

# 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,  
Annex IX (Definition of Reference Price Groups) and  
Annex X (Update of Comparative Figures)  
– Colony-stimulating Factors, Pegylated, 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 14.10.2024 B2), as follows:

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

**"Efbemalenograstim alfa**

Resolution of: 2 October 2024

Entry into force on: 2 October 2024

BAnz AT DD.MM YYYY Bx

A medical additional benefit of efbemalenograstim 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 "colony-stimulating factors, pegylated, 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 "colony-stimulating factors, pegylated, group 1" in tier 2 is worded as follows:

"Tier: 2

Active ingredient group: colony-stimulating factors, long-acting

Reference price group 1

no.:

Status: prescription-only

Active ingredients and Active ingredients

comparative figures:

Efbemalenograstim alfa

Comparative figures

20

Lipegfilgrastim	6
Pegfilgrastim	6

Group description: parenteral dosage forms  
Dosage forms: solution for injection"

- III. In Annex X in section "Reference price groups with comparative figure determination according to Section 1 of Annex I to Chapter 4 of the VerfO", the information "colony-stimulating factors, pegylated, group 1" is changed to "colony-stimulating factors, long-acting, group 1".
- IV. 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](http://www.g-ba.de).

Berlin, 2 October 2024

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

Prof. Hecken