Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) on the 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

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1. Legal basis

According to Section 35a, paragraph 3b, sentence 2 SGB V, the Federal Joint Committee 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 their session on 17 July 2025, the G-BA decided on the restriction of the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V for the use in relapsed and refractory diffuse large B-cell lymphoma. The active ingredient odronextamab in relapsed or refractory diffuse large B-cell lymphoma is the subject of a resolution on the requirement of a routine practice data collection in accordance with Section 35a, paragraph 3b, sentence 1 SGB V. The patient population on which the requirement of routine practice data collection and evaluations is based refers to adults with relapsed or refractory DLBCL after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplantation. The restriction of the authority to supply care for this patient group is also defined accordingly.

The restriction of the authority to supply care to those care providers who participate in the required routine practice data collection according to Section 35a, paragraph 3b SGB V aims to obtain complete and valid data from the care of insured persons with the medicinal product and to prevent only fragmentary data collection in order to obtain reliable, suitable data for the purposes of the benefit assessment.

The need for information for a benefit assessment of odronextamab has led to the research question of a (long-term) additional benefit compared to the appropriate comparator therapy for the approved patient population. A search by IQWiG for ongoing and planned data collection for the active ingredient odronextamab as part of the concept development for routine practice data collection showed that the ongoing and planned studies, including the Glo-BNHL platform study, are not suitable for addressing the existing gaps in the evidence. The ELM-1 and ELM-2 studies relate to a single-arm data collection for the active ingredient odronextamab and not to a comparative data collection. Collection of comparator data is required to address the research question of routine practice data collection and evaluations related to the patient group of adults with relapsed or refractory DLBCL after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplantation.

The expected eligible number of patients who can be treated with odronextamab is small because relapsed or refractory DLBCL is a rare haemato-oncological disease, not all patients with relapsed or refractory DLBCL are eligible for treatment with odronextamab according to the marketing authorisation, and approved therapeutic alternatives exist.

In order to ensure a sufficient data pool for the routine practice data collection, it is necessary that the data collection is as complete as possible, at least from the care context of insured persons with odronextamab administration.

Care providers within the meaning of Chapter 5 Section 66 of the G-BA's Rules of Procedure (VerfO) 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.

An exception provision for prescription by care providers who are not authorised to provide care solely for the purpose of further prescription and to ensure the success of the therapy is considered necessary in the present case.

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. In this context, efforts must also be made to ensure that the data transmission is as complete as possible.

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 National Association of Statutory Health Insurance Funds, and the representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions. The working group discussed the amendment of the AM-RL at their session on 4 July 2024.

The draft resolution to initiate a written statement procedure was discussed at the session of the Subcommittee on Medicinal Products on 9 July 2024 and the draft resolution was consented to.

At their session on 9 July 2024, 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 held on 26 August 2024.

The evaluation of the written statements received and the oral hearing was discussed at the session of the Subcommittee on 8 July 2025, and the proposed draft resolution was approved.

At their session on 17 July 2025, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
WG RPDC	4 July 2024	Consultation on the amendment of the AM-RL
Subcommittee on Medicinal Products	9 July 2024	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 August 2024	Consultation on the statements received
Subcommittee on Medicinal Products	26 August 2024	Conduct of the oral hearing
WG RPDC	3 July 2025	Consultation on the draft resolution and evaluation of the written statement procedure
Subcommittee on Medicinal Products	8 July 2025	Concluding discussion of the draft resolution
Plenum	17 July 2025	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 17 July 2025

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

Prof. Hecken