

Resolution

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL):

Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Odronextamab (relapsed or refractory diffuse large B-cell lymphoma);
restriction of the authority to supply care

of 17 July 2025

At their session on 17 July 2025, the Federal Joint Committee (G-BA) resolved to amend 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. In Annex XII, the following information shall be added after number 3 to the information on the requirement of routine practice data collection and evaluations of Odronextamab in accordance with the resolution of 17 July 2025:

Odronextamab

Resolution of: 17 July 2025

Entry into force on: Date of first placing on the market

Federal Gazette, BAnz AT DD. MM YYYY Bx

Restriction of the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V

For the active ingredient odronextamab in the treatment of:

"Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy, who are not eligible for CAR-T cell therapy and stem cell transplantation"

the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V is limited to those care providers who participate in the required routine practice data collection.

Care providers within the meaning of this resolution are physicians participating in SHI-accredited medical care, medical care centres and facilities according to Section 95 SGB V as well as hospitals approved for care provision according to Section 108 SGB V.

Care providers who are not authorised to supply the medicinal product may exceptionally prescribe the medicinal product at the expense of the statutory health insurance, provided that the prescription is made exclusively for the purpose of further prescribing the medicinal product and ensuring the success of the therapy after prior consultation with the care provider authorised to supply care and the same continues to be responsible for data collection, thus not jeopardising the purpose of the restriction of the authority to supply care, namely to obtain valid data from the supply of medicinal products to insured persons.

Participation in the required routine practice data collection is ensured by the proper (proven in writing) participation of the (approved) healthcare provider in the data collection for the required routine practice data collection on the basis of the confirmed study protocol of the pharmaceutical company.

The coordination of the unauthorised care provider with the authorised care provider should be documented in the patient record of the unauthorised care provider.

II. Entry into force

The resolution shall take effect from the day on which the medicinal product is first placed on the market in accordance with Section II. by publication in a directory service that has been set up on the basis of the necessary information (price and product information) to be provided by the pharmaceutical companies to the Federal Joint Committee and the National Association of Health Insurance Funds in accordance with Section 131 paragraph 4 SGB V for the purpose of creating pharmacological-therapeutic and price transparency. Alternatively, the effective date is the date on which the medicinal product is placed on the market - as communicated in the notification to the competent higher federal authority (Section 29 paragraph 1b of the German Medicinal Products Act).

The restriction of the authority to supply care to those care providers who participate in the required routine practice data collection, as regulated in the resolution, only takes effect with the start of the routine practice data collection, which is determined in a separate resolution.

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

Berlin, 17 July 2025

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

Prof. Hecken

Resolution has been repealed