Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment to the Pharmaceuticals Directive (AM-RL): Annex XII – Resolutions on the Benefit Assessment of Medicinal Products with New Active Ingredients in Accordance with Section 35a SGB V Damoctocog alfa pegol

From 20 June 2019

At its session on 20 June 2019, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (Pharmaceuticals Directive) in the version dated 18 December 2008/22 January 2009 (BAnz. No. 49a of 31 March 2009), as last amended on TT. Monat JJJJ (BAnz AT TT.MM.JJJJ BX), as follows:

I. Annex XII shall be amended in alphabetical order to include the active ingredient Damoctocog alfa pegol as follows:

Damoctocog alfa pegol

Resolution of: 20 June 2019
Entry into force on: 20 June 2019
BAnz AT TT. MM JJJJ Bx

Therapeutic indication (according to the marketing authorisation of 22 November 2018):

Treatment and prophylaxis of bleeding in previously treated patients 12 years of age and older with haemophilia A (congenital factor VIII deficiency).

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

Patients aged 12 and older with haemophilia A (congenital factor VIII deficiency)

Appropriate comparator therapy:

- Recombinant or human plasma-derived blood coagulation factor VIII preparations

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

An additional benefit is not proven.

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

Patients aged 12 and older with haemophilia A (congenital factor VIII deficiency)

Approx. 2,840–3,190 patients

3. Requirements for a quality-assured application

The requirements of 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 Jivi® (active ingredient: Damoctocog alfa pegol) at the following publicly accessible link (last access: 29 April 2019):

https://www.ema.europa.eu/documents/product-information/jivi-epar-product-information_de.pdf

Treatment with Damoctocog alfa pegol should be initiated and monitored by specialists experienced in the treatment of haemophilia.

4. Treatment costs

Patients aged 12 and older with haemophilia A (congenital factor VIII deficiency)

Annual treatment costs[1]:

Designation of the therapy	Annual treatment costs/patient	
Medicinal product to be assessed:		
Damoctocog alfa pegol	Adults	€ 507,106.60 – € 679,540.58
	12 – <18 years	€ 368,804.80 – € 485,386.13
Appropriate comparator therapy:		
Recombinant blood coagulation factor VIII		
Rurioctocog alfa pegol	Adults	€ 506,797.20 – € 615,396.60
	12 – <18 years	€ 361,998.00 – € 470,597.40
Efmoroctocog alfa	Adults	€ 184,120.97 – € 786,367.47
	12 – <18 years	€ 143,205.20 – € 581,228.13
Lonoctocog alfa	Adults	€ 200,986.24 – € 732,164.16
	12 – <18 years	€ 143,561.60 – € 559,890.24
Moroctocog alfa	Adults	€ 246,443.05 – € 739,329.15
	12 – <18 years	€ 176,030.75 – € 528,092.25
Octocog alfa[2]	Adults	€ 237,718.21 – € 713,154.62
	12 – <18 years	€ 169,798.72 – € 509,396.16
Simoctocog alfa[3]	Adults	€ 222,306.88 – € 666,920.63
	12 – <18 years	€ 158,790.63 – € 476,371.88
Turoctocog alfa	Adults	€ 269,642.10 – € 654,845.10
	12 – <18 years	€ 192,601.50 – € 500,763.90
Blood coagulation factor VIII derived from human plasma		
Human plasma preparations[4]	Adults	€ 210,873.95 – € 632,621.85
	12 – <18 years	€ 150,624.25 – € 451,872.75

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 01 June 2019)

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 20 June 2019.

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

[1] The prices are not subject to the Pharmaceutical Price Ordinance (AMPreisV).
[2] Cost representation based on the information provided in the summary of product characteristics for Kovaltry®. Further proprietary medicinal products are available.
[3] Cost representation based on the information provided in the summary of product characteristics for Nuwiq®. Further proprietary medicinal products are available.
[4] Cost representation based on the information provided in the summary of product characteristics for Fanhdi®. Further proprietary medicinal products are available.

Berlin, 20 June 2019

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

Prof. Hecken