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
Concizumab (haemophilia A, ≥ 12 years, with factor VIII inhibitors)

of 16 October 2025

At their session on 16 October 2025, 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 Concizumab as follows:

Concizumab

Resolution of: 16 October 2025
Entry into force on: 16 October 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 13 December 2024):

Concizumab (Alhemo) is indicated for routine prophylaxis of bleeding in patients 12 years of age or more with:

- haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors.
- haemophilia B (congenital factor IX deficiency) with FIX inhibitors.

Therapeutic indication of the resolution (resolution of 16 October 2025):

Concizumab is indicated for routine prophylaxis of bleeding in patients 12 years of age or more with haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors.

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

Adults and adolescents 12 years of age or more with haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors with an indication for routine prophylaxis

Appropriate comparator therapy:

- Emicizumab

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults and adolescents 12 years of age or more with haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors with an indication for routine prophylaxis

No suitable data versus the appropriate comparator therapy were presented.

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 and adolescents 12 years of age or more with haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors with an indication for routine prophylaxis

Approx. 80 to 125 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 Alhemo (active ingredient: concizumab) at the following publicly accessible link (last access: 7 October 2025):

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

Treatment with concizumab should only be initiated and monitored by specialists who are experienced in the treatment of patients with haemophilia and/or other blood coagulation disorders.

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for

[1] Data from the dossier assessment of the IQWiG (A25-55) and from the addendum (G25-27), unless otherwise indicated.

medical professionals and patients and caregivers (including patient identification card). In particular, the training material contains information and warnings on dealing with thromboembolic events and the use of bypassing agents.

4. Treatment costs

Annual treatment costs:

Adults and adolescents 12 years of age or more with haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors with an indication for routine prophylaxis

Designation of the therapy	Annual treatment costs/ patient	
Medicinal product to be assessed:		
Concizumab	Adults	€ 532,150.33 – € 859,627.45
	12 to < 18 years	€ 287,018.48 – € 777,758.17
Appropriate comparator therapy:		
Emicizumab	Adults	€ 315,011.97 – € 328,919.81
	12 to < 18 years	€ 221,215.56 – € 270,922.86

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2025)

Costs for additionally required SHI services: not applicable

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 and adolescents 12 years of age or more with haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors with an indication for routine prophylaxis

- 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.

6. Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product Alhemo is a medicinal product placed on the market from 1 January 2025.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is < 5% of the total number of study participants.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant extent within the scope of SGB V.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 October 2025.

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

Berlin, 16 October 2025

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

Prof. Hecken