HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
23 JUNE 2021

The legally binding text is the original French opinion version

infliximab
REMSIMA 100 mg powder for concentrate for solution for infusion

Re-evaluation

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

In the treatment of Crohn's disease (CD):

◗ 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 REMSIMA 100 mg (infliximab) is part of a symptomatic treatment regimen.

◗ The efficacy/adverse effects ratio of REMSIMA (infliximab), a biosimilar of REMICADE (infliximab), remains high.

◗ There are therapeutic alternatives (REMICADE and its other biosimilars: INFLECTRA, FLIXABI and ZESSLY, administered by the IV route) as well as two other TNFα inhibitors administered by the SC route: adalimumab (HUMIRA and its biosimilars) and infliximab (REMSIMA).

◗ REMSIMA (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), REMSIMA (infliximab) is unlikely to have an additional impact on public health. The new data is not likely to modify this assessment.

The Committee considers that the clinical benefit of REMSIMA (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 the studies submitted is not of a nature to modify its assessment of the clinical benefit formulated in its previous opinion of 21 January 2015.