



TRANSPARENCY COMMITTEE

SUMMARY

23 JUNE 2021

The legally binding text is the original French opinion version

infliximab

INFLECTRA 100 mg powder for concentrate for solution for infusion

Reevaluation

► Key points

Favourable opinion for maintenance of reimbursement in:

- the treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies,
- the treatment of fistulising, active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy).

COMMITTEE'S CONCLUSIONS

Considering all of this data and information and further to debate and voting, the Committee considers:

Clinical benefit

- ▶ Crohn's disease is a chronic inflammatory bowel disease (IBD). It progresses by flare-ups interspersed with remissions. It is a debilitating condition which can lead to a marked deterioration in quality of life.
- ▶ The proprietary medicinal product INFLECTRA 100 mg (infliximab) is a symptomatic medicinal product.
- ▶ The efficacy/adverse effects ratio of INFLECTRA (infliximab), a biosimilar of REMICADE (infliximab), remains substantial.
- ▶ There are therapeutic alternatives (REMICADE and its other biosimilars: REMSIMA, FLIXABI and ZESSLY, administered by the IV route) as well as two TNF α inhibitors administered by the SC route: adalimumab (HUMIRA and its biosimilars) and infliximab (REMSIMA).
- ▶ INFLECTRA (infliximab), like REMICADE (infliximab), is a second-line treatment in moderately to severely active or fistulising active forms of Crohn's disease, in patients not responding to or who are intolerant to or have medical contraindications to corticosteroids and/or immunosuppressive therapy.

Public health impact:

As a biosimilar of REMICADE (infliximab), INFLECTRA (infliximab) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of INFLECTRA (infliximab) remains substantial in the treatment of Crohn's disease in adults.

The Committee issues a favourable opinion for maintenance of inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies; the treatment of fistulising, active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy) and at the MA dosages.

Clinical Added Value

The Committee considers that the data from this study is not of a nature to modify its previous assessment of the medical benefit formulated in its previous opinion of 21 January 2015.