SUMMARY

basiliximab

SIMULECT 10 mg, 20 mg

powder for solution for injection or infusion

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 26 June 2024

Summary of opinion

Favourable opinion for reimbursement in the prophylaxis of acute organ rejection in *de novo* allogeneic renal transplantation in adult and paediatric patients (1-17 years).

No clinical added value of the new forms compared to the forms already available.

Transparency Committee's conclusions

Clinical Benefit

- The prevention of acute organ rejection in renal transplantation is a serious clinical situation with an impact on quality of life.
- This is a preventive medicinal product in combination with other immunosuppressive therapies.
- The efficacy/adverse effects ratio is high.
- This is a first-line treatment in view of the therapies available.

Public health benefit

SIMULECT (basiliximab) 10 mg and 20 mg powder for solution for injection or infusion is unlikely to have an additional impact on public health compared to the SIMULECT (basiliximab) medicinal products already available.

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The Committee considers that the clinical benefit of SIMULECT (basiliximab) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion in the list of covered drugs for in-patients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

These medicinal products are range supplements that do not provide any clinical added value (CAV V) compared to the forms already listed.