Zorginstituut Nederland

> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
PO Box 20350
2500 EJ THE HAGUE

Date 16 December 2024
Re: Package advice for lock procedure medicinal product bimekizumab (Bimzelx®) HS

Dear Ms Agema,

The National Health Care Institute advises you on the assessment of bimekizumab (Bimzelx®) for the treatment of moderate to severe hidradenitis suppurativa. The reason for this advice was the placement of bimekizumab (Il-17 inhibitor) in the lock procedure for expensive medicinal products.

Hidradenitis suppurativa (acne inversa) is a chronic inflammation of the skin. The most common inflammation occurs in the armpits, groin and anogenital area and is a type of boil that grows larger and deeper and can burst open. It is an unpleasant condition for people suffering from it because the inflammation is painful, unsightly and can smell unpleasant. The disease occurs in about 1% of the population and more in women than in men. The average age at diagnosis is between 21 and 23 years. Medical management starts with antibiotics. In the event of insufficient effect, the guideline recommends a systemic treatment with a biological agent; the TNF-alpha inhibitors adalimumab and infliximab or the IL-17 inhibitor secukinumab (in addendum).

Registered indication
Bimekizumab (Bimzelx®) is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic hidradenitis suppurativa therapy.

In addition, bimekizumab is indicated for plaque psoriasis, psoriatic arthritis, axial spondylarthritis. These indications are not taken into consideration in this assessment.

Claim by the marketing authorisation holder
Bimekizumab has an equal value to adalimumab and secukinumab in the present indication.

Package advice
The National Health Care Institute advises you to include bimekizumab in the basic health care package for patients with moderate to severe hidradenitis suppurativa who have had an inadequate response to conventional systemic therapy.

National Health Care Institute
Care
Medicinal Products

Date
16 December 2024

Our reference
2024042508

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 adalimumab and secukinumab. Due to lack of evidence, the relative effect of bimekizumab compared to infliximab cannot be determined with sufficient certainty. However, the physicians' association sees these medicinal products as all occupying the same place in the treatment. The National Health Care Institute recommends that bimekizumab should only be included in the package if it does not incur additional costs compared to the costs associated with the current treatment with adalimumab, infliximab or secukinumab. We explain the preparation of this package advice below.

General

At your request, the National Health Care Institute assesses whether 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 option was chosen because bimekizumab is the fourth biological and second IL-17 inhibitor for this indication. The marketing authorisation holder was consulted during the process.

Comprehensive weighting of package criteria

Effectiveness

Established medical science and medical practice

Bimekizumab has been studied in adult patients with moderate to severe hidradenitis suppurativa in the BE HEARD I and II studies. In these randomised clinical studies, bimekizumab shows a statistically significant response improvement compared to placebo. These bimekizumab studies have been compared indirectly, through a network meta-analysis (NMA) to the already reimbursed medicinal products adalimumab and secukinumab. 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 an equal value of bimekizumab to adalimumab and secukinumab in the treatment of patients with severe hidradenitis suppurativa. For infliximab, only a short, relatively small study of very low quality is available for this patient group. As a result, the relative effect of bimekizumab compared to infliximab in these patients cannot be assessed with sufficient certainty. The physicians' association sees all these medicinal products as occupying the same place in the treatment (see PT report).

Cost-effectiveness

Due to an equal value of bimekizumab compared to adalimumab and secukinumab, a cost-effectiveness analysis is not relevant.

Budget impact analysis

The total costs, based on the pharmacy purchase price (AIP) of €2,206 (€1,103 per syringe) for bimekizumab, are €28,678 per patient per year. It is expected that in year 3, 1,423 patients will be treated with a biological (adalimumab, infliximab, secukinumab or bimekizumab) for the above indication. The National Health Care Institute estimates that with the expected market penetration of 25% as indicated by the physicians' association, 356 patients per year will be treated with bimekizumab for this indication in year 3 after inclusion in the package. When substitution of the other biologicals (adalimumab, infliximab and secukinumab) is taken into consideration, the budget impact in year 3 amounts to

an additional cost of €5.1 million. The main issue is the uncertainty about market penetration. The additional costs are due in particular to the registered higher dosage and therefore higher price of bimekizumab specifically for this indication. The National Health Care Institute notes that the budget impact analysis uses list prices for the calculations. However, for the biologicals used for hidradenitis suppurativa among other things, purchasing arrangements have been made which will probably lower the actual expenditure.

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

Yours sincerely,

Mark Janssen
Chairperson of the Executive Board

National Health Care Institute
Care
Medicinal Products

Date
16 December 2024

Our reference
2024042508