

Clinical Expert Summary
**Ustekinumab (Stelara®) 45 mg solution for injection, 45 mg and 90 mg
solution for injection in pre-filled syringe**

Ustekinumab (Stelara®) 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.

1. Existing guidelines

The following guidelines were highlighted:

- National Institute for Health and Clinical Excellence (NICE). Clinical guideline 153. Psoriasis: assessment and management (2012).
- British Association of Dermatologists' guidelines for biologic interventions for psoriasis (2009).
- Other NICE guidance for use of specific biological therapies in psoriasis

2. Disease prevalence/incidence

One expert stated that within their catchment area, with a population of 250,000, they were not aware of any children qualifying for biological therapies. They were aware that within Wales, some children do qualify for biological therapies and some are currently on either etanercept or adalimumab, but they could not comment on numbers or location.

3. Current treatment options

It was stated that the vast majority of children are treated with topical remedies. Some are put on second line systemic therapies such as methotrexate and the majority do not need more than this. Psoriasis is very rare before the third decade of life so population numbers are very small.

4. Unmet needs

It was highlighted that the frequency of injection of ustekinumab is every three months, as opposed to once or twice a week with etanercept and every two weeks with adalimumab. Therefore, it was suggested that although very rare in children, should a child have psoriasis and need biological therapies, ustekinumab may be more tolerable for a younger population.

5. Knowledge of product in given indication

Expert opinion suggests that ustekinumab would fit in as a third line therapy for adolescents with psoriasis. Due to the infrequency of injection, ustekinumab may be given priority over other biological therapies currently licensed for children. However, equally due to its longer half-life, it might be more prudent to use etanercept first line as side effects would take longer to dissipate if they occur. It was felt that these are the arguments clinicians would have to be aware of when prescribing. Furthermore, it was also highlighted that ustekinumab would be the only non anti-TNF therapy.