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)
Marstacimab (severe haemophilia B, ≥ 12 years, without factor IX inhibitors)

From 17. July 2025

At their session on 17. July 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. In Annex XII, the following information shall be added after No. 6 to the information on the benefit assessment of Marstacimab in the version of the resolution of 17 July 2025 on the therapeutic indication "Severe haemophilia A, ≥ 12 years, without factor VIII inhibitors":

Marstacimab

Resolution of: 17. July 2025
Entry into force on: 17. July 2025
BAnz AT TT. MM JJJJ Bx

Therapeutic indication (according to the marketing authorisation of 18. November 2024):

Hympavzi is indicated for routine prophylaxis of bleeding episodes in patients 12 years of age and older, weighing at least 35 kg, with:

- severe haemophilia A (congenital factor VIII deficiency, FVIII < 1%) without factor VIII inhibitors, or

- severe haemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors.

Therapeutic indication of the resolution (resolution of 17. July 2025):

Hympavzi is indicated for routine prophylaxis of bleeding episodes in patients 12 years of age and older, weighing at least 35 kg, with severe haemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors.

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

Adults and adolescents 12 years of age and older with severe haemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors for routine prophylaxis

Appropriate comparator therapy:

- Routine prophylaxis with human plasma-derived and recombinant coagulation factor IX products

Extent and probability of the additional benefit of Marstacimab 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 and older with severe haemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors 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 and older with severe haemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors for routine prophylaxis

approx. 300 – 310 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 Hympavzi (active ingredient: Marstacimab) at the following publicly accessible link (last access: 8. Juli 2025):

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

Treatment with marstacimab should only be initiated and monitored by specialists experienced in treating patients with haemophilia B.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-17) unless otherwise indicated.

4. Treatment costs

Annual treatment costs:

Adults and adolescents 12 years of age and older with severe haemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors for routine prophylaxis

Designation of the therapy	Annual treatment costs/ patient	
Medicinal product to be assessed:		
Marstacimab	€ 370,067.86 - € 740,135.73	
Appropriate comparator therapy:		
recombinant blood coagulation factor IX products		
Albutrepenonacog alfa		
	Adults	€ 283,563.11 - € 393,582.80
	12 to < 18 years	€ 154,940.71 - € 347,681.86
Eftrenonacog alfa		
	Adults	€ 254,823.18 - € 345,048.37
	12 to < 18 years	€ 141,874.55 - € 295,793.45
Nonacog alfa		
	Adults	€ 329,950.90 - € 439,814.06
	12 to < 18 years	€ 189,353.46 - € 375,201.10
Nonacog beta pegol		
	Adults	€ 317,484.38
	12 to < 18 years	€ 181,529.95 - € 270,839.77
Nonacog gamma		
	Adults	€ 347,735.22 - € 695,939.02
	12 to < 18 years	€ 199,468.59 - € 598,552.25
Human plasma-derived coagulation factor IX products		
Human plasma-derived products[2]		
	Adults	€ 157,671.45 - € 368,378.60
	12 to < 18 years	€ 78,835.72 - € 315,256.55

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1. Juli 2025)

Costs for additionally required SHI services: not applicable

[2] Cost representation based on the requirements in the product information for AlphaNine. Other proprietary medicinal products are available.

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 and older with severe haemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors for routine prophylaxis

- 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.

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 Hympavzi 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% (0.0%) 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 17. July 2025.

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

Berlin, 17. July 2025

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

Prof. Hecken