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: hidradenitis suppurativa (acne inversa))

of 22 November 2024

At its session on 22 November 2024, 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 accordance with the resolution of 21 December 2023:

Bimekizumab

Resolution of: 22 November 2024
Entry into force on: 22 November 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 19 April 2024):

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

Therapeutic indication of the resolution (resolution of 22 November 2024):

See new therapeutic indication according to marketing authorisation.

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

Adults with active moderate to severe hidradenitis suppurativa (HS) with an inadequate response to conventional systemic HS therapy

Appropriate comparator therapy:

Adalimumab 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]

Adults with active moderate to severe hidradenitis suppurativa (HS) with an inadequate response to conventional systemic HS therapy

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-64) unless otherwise indicated.

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		

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

Adults with active moderate to severe hidradenitis suppurativa (HS) with an inadequate response to conventional systemic HS therapy

Approx. 2,800 – 6,400 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: 7 October 2024):

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 treating hidradenitis suppurativa.

4. Treatment costs

Annual treatment costs:

Adults with active moderate to severe hidradenitis suppurativa (HS) with an inadequate response to conventional systemic HS therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Bimekizumab	€ 33,333.08
Additionally required SHI services	€ 75.42
Total	€ 33,408.50
Appropriate comparator therapy:	
Adalimumab	€ 22,392.84 - € 22,435.82
Additionally required SHI services	€ 86.82
Total	€ 22,479.66 - € 22,522.64
Secukinumab	€ 18,608.12 - € 40,472.66

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 November 2024)

5. Designation of 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 the assessed medicinal product

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:

Adults with active moderate to severe hidradenitis suppurativa (HS) with an inadequate response to conventional systemic HS therapy

No medicinal product with new active ingredients that can be used in a combination therapy and 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 22 November 2024.

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

Berlin, 22 November 2024

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

Prof. Hecken