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

of 16 March 2023

At its session on 16 March 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) is amended as follows:

1. In the table in section 1.1 "Questioning according to PICO scheme", the "Outcome" row shall be amended as follows:

   a) The words "SAE; overall rate" shall be replaced by the words "operationalised as events leading to hospitalisation or prolonging an existing hospitalisation and events leading to death; overall rate".

   b) The words "severe adverse events" shall be replaced by the words "adverse events leading to hospitalisation or prolonging an existing hospitalisation".

   c) The words "discontinuation due to adverse events (overall rate)" shall be deleted.

   d) The words "(with information on the respective severity grade)" shall be replaced by the following words: "(with information on the respective severity grade including specific adverse events leading to a significant impairment of the activity of daily living or with CTCAE grade ≥ 3):

      - Cytokine Release Syndrome (CRS)

- Neurologic events (including immune effector cell-associated neurotoxicity syndrome, encephalopathy and peripheral neuropathy)
- Infections
- Cytopenias (anaemia, leukopenia, thrombocytopenia)
- Hypogammaglobulinemia
- Tumour Lysis Syndrome (TLS)
- Graft-versus-Host Disease (GvHD)
- Secondary neoplasms
- Cardiac arrhythmias
- Heart failure (new onset)"

2. In Section 1.4 "Evaluations of the data for the purpose of the benefit assessment", "2 interim analyses" shall be replaced by "3 interim analyses".

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

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

Berlin, 16 March 2023

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

Prof. Hecken