a contraindication to, these treatments. The applicant company acknowledge that the need for biological therapy such as adalimumab in the paediatric population with severe plaque psoriasis would only be an option where standard systemic therapies and phototherapy have failed.

Budget impact

- The prevalence of psoriasis is estimated as 0.55% in those younger than 10 years of age, and 1.4% in adolescents. NICE quote UK prevalence for those with severe psoriasis currently eligible for biological therapy to be 1.10% of all psoriasis patients.
- The applicant company calculate 13 children in Wales < 10 years of age with severe psoriasis who would be eligible for treatment with adalimumab and 43 children over 10 years of age.
- The company's budget impact analysis assumes that all eligible children in Wales are treated with adalimumab and the cost per dose has been based on the patients' weight. The applicant company therefore estimate the annual budget impact for treating those under 10 years of age to be £52,420, and £357,250 for those over the age of 10 years; resulting in a total estimated annual budget impact of £409,670.
- The vials are for single use only in line with the licence; however, the cost associated with vial wastage has not been taken into consideration in the company's budget impact estimate.

Additional information

AWTTC is of the opinion that, if recommended, adalimumab (Humira®) is appropriate for specialist only prescribing within NHS Wales for the indication under consideration.

Adalimumab (Humira®) should be discontinued in people whose psoriasis has not responded adequately at 16 weeks.

The company anticipate that adalimumab (Humira®) may be supplied by a home healthcare provider.

Evidence search

Date of evidence search: 2 and 3 July 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 AWTTC at AWTTC@Wales.nhs.uk for further information.

This report should be cited as: All Wales Therapeutics and Toxicology Centre. AWMSG Secretariat Assessment Report. Adalimumab (Humira®) 40mg/0.8ml solution for injection Reference number: 2571. October 2015