OPINION ON MEDICINAL PRODUCTS

infliximab

REMICADE 100 mg,

powder for solution for dilution for infusion

Reassessment

Adopted by the Transparency Committee on 23 November 2022

SUMMARY

The legally binding text is the original French opinion version

Key points

Favourable opinion for maintenance of reimbursement in the treatment of:

- severe active Crohn's disease, in children and adolescents aged 6 to 17 years, who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. REMICADE has been studied only in combination with conventional immunosuppressive therapy.
- severe active ulcerative colitis in children and adolescents aged 6 to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies.

Committee's conclusions

Clinical Benefit

Paediatric Crohn's disease

- Crohn's disease is an incapacitating chronic inflammatory disease which may significantly impair quality of life. In children and adolescents, the primary severity factor is linked with the risk of growth delay frequently associated with delayed puberty.
- The proprietary medicinal product REMICADE (infliximab) is a symptomatic medicinal product.
- The efficacy/adverse effect ratio remains significant.
- Alternative medications are available.

- REMICADE (infliximab) remains a second-line treatment after failure to respond to conventional therapy including a corticosteroid, an immunosuppressive and nutrition therapy.

Paediatric ulcerative colitis

- Ulcerative colitis is a chronic inflammatory bowel disease causing significant impairment of quality of life and exposing patients to serious complications with a two-fold higher risk for children than for adults.
- The proprietary medicinal product REMICADE (infliximab) is a symptomatic medicinal product.
- The efficacy/adverse effect ratio remains significant.
- Alternative medications are available.
- REMICADE (infliximab) remains a second-line treatment in the event of failure to respond (insufficient response, contraindication or intolerance) to a treatment including corticosteroids, azathioprine and/or 6-mercaptopurine.

- **Public health benefit (for both indications):** REMICADE (infliximab) is not likely to have an additional impact on public health.

The Committee deems that the actual clinical benefit of REMICADE (infliximab) remains significant for the treatment of:

- **severe active Crohn's disease, in children and adolescents aged 6 to 17 years, who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. REMICADE has been studied only in combination with conventional immunosuppressive therapy.**
- **severe active ulcerative colitis in children and adolescents aged 6 to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies.**

The Committee approves inclusion in the list of proprietary medicinal products approved for community use for the marketing authorisation indications and at the marketing authorisation dosages.

Clinical Added Value

The Committee deems that the data from this study are not likely to modify the assessment of the clinical added value expressed in the previous opinions of 4 March 2009 and 6 March 2013.