Gemeinsamer Bundesausschuss

# Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V: Autologous Anti-CD19-transduced CD3+ Cells (relapsed or refractory mantle cell lymphoma); requirement of routine practice data collection and evaluations – change

of 16 November 2023

At its session on 16 November 2023, the Federal Joint Committee (G-BA) resolved to amend Annex XII of the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

**I. The information on the requirement of routine practice data collection and evaluations according to Section 35a, paragraph 3b, sentence 1 SGBV on the active ingredient Autologous anti-CD19-transduced CD3+ cells in the version of the resolution of 21 July 2022 (BAnz AT XXXXXX B4), last amended by resolution of 16 March 2023 (BAnz AT XXXXXX B4), is amended as follows:**

In section 1.1 "Question according to PICO scheme", the table is amended as follows:

1. The "Comparator" row is worded as follows:

   "Patient-individual therapy with selection of:

   - Bendamustine + rituximab
   - Bortezomib ± rituximab
   - Lenalidomide ± rituximab
   - R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)
   - VRCAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone)
   - Ibrutinib
   - R-BAC (rituximab + bendamustine + cytarabine)
   - Temsirolimus
   - R-FCM (fludarabine + cyclophosphamide + mitoxantrone + rituximab)
   - R-Cb (rituximab + chlorambucil)

- Venetoclax
- High-dose therapy with allogeneic stem cell transplantation
- High-dose therapy with autologous stem cell transplantation

taking into account the response and duration of remission of previous therapies and the general condition."

2. Footnote b is cancelled.

**II. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 November 2023.**

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

Berlin, 16 November 2023

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

Prof. Hecken