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
Brexucabtagene Autoleucel (Relapsed or Refractory B-cell Precursor Acute Lymphoblastic Leukaemia);
Restriction of the Authority to Supply Care

of 20 July 2023

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 20 July 2023, the G-BA decided to suspend the consultation procedure on the requirement of routine practice data collection and evaluations for the active ingredient brexucabtagene autoleucel for the treatment of adults aged 26 years and older with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL).

Since the active ingredient brexucabtagene autoleucel is thus not the subject of a resolution according to Section 35a, paragraph 3b, sentence 1 SGB V for the above-mentioned therapeutic indication , 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 brexucabtagene autoleucel in the treatment of:

"Adults 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL)."

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 17 April 2023.

The draft resolution to initiate a written statement procedure was discussed at the session of the Subcommittee on Medicinal Products on 3 May 2023 and the draft resolution was consented to.

At its session on 3 May 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.

The written statement procedure was carried out. 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 11 July 2023, and the proposed resolution was approved.

At its session on 20 July 2023, the plenum adopted a resolution not to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
WG RPDC	17 April 2023	Consultation on the amendment of the AM-RL
Subcommittee Medicinal products	3 May 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	19 June 2023 6 July 2023	Consultation on the draft resolution and evaluation of the written statement procedure
Subcommittee Medicinal products	11 July 2023	Concluding discussion of the draft resolution
Plenum	20 July 2023	Adoption of the resolution on the non-amendment of Annex XII AM-RL

Berlin, 20 July 2023

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

Prof. Hecken