SUMMARY

bimekizumab

BIMZELX 160 mg,

Solution for injection in pre-filled syringe or pre-filled pen

Indication extension

Adopted by the Transparency Committee on 6 November 2024

Summary of opinion

Favourable opinion for maintenance of reimbursement in the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy.

Transparency Committee's conclusions

Clinical Benefit

- Hidradenitis suppurativa is a dermatological condition that can progress to an incapacitating chronic form significantly impairing quality of life.
- BIMZELX 160 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is low.
- This proprietary medicinal product is a second-line treatment, following an inadequate response to antibiotic therapy in active moderate to severe HS in adults. BIMZELX (bimekizumab) may be used after antibiotic therapy or in combination with it. In the absence of comparative data versus HUMIRA (adalimumab, TNFα antagonist) and COSENTYX (secukinumab, IL17A inhibitor), the role of BIMZELX (bimekizumab) compared to these medicinal products cannot be specified.

Public health benefit

Considering:

- the chronic nature of the disease and its significant impact in terms of quality of life,
- its low prevalence,
- the partially met medical need in moderate to severe forms of HS, particularly in the event of an inadequate response to conventional systemic treatment (antibiotic therapy) for HS,
- the partial response to the identified need:
  - the absence of evidence of an additional impact on morbidity and/or quality of life compared to adalimumab or secukinumab,

- the lack of evidence of an additional impact on the care or life pathway of patients or on the organisation of care, in particular recourse to elective surgery (cancellation, delay or reduction of its extent),

BIMZELX (bimekizumab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of BIMZELX 160 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen is low in the MA indication.

The Committee issues a favourable opinion for inclusion of BIMZELX 160 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

Considering:

- demonstration in two phase 3 clinical studies (BE HEARD I and II) with the same protocol having included adult patients with active moderate to severe hidradenitis suppurativa, most of whom were treated with antibiotic therapy (approximately 80%) before inclusion:
  - of the superiority of bimekizumab (320 mg every 2 weeks) compared to placebo in both studies, with a modest effect size, on HiSCR50 response (primary endpoint; differences in the region of 19%, $p = 0.006$) and HiSCR75 response (differences of 15% to 20% depending on the studies, $p < 0.03$) and on the skin pain score (HSSDD),
  - of the superiority of bimekizumab (320 mg every 4 weeks) compared to placebo only in the BE HEARD II study, with a modest effect size, on HiSCR50 response (difference of 21.6%, $p = 0.004$) and HiSCR75 response (difference of 18.1%, $p = 0.007$);
- exploratory medium-term results, at week 48, suggesting maintenance of the clinical responses observed at week 16 for the two dosage regimens;
- the safety profile of bimekizumab in the short term (16 weeks) and medium term (48 weeks) similar to that established in the other MA indications;
- the lack of evidence of a clinically relevant benefit in terms of quality of life, which is nonetheless particularly impaired in moderate to severe forms of this disease;
- the lack of evidence of an impact on recourse to elective surgery (cancellation, delay or reduction of its extent);
- the absence of direct comparison in a phase 3 study with adalimumab (HUMIRA), another treatment with an MA in hidradenitis suppurativa with an identical indication wording to that of BIMZELX (bimekizumab),
- the absence of direct comparison with secukinumab (COSENTYX) in a phase 3 study given their concomitant development;

the Committee deems that BIMZELX 160 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen provides no clinical added value (CAV V) in the current treatment of active moderate to severe hidradenitis suppurativa in adults with an inadequate response to

conventional systemic HS therapy, which includes HUMIRA (adalimumab) and COSENTYX (secukinumab).