

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 and Annex IX (Definition of Reference Price Groups) – Coagulation Factors VIII, Recombinant, Group 1, in Tier 2

of 2 October 2024

At its session on 2 October 2024, the Federal Joint Committee 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 18 July 2024 (BAnz AT 16.10.2024 B3), as follows:

- I. Annex XII shall be amended in alphabetical order to include the active ingredient "efanesoctocog alfa" as follows:

"Efanesoctocog alfa

Resolution of: 2 October 2024

Entry into force on: 2 October 2024

BAnz AT DD.MM YYYY Bx

A medical additional benefit of efanesoctocog alfa as therapeutic improvement according to Section 35, paragraph 1b, sentences 1 to 5 SGB V over the other active ingredients in the reference price group "coagulation factors VIII, recombinant, group 1" in tier 2 is considered as not proven according to Section 35a, paragraph 1, sentences 4 and 5 SGB V."

- II. In Annex IX, the reference price group "coagulation factors VIII, recombinant, group 1" in tier 2 is worded as follows:

"Tier: 2

Active ingredient group: coagulation factors VIII, recombinant

Reference price group no.: 1

Status: prescription-only

Active ingredients and comparative figures:	Active ingredients	Comparative figures
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	Damoctocog alfa pegol	6248
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	Efanesoctocog alfa	4250
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Efmoroctocog alfa	7650
Lonoctocog alfa	7438
Moroctocog alfa	7395
Octocog alfa	6885
Rurioctocog alfa pegol	7650
Simoctocog alfa	7395
Turoctocog alfa	9118
Turoctocog alfa pegol	7650

Group description: parenteral dosage forms

Dosage forms: Powder and solvent for solution for injection, powder and solvent for solution for injection/ infusion"

- III. The resolution will enter into force on the day of its publication on the internet on the website of the Federal Joint Committee on 2 October 2024.

The justification to this resolution will be published on the website of the Federal Joint Committee at www.g-ba.de.

Berlin, 2 October 2024

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

Prof. Hecken