

Re-assessment after 4 years of provisional inclusion in the Nza 'Expensive Medicines' policy regulation

## Pharmacotherapeutic report Infliximab (Remicade®) for the indication 'plaque psoriasis'

**Infliximab (Remicade), 100 mg powder for concentrate for solution for infusion**

### Summary

#### Therapeutic value

**Intended effects.** Based on an indirect comparison, infliximab, etanercept, adalimumab and ustekinumab are equally effective in the long-term treatment of psoriasis.

**Unintended effects.** There are no indications of relevant differences in side effects between infliximab and the compared treatments. Infections form the most frequent side effects.

**Experience.** Experience obtained with infliximab is similar to experience with etanercept and more than with adalimumab and ustekinumab. Experience with these drugs was partly obtained with other indications than psoriasis.

**Applicability.** The applicability of infliximab is similar to the comparative treatments. Etanercept and ustekinumab are the preferred drugs for patients with heart failure.

**Ease of use.** As infliximab is administered intravenously, it is less easy to use than the comparative treatments which are administered subcutaneously. Infliximab is administered less frequently than adalimumab and etanercept, but more frequently than ustekinumab.

**Final conclusion.** Infliximab and adalimumab, etanercept and ustekinumab are of equal therapeutic value in the treatment of adults suffering from mild to moderately severe plaque psoriasis who do not respond sufficiently to - or do not tolerate - other systemic therapies, including ciclosporin, methotrexate and PUVA.

#### Comparison between t = 0 and t = 4

When assessing infliximab's provisional inclusion (t = 0) in the Expensive Medicines Policy Regulation (BDG), the CFH concluded, on the basis of 3 short-term, placebo-controlled RCTs, that infliximab had a therapeutic added value [*sic*] in the treatment of plaque psoriasis. No conclusion was formed about the value of infliximab with respect to the indirectly compared drugs etanercept and efalizumab. Between t = 0 and the assessment for continued inclusion in the BDG (t = 4), efalizumab was taken off the market, the drugs adalimumab and ustekinumab have been registered for psoriasis, and long-term results of placebo-controlled trials have been published. Even at t = 4, the therapeutic value of infliximab can still only be determined by means of indirect comparison. The most important outcome parameter for efficacy is the same as at t = 0, i.e., the 'psoriasis area and severity index' (PASI)-score. The conclusion that infliximab has a similar therapeutic value as etanercept, adalimumab and ustekinumab, is based mainly on the long-term efficacy data that have become available.

Finalized October 24, 2011.

*The original text of the summary of this outcome of assessment was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of the summary of the report.*

*Furthermore, CVZ points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.*