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) Spesolimab (Generalised Pustular Psoriasis, Acute Treatment)

of 20 July 2023

At its session on 20 July 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. Annex XII shall be amended in alphabetical order to include the active ingredient Spesolimab as follows:

Spesolimab

Resolution of: 20 July 2023
Entry into force on: 20 July 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 9 December 2022):

Spevigo is indicated for the treatment of flares in adult patients with generalised pustular psoriasis (GPP) as monotherapy.

Therapeutic indication of the resolution (resolution of 20 July 2023):

See therapeutic indication according to marketing authorisation.

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

Adults with generalised pustular psoriasis with an acute flare

Appropriate comparator therapy:

Therapy according to doctor's instructions, taking into account systemic glucocorticoids and best supportive care

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with generalised pustular psoriasis with an acute flare

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		

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

Adults with generalised pustular psoriasis with an acute flare

approx. 170 - 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 Spevigo (active ingredient: spesolimab) at the following publicly accessible link (last access: 4 July 2023):

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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-05) unless otherwise indicated.

Treatment with spesolimab should only be initiated and monitored by doctors experienced in the treatment of inflammatory skin disorders.

4. Treatment costs

Annual treatment costs:

Adults with generalised pustular psoriasis with an acute flare

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Spesolimab	€ 21,395.63
Appropriate comparator therapy:	
Therapy according to doctor's instructions	
Prednisolone	Different from patient to patient
Prednisone	Different from patient to patient
Best supportive care[2]	Different from patient to patient

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

Costs for additionally required SHI services: not applicable

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 spesolimab

Medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients that can be used in a combination therapy with spesolimab for the treatment of a flare of a generalised pustular psoriasis on the basis of the marketing authorisation granted under Medicinal Products Act:

Adults with generalised pustular psoriasis with an acute flare

- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

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

[2] In the case of a comparison with best supportive care, also to be used additionally for the medicinal product to be assessed.

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 20 July 2023.

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

Berlin, 20 July 2023

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

Prof. Hecken