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:
Albutrepenonacog alfa (exceeding € 50 million turnover limit: haemophilia B, congenital factor IX deficiency)

of 7 April 2022

At its session on 7 April 2022, 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 is amended as follows:

1. **The information on Albutrepenonacog alfa in the version of the resolution of 1 December 2016 (Federal Gazette, BAnz AT 27.01.2017 B6) is repealed.**
2. **Annex XII shall be amended in alphabetical order to include Albutrepenonacog alfa as follows:**

Albutrepenonacog alfa

Resolution of: 7 April 2022
Entry into force on: 7 April 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 11 May 2016):

Treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency).

Idelvion can be used for all age groups.

Therapeutic indication of the resolution (resolution of 7 April 2022):

See therapeutic indication according to marketing authorisation.

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

Patients of all age groups with haemophilia B

Appropriate comparator therapy of Albutrepenonacog alfa:

recombinant or human plasma-derived blood coagulation factor IX preparations

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Patients of all age groups with haemophilia B

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-137) 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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

There are no assessable data.

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

Patients of all age groups with haemophilia B

approx. 560 - 720 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 Idelvion (active ingredient: albutrepenonacog alfa) at the following publicly accessible link (last access: 19 January 2022):

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

Treatment with albutrepenonacog alfa should only be initiated and monitored by doctors experienced in treating patients with haemophilia B.

The safety and efficacy of Idelvion in previously untreated patients has not yet been established.

4. Treatment costs

Annual treatment costs:

Patients of all age groups with haemophilia B

Designation of the therapy	Annual treatment costs/ patient	
Medicinal product to be assessed:		
Albutrepenonacog alfa	Adults	€ 361,672.47 - € 546,269.59
	12 - < 18 years	€ 271,285.22 - € 399,845.82
	6 - < 12 years	€ 152,667.59 - € 214,453.50
	< 6 years	€ 92,926.08 - € 121,527.42
Appropriate comparator therapy:		
Recombinant blood coagulation factor IX		
Nonacog alfa	Adults	€ 329,945.42 - € 439,806.76
	12 - < 18 years	€ 237,820.07 - € 317,006.59
	6 - < 12 years	€ 144,541.60 - € 192,669.36
	< 6 years	€ 54,822.75 - € 128,060.04
Nonacog beta pegol	Adults	€ 323,538.92
	12 - < 18 years	€ 230,424.23
Nonacog gamma	Adults	€ 292,477.72 - € 585,800.52
	12 - < 18 years	€ 211,006.17 - € 419,077.60
	6 - < 12 years	€ 128,026.34 - € 310,478.61
	< 6 years	€ 64,881.43 - € 142,598.32
Eftrenonacog alfa	Adults	€ 404,653.41 - € 564,595.51
	12 - < 18 years	€ 308,190.26 - € 414,572.84
	6 - < 12 years	€ 169,829.33 - € 190,016.52
	< 6 years	€ 96,463.15
Blood coagulation factor IX derived from human blood plasma		
Human plasma-derived preparations[2]	Adults	€ 160,717.22 - € 375,482.23
	12 - < 18 years	€ 120,971.59 - € 268,366.76
	6 - < 12 years	€ 80,358.61 - € 161,251.28

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 March 2022)

[2] Cost representation based on the information in the Haemonine® product information. Other proprietary medicinal products are available.

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 7 April 2022.

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

Berlin, 7 April 2022

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

Prof. Hecken