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)
Talquetamab (relapsed and refractory multiple myeloma, at least 3 prior therapies);
restriction of the authority to supply care

of 18 July 2024

Contents

1. Legal basis 2

2. Key points of the resolution 2

3. Bureaucratic costs calculation 3

4. Process sequence 3

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 its session on 18 July 2024, 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 multiple myeloma after at least three prior therapies. The active ingredient talquetamab for relapsed and refractory multiple myeloma after at least three prior therapies is the subject of a resolution on the requirement of routine practice data collection according to Section 35a, paragraph 3b, sentence 1 SGB V.

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 talquetamab has led to the question of a (long-term) additional benefit compared to the appropriate comparator therapy for the approved patient population. IQWiG's corresponding research as part of drawing up of the concept for routine practice data collection showed that the ongoing and planned studies are unsuitable for addressing existing gaps in the evidence. Three studies commissioned by the regulatory authorities were identified, two of which did not include a comparison. Talquetamab is not used as monotherapy in the commissioned, randomised controlled trial MonumenTAL-3; it therefore does not cover the approved therapeutic indication for talquetamab. The question of routine practice data collection requires the collection of comparator data in the approved therapeutic indication.

The expected eligible number of patients who can be treated with talquetamab is small because multiple myeloma is a rare haemato-oncological disease, treatment with talquetamab is not suitable for all patients with multiple myeloma after at least three prior therapies according to the marketing authorisation and approved therapeutic alternatives exist.

In order to ensure a sufficient data stock 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 talquetamab 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 of the Rules of Procedure of the G-BA 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 2 May 2024.

The draft resolution to initiate a written statement procedure was discussed at the session of the Subcommittee on Medicinal Products on 7 May 2024 and the draft resolution was consented to.

At its session on 7 May 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. After submitting their written statement, the assessment expert waived their right to an oral hearing.

The evaluation of the written statements received and the oral hearing was discussed at the session of the subcommittee on 9 July 2024, and the proposed resolution was approved.

At its session on 18 July 2024, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
WG RPDC	2 May 2024	Consultation on the amendment of the AM-RL
Subcommittee Medicinal products	7 May 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	17 June 2024	Consultation on the statements received
WG RPDC	4 July 2024	Consultation on the draft resolution and evaluation of the written statement procedure
Subcommittee Medicinal products	9 July 2024	Concluding discussion of the draft resolution
Plenum	18 July 2024	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 18 July 2024

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

Prof. Hecken