

SUMMARY

belatacept

NULOJIX 250 mg,

powder for concentrate for solution for infusion

Reassessment

Original French opinion adopted by the Transparency Committee on
19 July 2023

The legally binding text is the original French opinion version

Committee's conclusions

Clinical Benefit

- Immunosuppressive therapies, associated with organ transplants, are administered in serious, life-threatening clinical situations.
- The proprietary medicinal product NULOJIX (belatacept) is a preventive treatment combined with other immunosuppressive therapies.
- Its efficacy/adverse effects ratio in newly transplanted EBV+ patients and in the context of a combination remains high.
- Therapeutic alternatives are available, particularly ciclosporin and tacrolimus.
- This medicinal product remains a first-line treatment.

→ Public health benefit

The new data available from the BENEFET-EXT study after 7 years are not of a nature to modify the Committee's conclusions of 9 November 2016: NULOJIX (belatacept) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of NULOJIX (belatacept) remains substantial in the MA indication "in combination with corticosteroids and a mycophenolic acid (MPA) for prophylaxis of graft rejection in adult recipients of a renal transplant" in newly transplanted patients.

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 indication "in combination with corticosteroids and a mycophenolic acid (MPA) for prophylaxis of graft rejection in adult recipients of a renal transplant" in newly transplanted patients and at the MA dosages.

Clinical Added Value

Not applicable