

SUMMARY

bimekizumab

BIMZELX 320 mg,**solution for injection in pre-filled syringe or pre-filled pen****Inclusion on list: First listing****Range supplement****Adopted by the Transparency Committee on 11 December 2024****Summary of opinion**

Favourable opinion for reimbursement in the MA indications, in adults, in plaque psoriasis, psoriatic arthritis and hidradenitis suppurativa (for more information see the MA).

No clinical added value of the new forms compared to the forms already available: BIMZELX 160 mg (bimekizumab) solution for injection in pre-filled syringe (B/2) and solution for injection in pre-filled pen (B/2).

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Transparency Committee's conclusions

Clinical Benefit

Plaque psoriasis

- ➔ Psoriasis is a chronic inflammatory skin condition, usually benign, that can, in its moderate to severe forms, have a significant impact on quality of life.
- ➔ BIMZELX 320 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen has a suspensive effect on symptoms.
- ➔ Its efficacy/adverse effects ratio is high.
- ➔ There are a very large number of medicinal alternatives.
- ➔ This proprietary medicinal product is a second-line systemic treatment for moderate to severe forms of adult plaque psoriasis in the event of failure (lack of efficacy, contraindication or intolerance) of a first-line non-biological systemic treatment (methotrexate, ciclosporin or acitretin), and of phototherapy if applicable.

The decision to initiate treatment must take account of the history of the disease, patient characteristics, treatment history and disease severity, which is appraised in terms of the appearance of the lesions as well as in terms of their extent, the impact of the disease on quality of life and the extent of its psychosocial impact.

➔ Public health benefit

BIMZELX 320 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of BIMZELX 320 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion 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.

Psoriatic arthritis

- ➔ Psoriatic arthritis is a chronic disease, which can be serious and disabling in certain forms.
- ➔ BIMZELX 320 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen is a symptomatic medicinal product.
- ➔ The efficacy/adverse effects ratio has not been adequately established given the absence of robust comparative data versus the other biological medicinal products available.
- ➔ BIMZELX (bimekizumab) is a third and later-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

BIMZELX 320 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of BIMZELX 320 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 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.

Hidradenitis suppurativa

- Hidradenitis suppurativa is a dermatological condition that can progress to an incapacitating chronic form significantly impairing quality of life.
- BIMZELX 320 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, TNF α antagonist) and COSENTYX (secukinumab, IL17A inhibitor), the role of BIMZELX (bimekizumab) compared to these medicinal products cannot be specified.

→ Public health benefit

This proprietary medicinal product is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of BIMZELX 320 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 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

Plaque psoriasis

These medicinal products are a range supplement that do not provide any clinical added value (CAV V) compared to BIMZELX 160 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen.

Psoriatic arthritis

These medicinal products are a range supplement that do not provide any clinical added value (CAV V) compared to BIMZELX 160 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen.

Hidradenitis suppurativa

These medicinal products are a range supplement that do not provide any clinical added value (CAV V) compared to BIMZELX 160 mg (bimekizumab) solution for injection in pre-filled syringe or pre-filled pen.