



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
P.O. Box 20350
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2024029166

Date 19 August 2024
Re: Package advice lock procedure medicinal product bimekizumab
(Bimzelx®) PsA

**National Health Care
Institute**

Care
Medicinal Products

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Contact

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Our reference

2024029166

Dear Ms Agema,

The National Health Care Institute advises you on the assessment of bimekizumab (Bimzelx®) for the treatment of active psoriatic arthritis (PsA). The reason for this advice was the placement of bimekizumab in the lock procedure for expensive medicinal products. A concurrent dossier for bimekizumab for the treatment of axial spondylarthritis will be handled by a separate package advice.

Registered indication

Bimekizumab is registered for plaque psoriasis, psoriatic arthritis, hidradenitis suppurativa and axial spondylarthritis. This package advice is about psoriatic arthritis.

Indication for psoriatic arthritis: bimekizumab, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).

Clinical picture

Psoriatic arthritis is a chronic inflammatory disease of joints and skin. These inflammations can vary in intensity with both flare-ups and quiet periods. Psoriatic arthritis affects a portion of people who suffer from the skin disease psoriasis. Psoriatic arthritis may develop at any age but is more common in people aged between 30 and 50 years. In the Netherlands, an estimated 18,000 to 162,000 people suffer from this disease.

Claim by the marketing authorisation holder

Bimekizumab is equivalent to secukinumab and ixekizumab in the treatment of patients with psoriatic arthritis who have had an inadequate response to one or more TNF-alpha inhibitors.

Package advice

The National Health Care Institute recommends that bimekizumab, alone or in combination with methotrexate, be included in the basic healthcare package for patients with psoriatic arthritis who have had an inadequate response to one or more TNF-alfa inhibitors. The National Health Care Institute has established that

bimekizumab for the mentioned indication meets the legal criterion of 'established medical science and medical practice' and that there is an equal value compared to secukinumab and ixekizumab. Due to the equal value to secukinumab and ixekizumab, the inclusion of bimekizumab should not lead to additional costs compared to the costs associated with secukinumab or ixekizumab treatment.

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We explain the preparation of this package advice below.

General

At your request, the National Health Care Institute assesses whether new care should be part of the standard health insurance package from the perspective of the basic healthcare package paid from joint premiums.

The National Health Care Institute has carried out an abbreviated assessment of bimekizumab. This was chosen because bimekizumab is the third IL-17 inhibitor in this indication. The marketing authorisation holder was consulted during the process.

Comprehensive weighting of package criteria

Effectiveness

Established medical science and medical practice

Bimekizumab (with or without methotrexate) has been studied in adult patients with psoriatic arthritis who have had an inadequate response to TNF-alpha inhibitor therapy in the BE COMPLETE study. In this randomised clinical trial, bimekizumab response showed a statistically significant improvement compared to placebo. This study was included in a network meta-analysis in which bimekizumab was indirectly compared to the already reimbursed medicinal products secukinumab and ixekizumab. Although an indirect comparison involves uncertainty, due to the corresponding study design and baseline characteristics of the studies used, the National Health Care Institute has sufficient confidence in this indirect comparison to establish a similar value of bimekizumab to secukinumab and ixekizumab in the treatment of patients with psoriatic arthritis. The professional group also sees these medicinal products all in the same place.

Cost-effectiveness

Due to a similar value of bimekizumab compared to secukinumab and ixekizumab, a cost-effectiveness analysis is not relevant.

Budget impact analysis

The total costs, calculated on the basis of the pharmacy purchase price (€1,103), are €14,339 per patient per year. In year 3, it is expected that 4,669 patients will be treated with an IL-17 inhibitor for the above indication. The National Health Care Institute estimates that, based on a market penetration of 16%, 747 patients will be treated with bimekizumab for this indication in year 3 after inclusion in the package. When substitution of the other IL-17 inhibitors (secukinumab and ixekizumab) is taken into consideration, the budget impact in year 3 amounts to cost savings of €900,000.

The National Health Care Institute notes that the budget impact analysis uses list prices for the calculations. However, for the biological DMARDs used for psoriatic arthritis, purchasing arrangements have been made that are likely to result in lower net prices.

Should you need any further information, please do not hesitate to contact us. The assessment reports have been added as appendices (pharmacotherapeutic assessment and budget impact analysis).

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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