Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Turoctocog Alfa Pegol

of 6 February 2020

At its session on 6 February 2020, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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 on DD 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 turoctocog alfa pegol as follows:

Turoctocog alfa pegol

Resolution of: 6 February 2020
Entry into force on: 6 February 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 1 August 2019):

Treatment and prophylaxis of bleeding in patients 12 years and above with haemophilia A (congenital factor VIII deficiency).

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

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

Appropriate comparator therapy:

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

Extent and probability of additional benefit of turoctocog alfa pegol compared with the appropriate comparator therapy:

An additional benefit is not proven.

Summary of results for relevant clinical endpoints

Endpoint category	Effect	Summary
Mortality	∅	No suitable data were submitted for the benefit assessment.
Morbidity	∅	No suitable data were submitted for the benefit assessment.
Health-related quality of life	∅	No suitable data were submitted for the benefit assessment.
Side effects	∅	No suitable data were submitted for the benefit assessment.

Explanations:
↑, ↓: statistically significant and relevant effect with high or unclear risk of bias
↑↑, ↓↓: statistically significant and relevant effect with low risk of bias
↔: no relevant difference
∅: no data available
n.r.: not rateable

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

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

approx. 2,840–3,190 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 Esperoct® (active ingredient: turoctocog alfa pegol) at the following publicly accessible link (last access: 19 December 2019):

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

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

4. Treatment costs

Annual treatment costs:[1]

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

Designation of the therapy	Annual treatment costs/patient	
Medicinal product to be assessed:		
Turoctocog alfa pegol	Adults	€ 584,766.00 – 844,662.00
	12 – <18 years	€ 454,818.00 – 649,740.00
Appropriate comparator therapy:		
Recombinant blood coagulation factor VIII		
Damoctocog alfa pegol	Adults	€ 484,056.30 – 679,540.58
	12 – <18 years	€ 345,754.50 – 485,386.13
Rurioctocog alfa pegol	Adults	€ 390,710.32 – 474,433.96
	12 – <18 years	€ 279,078.80 – 362,802.44
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

[1]The prices are not subject to the Pharmaceutical Price Ordinance (AMPreisV).

Designation of the therapy	Annual treatment costs/patient	
	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 products[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: 15 January 2020

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 6 February 2020.

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

Berlin, 6 February 2020

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken

[2] Cost representation based on the information provided in the product information for Kovaltry®. Further proprietary medicinal products are available.
[3] Cost representation based on the information provided in the product information for Nuwiq®. Further proprietary medicinal products are available.
[4] Cost representation based on the information provided in the product information for Fanhdi®. Further proprietary medicinal products are available.