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
Exagamglogene autotemcel (β-thalassaemia);
restriction of the authority to supply care

of 1 February 2024

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 its session on 1 February 2024, the G-BA decided to suspend the consultation procedure on the requirement of routine practice data collection and evaluations for the active ingredient exagamglogene autotemcel for the treatment of β-thalassaemia.

Since the active ingredient exagamglogene autotemcel is thus not the subject of a resolution according to Section 35a, paragraph 3b, sentence 1 SGB V for the therapeutic indication of β-thalassaemia currently in the marketing authorisation procedure, the G-BA decides by the present resolution a non-amendment of Annex XII of the Pharmaceuticals Directive with regard to a restriction of the authority to supply care for the active ingredient exagamglogene autotemcel in the treatment of: "patients 12 years and older with transfusion-dependent β-thalassaemia for whom no human leukocyte antigen (HLA)-identical, related haematopoietic stem cell donor is available."

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 20 November 2023.

The draft resolution to initiate a written statement procedure was discussed at the session of the Subcommittee on Medicinal Products on 28 November 2023 and the draft resolution was consented to.

At its session on 28 November 2023, 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.

Statements were received during the written statement procedure. The oral hearing was scheduled for 8 January 2024. After submitting their written statements, the assessment experts waived their right to an oral hearing.

At its session on 1 February 2024, the plenum adopted a resolution not to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
WG RPDC	20 November 2023	Consultation on the amendment of the AM-RL
Subcommittee Medicinal products	28 November 2023	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	5 January 2024	Consultation on the statements received
Subcommittee Medicinal products	8 January 2024	Conduct of the oral hearing (cancelled)
WG RPDC	15 January 2024	Consultation on the draft resolution and evaluation of the written statement procedure
Subcommittee Medicinal products	23 January 2024	Concluding discussion of the draft resolution
Plenum	1 February 2024	Adoption of the resolution on the non-amendment of Annex XII AM-RL

Berlin, 1 February 2024

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

Prof. Hecken