

Turoctocog alfa pegol

Resolution of: 6 February 2020
 Entry into force on: 6 February 2020
 Federal Gazette, BAnz AT 24 March 2020 B5

valid until: unlimited

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
Morooctocog 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

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

Designation of the therapy	Annual treatment costs/patient	
		12 – <18 years
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

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.