

Enc 8 Appx 3

Clinical Expert Summary **Adalimumab (Humira®) 40mg/0.8ml solution for injection for paediatric use**

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.

1. Existing guidelines

- British Association of Dermatologists' guidelines for biologic interventions for psoriasis 2009.

It was highlighted that the only biologic intervention recommended for children is etanercept.

2. Disease prevalence/incidence

One expert predicted that in their catchment area (population 250,000) there would currently be no patients under the age of 18 with disease severe enough to warrant biological therapy.

3. Current treatment options

Most patients are treated with topical therapies including steroids, vitamin D analogues and moisturisers. The next treatment used would be intensive therapy in day units or dermatology wards with dithranol and crude coal tar. If further treatment were required the next option is ultraviolet light therapy, either narrow band UVB or psoralen with UVA (PUVA). The next option would be retinoids (acitretin) and then systemic immunosuppressants (methotrexate, mycophenolate mofetil, short term cyclosporin, fumaric acid esters, apremilast). If these treatments fail then biologic therapies would be considered (infliximab, etanercept, adalimumab, ustekinumab and secukinumab).

4. Unmet needs

A lack of provision of inpatient and day treatment was highlighted, it was suggested that such units would result in more expensive medicines (like biologics) becoming unnecessary. It was also suggested that fumaric acid esters are not used enough due to high import duty resulting in a costly medicine.

5. Knowledge of product in given indication

Expert opinion was that this product would be used after etanercept has failed in patients with severe plaque psoriasis that need biological therapy.

It should be noted that one expert involved in compiling this response declared a personal specific interest in relation to adalimumab for the indication under consideration.