SUMMARY

bimekizumab

BIMZELX 160 mg,

solution for injection in pre-filled syringe and pre-filled pen

Indication extension

Original French opinion adopted by the Transparency Committee on 27 March 2024

The legally binding text is the original French opinion version

Summary of opinion

Approval of reimbursement "BIMZELX, alone or in association with methotrexate, is indicated for the treatment of active psoriatic arthritis in adults who have responded inadequately or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs)"

Transparency Committee's Conclusions

Clinical Benefit

- Psoriatic arthritis is a chronic disease, which in some of its forms, can be severe and incapacitating.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is poorly defined, in the absence of robust comparative data versus the other biological medicinal products available.
- BIMZELX (bimekizumab) is a third-line and further-line treatment in view of the therapies available, i.e. after inadequate response or intolerance to one or more DMARDs including at least one TNF inhibitor.

Public health benefit

In view of:

- the seriousness and prevalence of psoriatic arthritis;
- the medical need related to treatment failure and/or tolerance phenomena of the medicinal products currently available;
- the lack of response to the identified need considering:
  - the lack of evidence of an additional impact on morbidity-mortality and quality of life compared to the medicinal alternatives,

- the lack of evidence of an impact on the organisation of care and the patient's life pathway,

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

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

The Committee approves inclusion of BIMZELX (bimekizumab) 160 mg solution for injection in pre-filled syringe and pre-filled pen, in the list of covered drugs for outpatients and in the list of covered drugs for inpatients for the indication and at the dosage of the marketing authorisation.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 15%**

Clinical Added Value

In view of:

- the evidence of superiority versus placebo;
- but the lack of robust comparison to a clinically relevant comparator despite being feasible;

the Committee deems that BIMZELX (bimekizumab) provides no clinical added value (CAV V) in the current therapeutic strategy which includes the relevant comparators listed.