**OPINION ON MEDICINAL PRODUCTS**

adalimumab

# HUMIRA 20 mg, 40 mg and 80 mg,

**solution for injection in prefilled syringe and in prefilled pen**

Reassessment

**Adopted by the Transparency Committee on 14 December 2022**

**SUMMARY**

**The legally binding text is the original French opinion version**

## Key points

Approval of retention of reimbursement for the treatment of severe active Crohn's disease in children and adolescents aged from 6 years having failed to respond to a conventional treatment including first-line nutritional treatment and a corticosteroid and/or an immunomodulatory drug, or in whom these treatments are poorly tolerated or contraindicated.

# Committee's conclusions

## Actual Clinical Benefit

- 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 HUMIRA (adalimumab) is a symptomatic medicinal product.
- The efficacy/adverse effect ratio remains significant for severe forms. It remains poorly established for moderate forms.
- Alternative medications are available.
- HUMIRA (adalimumab) is a second-line medicinal product after failure to respond to a conventional treatment including a corticosteroid, an immunosuppressant and a nutritional treatment.

- **Public health benefit**:

HUMIRA (adalimumab) is not likely to have an additional impact on public health.

**The Committee deems that the actual clinical benefit of HUMIRA (adalimumab) remains significant for the treatment of severe active Crohn's disease, in children and adolescents aged from 6 years having failed to respond to a conventional treatment including a corticosteroid and/or an immunomodulatory drug and a first-line nutritional treatment; or in whom these treatments are poorly tolerated or contraindicated.**

**The Committee approves continued inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary products approved for community use for the treatment of severe active Crohn's disease, in children and adolescents aged from 6 years having failed to respond to a conventional treatment including a corticosteroid and/or an immunomodulatory drug and a first-line nutritional treatment; or in whom these treatments are poorly tolerated or contraindicated, and at the marketing authorisation dosages.**

## Clinical Added Value

**The Committee deems that the new data are not likely to modify the assessment of the clinical added value expressed in the previous opinion of 24 July 2013.**