SUMMARY

ublituximab

BRIUMVI 150 mg

concentrate for solution for infusion

First listing

Adopted by the Transparency Committee on 15 January 2025

Summary of opinion

Favourable opinion for reimbursement in the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

Transparency Committee's conclusions

Clinical Benefit

- Multiple sclerosis (MS) is a serious, progressive and disabling chronic neurological disease. It corresponds to inflammation and selective, chronic demyelination of the central nervous system. The manifestations are multiple: motor and sensory disorders, sensory, bladder-sphincter and sexual disturbances, cognitive function and mood disorders. They can considerably reduce patients' autonomy and impair their quality of life. Disease severity is highly variable, ranging from mild forms to forms resulting in severe impairment in a matter of years.
- This is a medicinal product to prevent active episodes and progression of disability.
- The efficacy/adverse effects ratio is high.
- It is a first- or second-line treatment in relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features, in the same way as the other anti-CD20 antibodies authorised in this indication, OCREVUS (ocrelizumab) and KESIMPTA (ofatumumab), which were developed concomitantly.

Public health benefit

Considering:

- the seriousness of RMS and its prevalence,
- the partially met medical need,
- the lack of additional response to the identified need due to:
  - the lack of any expected additional impact on morbidity and mortality,
  - the lack of evidence of an impact on quality of life,
  - the lack of evidence of an impact on the organisation of care,

BRIUMVI (ublituximab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of BRIUMVI (ublituximab) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of BRIUMVI (ublituximab) in the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

Considering:

- evidence of the superiority of ublituximab compared to teriflunomide, in two randomised, double-blind phase 3 studies in a selected population, with the majority of those included having early-stage relapsing-remitting MS (RRMS) in terms of disease duration and inflammatory activity:
  - on the annualised relapse rate, the primary endpoint, with a clinically relevant reduction of 59.4% (RR = 0.406 95% CI: [0.268; 0.615], p<0.0001) in the ULTIMATE-I study and 49.1% (RR = 0.509 95% CI: [0.330; 0.784], p<0.002) in the ULTIMATE-II study;
  - on the total number of Gd-enhancing T1 lesions and the total number of new and/or enlarging T2 hyperintense lesions, ranked secondary endpoints,

but in view of:

- the lack of evidence of a difference versus teriflunomide on the time to onset of disability progression, a clinically relevant third ranked secondary endpoint, while the other anti-CD20 antibodies authorised in this indication, OCREVUS (ocrelizumab) and KESIMPTA (ofatumumab), have demonstrated their superiority on this endpoint,
- the absence of robust comparative data versus the available first-line alternatives, including the other anti-CD20 antibodies, rituximab, ocrelizumab and ofatumumab, the latter having been developed concomitantly,
- the absence of robust data versus teriflunomide concerning quality of life in a disease that causes the progressive disability of patients,
- the absence of long-term safety data (median follow-up of 95 weeks in the studies concerned), in particular concerning the long-term risk of hypogammaglobulinaemia,

the Transparency Committee deems that BRIUMVI (ublituximab) 150 mg concentrate for solution for infusion:

- provides no clinical added value (CAV V) in the care pathway for patients with early-stage RRMS in terms of disease duration and inflammatory activity,
- provides no clinical added value (CAV V) in the care pathway for patients with highly active or severe RMS.