Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) on the Non-amendment of the Pharmaceuticals Directive (AM-RL):
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V)
Marstacimab (haemophilia A and B);
restriction of the authority to supply care

of 5 December 2024

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1. Legal basis

According to Section 35a, paragraph 3b, sentence 2 SGB V, the Federal Joint Committee (G-BA) may decide for a medicinal product that is the subject of a resolution according Section 35a, paragraph 3b, sentence 1 SGB V that the authority to supply insured persons such a medicinal product at the expense of the statutory health insurance is restricted to those care providers who participate in the required routine practice data collection according to Section 35a, paragraph 3b SGB V (restriction of the care providers' authority to supply care). The resolution is to be published online and is part of the Pharmaceuticals Directive (AM-RL).

2. Key points of the resolution

At its session on 5 December 2024, the G-BA decided to suspend the consultation procedure on the requirement of routine practice data collection and evaluations for the active ingredient marstacimab for the treatment of haemophilia A and B.

Since the active ingredient marstacimab is thus not the subject of a resolution according to Section 35a, paragraph 3b, sentence 1 SGB V, the G-BA decides by the present resolution not to amend Annex XII of the Medicinal Products Guideline with regard to a restriction of the authority to supply the active ingredient marstacimab in the treatment of:

"Adults and adolescents aged 12 years and older with severe haemophilia A without factor VIII inhibitors or with moderate-to-severe haemophilia B without factor IX inhibitors".

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

In order to hold consultations and prepare a recommendation for a resolution on the initiation of a written statement procedure for the restriction of the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V, the Subcommittee on Medicinal Products commissioned a working group (WG routine practice data collection (RPDC)) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and the representative(s) of the patient organisations. Representatives of the IQWiG also participate in the sessions. The working group discussed the amendment of the AM-RL in its session on 5 September 2024.

The draft resolution to initiate a written statement procedure was discussed at the session of the Subcommittee on Medicinal Products on 10 September 2024 and the draft resolution was consented to.

At its session on 10 September 2024, the Subcommittee unanimously decided to initiate the written statement procedure according to Chapter 1 Section 10, paragraph 1 of the G-BA's Rules of Procedure.

A statement was received during the written statement procedure. After submitting their written statement, the assessment expert waived their right to an oral hearing.

The draft resolution on the non-amendment of the Pharmaceuticals Directive was discussed and approved at the session of the subcommittee on 26 November 2024.

At its session on 5 December 2024, the plenum adopted a resolution not to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	**Date**	**Subject of consultation**
WG RPDC	7 March 2024	Consultation on the amendment of the AM-RL
Subcommittee Medicinal products	10 September 2024	Discussion and consensus on the draft resolution Resolution to initiate the written statement procedure on the amendment of the AM-RL Scheduling the oral hearing
WG RPDC	21 October 2024	Consultation on the statements received
WG RPDC	18 November 2024	Consultation of the draft resolution
Subcommittee Medicinal products	26 November 2024	Concluding discussion of the draft resolution
Plenum	5 December 2024	Adoption of the resolution on the non-amendment of Annex XII AM-RL

Berlin, 5 December 2024

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken