Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V)
Bimekizumab (new therapeutic indication: non-radiographic axial spondyloarthritis)

of 21 December 2023

At its session on 21 December 2023, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of Bimekizumab in the version of the resolution of 21 December 2023 on the therapeutic indication "ankylosing spondylitis":

Bimekizumab

Resolution of: 21 December 2023
Entry into force on: 21 December 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 5 June 2023):

Bimzelx is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis 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 nonsteroidal anti-inflammatory drugs (NSAIDs).

Therapeutic indication of the resolution (resolution of 21 December 2023):

See new therapeutic indication according to marketing authorisation.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

a) Adults with active non-radiographic axial spondyloarthritis 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 nonsteroidal anti-inflammatory drugs (NSAIDs)

Appropriate comparator therapy for bimekizumab:

- a TNF-α inhibitor (adalimumab or certolizumab pegol or etanercept or golimumab) or an IL17 inhibitor (ixekizumab or secukinumab)

Extent and probability of the additional benefit of bimekizumab compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults with active non-radiographic axial spondyloarthritis 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 previous biological disease-modifying antirheumatic drug (bDMARD) therapy

Appropriate comparator therapy for bimekizumab:

- Switching to a different biological disease-modifying antirheumatic drug: TNF-α inhibitor (adalimumab or certolizumab pegol or etanercept or golimumab) or IL17 inhibitor (ixekizumab or secukinumab)

Extent and probability of the additional benefit of bimekizumab compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with active non-radiographic axial spondyloarthritis 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 nonsteroidal anti-inflammatory drugs (NSAIDs)

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

b) Adults with active non-radiographic axial spondyloarthritis 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 previous biological disease-modifying antirheumatic drug (bDMARD) therapy

There are no assessable data.

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[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) unless otherwise indicated.

2. Number of patients or demarcation of patient groups eligible for treatment

a) Adults with active non-radiographic axial spondyloarthritis 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 nonsteroidal anti-inflammatory drugs (NSAIDs)

approx. 12,700 patients

b) Adults with active non-radiographic axial spondyloarthritis 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 previous biological disease-modifying antirheumatic drug (bDMARD) therapy

approx. 6,800 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Bimzelx (active ingredient: bimekizumab) at the following publicly accessible link (last access: 10 August 2023):

https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

Treatment with bimekizumab should only be initiated and monitored by doctors experienced in the therapy of non-radiographic axial spondyloarthritis.

4. Treatment costs

Annual treatment costs:

a) Adults with active non-radiographic axial spondyloarthritis 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 nonsteroidal anti-inflammatory drugs (NSAIDs)

and

b) Adults with active non-radiographic axial spondyloarthritis 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 previous biological disease-modifying antirheumatic drug (bDMARD) therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Bimekizumab Additionally required SHI services:	€ 18,700.37 € 74.78

Designation of the therapy	Annual treatment costs/ patient
Total:	€ 18,775.15
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services: Total:	€ 11,434.54 € 181.18 € 11,615.72
Certolizumab pegol Additionally required SHI services: Total:	€ 12,381.20 - € 12,428.82 € 181.18 € 12,562.38 - € 12,610.00
Etanercept Additionally required SHI services: Total:	€ 11,412.64 € 181.18 € 11,593.82
Golimumab Additionally required SHI services: Total:	€ 10,415.84 € 181.18 € 10,597.02
Ixekizumab	€ 16,583.41
Secukinumab	€ 8,929.06

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 December 2023

5. Medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with Bimekizumab

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

a) Adults with active non-radiographic axial spondyloarthritis 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 nonsteroidal anti-inflammatory drugs (NSAIDs)

- No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Adults with active non-radiographic axial spondyloarthritis 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 previous biological disease-modifying antirheumatic drug (bDMARD) therapy

- No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. **The resolution will enter into force on the day of its publication on the website of the G-BA on 21 December 2023.**

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 21 December 2023

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken