

SUMMARY

belimumab

**BENLYSTA 120 mg, 200 mg
and 400 mg****powder for concentrate for solution for infusion (120 mg
and 400 mg) and solution for injection in pre-filled pen
(200 mg)****Reassessment at pharmaceutical company's
request****Adopted by the Transparency Committee on 11 December 2024****Summary of opinion**

Favourable opinion for maintenance of reimbursement as add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite well-managed standard therapy with synthetic anti-malarials, NSAIDs, corticosteroids and, potentially, immunosuppressives, depending on specific organ involvement.

Transparency Committee's conclusions**Clinical Benefit**

The new data available are not of a nature to modify the Committee's previous conclusions (opinions of 25/06/2014 and 04/04/2018): the clinical benefit of BENLYSTA 120 mg and 400 mg (belimumab) powder for concentrate for solution for infusion and BENLYSTA 200 mg (belimumab) solution for injection in pre-filled pen remains substantial as add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite well-managed standard therapy with synthetic anti-malarials, NSAIDs, corticosteroids and, potentially, immunosuppressives, depending on specific organ involvement.

The Committee issues a favourable opinion for maintenance of inclusion of:

- BENLYSTA 120 mg and 400 mg (belimumab) powder for concentrate for solution for infusion and BENLYSTA 200 mg (belimumab) solution for injection in pre-filled pen in the list of covered drugs for inpatients approved for use and**
- BENLYSTA 200 mg (belimumab) solution for injection in pre-filled pen in both lists of covered drugs for inpatients and outpatients approved for use,**

in the MA indication and at the MA dosages.

- Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%

Clinical Added Value

The new data are not of a nature to modify the previous conclusions of the Committee (opinions of 25/06/2014 and 04/04/2018):

- BENLYSTA 120 mg and 400 mg (belimumab) powder for concentrate for solution for infusion provide a minor clinical added value (CAV IV) in the care pathway for adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity despite treatment with synthetic anti-malarials, NSAIDs, corticosteroids and/or immunosuppressives, depending on specific organ involvement.
- BENLYSTA 200 mg solution for injection in pre-filled pen is a range supplement that does not provide any clinical added value (CAV V) compared to BENLYSTA 120 mg and 400 mg powder for concentrate for solution for infusion.