Gemeinsamer Bundesausschuss

# Justification

to 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
Belumosudil (chronic graft-versus-host disease);
restriction of the authority to supply care

of 6 November 2025

**Contents**

## 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 their session on 6 November 2025, the G-BA decided to suspend the consultation procedure on the requirement of routine practice data collection and evaluations for the active ingredient belumosudil for the treatment of patients from 12 years of age with chronic graft-versus-host disease (chronic GvHD) after failure of at least two previous lines of systemic therapy.

Since the active ingredient belumosudil 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 belumosudil in the treatment of:

"Patients from 12 years of age with chronic graft-versus-host disease (chronic GvHD) after failure of at least two previous lines of systemic therapy".

## 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 National Association of Statutory Health Insurance Funds, 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 at their session on 21 July 2025.

The draft resolution to initiate a written statement procedure was discussed at the session of the Subcommittee on Medicinal Products on 29 July 2025 and the draft resolution was consented to.

At their session on 29 July 2025, 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 evaluation of the written statements received was discussed at the session of the subcommittee on 28 October 2025, and the draft resolution was approved.

At their session on 6 November 2025, the plenum adopted a resolution not to amend the Pharmaceuticals Directive.

**Chronological course of consultation**

| Session | Date | Subject of consultation |
|---|---|---|
| WG RPDC | 21 July 2025 | Consultation on the amendment of the AM-RL |
| Subcommittee on Medicinal Products | 29 July 2025 | Discussion and consensus on the draft resolution<br>Resolution to initiate the written statement procedure on the amendment of the AM-RL<br>Scheduling the oral hearing |
| WG RPDC | 15 September 2025 | Consultation on the statements received |
| WG RPDC | 2 October 2025 | Consultation on the draft resolution and evaluation of the written statement procedure |
| Subcommittee on Medicinal Products | 28 October 2025 | Concluding discussion of the draft resolution |
| Plenum | 6 November 2025 | Adoption of the resolution on the amendment of Annex XII AM-RL |

Berlin, 6 November 2025

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

Prof. Hecken