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National Health Care Institute
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Our reference
2024029243

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Date 19 August 2024
Subject Package advice lock procedure medicinal product bimekizumab (Bimzelx®) axSpA

Dear Ms Agema,

The National Health Care Institute advises you on the assessment of bimekizumab (Bimzelx®) for the treatment of axial spondylarthritis (axSpA). 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 psoriatic arthritis (PSA) will be handled by a separate package advice.

Registered indication
Bimekizumab is registered for plaque psoriasis, psoriatic arthritis, hidradenitis suppurativa and axial spondylarthritis (axSpA). This package advice deals with axial spondylarthritis, which can be divided into non-radiographic axial spondylarthritis (nr-axSpA) and ankylosing spondylitis (AS, radiographic axial spondylarthritis).

Nr-axSpA indication: bimekizumab is indicated for the treatment of adults with active non-radiographic axial spondylarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).
AS indication: bimekizumab is indicated for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.

Clinical picture
Axial spondylarthritis is a form of spondylarthritis. Spondylarthritis is a collective name for a group of rheumatic diseases. In axial spondylarthritis, patients are particularly affected in their pelvis and spine. Back pain and back stiffness are common. There are two forms of axial spondylarthritis. One form, AS, is visible on an X-ray; the other form, nr-axSpA, has the same symptoms, but X-rays do not show any abnormalities. The disease starts between the age of 15 and 35; in the Netherlands, some 90,000 people have axial spondylarthritis.

Claim by the marketing authorisation holder
Bimekizumab is equivalent to secukinumab and ixekizumab in the treatment of patients with axial spondylarthritis (including nr-axSpA and AS) who have had an

inadequate response to one or more TNF-alpha inhibitors.

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Package advice
The National Health Care Institute recommends that bimekizumab be included in the basic health care package for patients with axial spondylarthritis who have had an inadequate response to one or more TNF-alpha 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 and ixekizumab treatment.

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
Established medical science and medical practice

Effectiveness in nr-axSpA:
Bimekizumab has been studied in patients with nr-axSpA in the BE MOBILE 1 study. In this randomised clinical trial, bimekizumab showed 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.
There was no statistically significant difference in the response to bimekizumab compared to secukinumab and ixekizumab in a population mainly (>50%) pre-treated with a disease-modifying anti-rheumatic drug (DMARD), including TNF-alpha inhibitors. In the absence of available data from a population previously using TNF-alpha inhibitors, this is the best matching population for which an analysis is available. This data therefore has only a limited relevance to Dutch practice and there is a measure of uncertainty at play.

Effectiveness in AS:
Bimekizumab has been studied in patients with AS in the BE MOBILE 2 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. There was no statistically significant difference in the response of bimekizumab compared to secukinumab and ixekizumab in patients previously treated with DMARDS.

Despite the aforementioned uncertainties about the populations for which data is

available and the uncertainty associated with an indirect comparison, the National Health Care Institute has, due to the corresponding study design and baseline characteristics of the studies used, sufficient confidence in the indirect comparison with secukinumab and ixekizumab to determine a similar therapeutic value for bimekizumab in the treatment of axial spondylarthritis (nr-axSpA and AS). The professional association also sees the same place for these products.

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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 budget impact analysis assumes axial spondylarthritis and no further distinction is made between AS or nr-axSpA since both are assumed to be equal to the current secukinumab and ixekizumab treatment options.

The total costs, calculated on the basis of the pharmacy purchase price (€1,103), are €14,339 per patient per year. It is expected that in year 3, 2175 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 6.8%, 147 patients per year will be treated per year with bimekizumab for this indication in year 3 after inclusion in the package. If substitution of secukizumab (calculated from a baseline dose of 150 mg/day; base case) and ixekizumab is considered, the budget impact will result in additional costs of approximately €500,000. When taking into account any dose increases of secukinumab (300 mg, scenario) for the majority of patients (based on German data), the additional costs of bimekizumab are approximately €300,000.
The National Health Care Institute notes that the budget impact analysis uses list prices for the calculations. However, for the biological DMARDs (including secukinumab and ixekizumab) used for axial spondylarthritis, 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 annexes (pharmacotherapeutic assessment and budget impact analysis).

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board