

Resolution

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) and Annex IX (Definition of reference price groups) - Benzodiazepine-related agents, Group 1, tier 2

of 6 May 2021

At its meeting on 6 May 2021, 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 (Federal Gazette, BAnz. No. 49a of 31 March 2009), last amended on D. month YYYY (BAnz AT DD.MM.YYYY V), as follows:

- I. Annex XII shall be amended in alphabetical order to include the active ingredient “eszopiclone” as follows:

“Eszopiclone

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Entry into force on: 6 May 2021

BAnz AT DD.MM YYYY Bx

A medical additional benefit as therapeutic improvement according to § 35, paragraph 1b sentences 1 to 5, SGB V of eszopiclone compared to the other active ingredients in the reference price group “Benzodiazepine-related agents, group 1” in tier 2 is considered as not proven according to § 35a, paragraph 1, sentences 4 and 5, SGB V”

- II. In Annex IX of the Pharmaceuticals Directive, the reference price group “Benzodiazepine-related agents, group 1” in tier 2 is amended as follows:

“Tier: 2

Active ingredient group: Benzodiazepine-related agents

Fixed amount group no.: 1

Status: prescription

Active ingredients and comparators:	Active ingredient	Comparative figure
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Eszopiclone	2
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	Zaleplon	8.6
	Zolpidem Zolpidem tartrate	7.9
	Zopiclone	7.2
Group Description:	divided oral dosage forms	
Dosage forms:	Film-coated tablets, hard capsules, capsules, sublingual tablets”	

III. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 6 May 2021.

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

Berlin, 6 May 2021

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

Prof. Hecken