Gemeinsamer Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (G-BA) on the Suspension of the Benefit Assessment pursuant to Section 35a SGB V of
Idecabtagene Vicleucel (reassessment of an orphan drug after exceeding the EUR 30 million turnover limit; multiple myeloma, at least 3 previous therapies)

of 2 May 2024

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet. According to Section 35a paragraph 3 SGB V, the G-BA decides on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient idecabtagene vicleucel was listed for the first time on 1 January 2022 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices. Idecabtagene vicleucel is approved as a medicinal product for the treatment of rare diseases in accordance with Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999.

At its session on 16 June 2022, the G-BA decided on the benefit assessment of idecabtagene vicleucel in the therapeutic indication "treatment of adult patients with relapsed and refractory multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy".

If the sales of the orphan drug through the statutory health insurance at pharmacy sales prices and outside the scope of SHI-accredited medical care, including value-added tax, exceed an amount of € 30 million in the last twelve calendar months, the pharmaceutical company must submit evidence in accordance with Section 5, paragraphs 1 to 6 within three months of being requested to do so by the Federal Joint Committee, and in this evidence must demonstrate the additional benefit compared to the appropriate comparator therapy.

In a letter dated 28 November 2023, the pharmaceutical company was informed that the EUR 30 million turnover limit for idecabtagene vicleucel had been exceeded within the period from

July 2022 till end of June 2023. By this letter, the pharmaceutical company was requested to submit a dossier for the benefit assessment according to Section 35a SGB V by 1 March 2024, due to exceeding the € 30 million turnover limit.

The pharmaceutical company has submitted the final dossier for the therapeutic indication of multiple myeloma after at least three prior therapies in due time to the G-BA on 29 February 2024 in accordance with Section 4, paragraph 3, number 6 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5 Section 8, paragraph 1, number 6 VerfO.

On 25 January 2024, the EMA issued a positive opinion for the medicinal product Abecma with the active ingredient idecabtagene vicleucel for the following new therapeutic indication, which completely replaces the previously approved therapeutic indication after at least three prior therapies: "Treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy". On 19 March 2024, the European Commission granted marketing authorisation for this new therapeutic indication.

The pharmaceutical company has submitted the final dossier for the new therapeutic indication of multiple myeloma after at least 2 prior therapies in due time to the G-BA on 27 March 2024 in accordance with Section 4, paragraph 3, number 2 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5 Section 8, paragraph 1, number 2 VerfO. The benefit assessment procedure started on 1 April 2024.

Due to the cumulative submission of the following requirements, the G-BA merged the procedure started on 1 March 2024 with the procedure started on 1 April 2024 under the summary question of multiple myeloma after at least two prior therapies:

- The previously approved therapeutic indication (at least 3 prior therapies) has been completely replaced by the newly approved therapeutic indication (at least 2 prior therapies),
- the positive opinion for the new therapeutic indication (at least 2 prior therapies) was issued before the relevant date for the start of the benefit assessment of the previously approved therapeutic indication (at least 3 prior therapies) and
- the dossier for the new therapeutic indication (at least 2 prior therapies) was submitted within one month of the start of the procedure for the previously approved therapeutic indication (at least 3 prior therapies).

This eliminates the need for a separate benefit assessment for the sub-population of patients with at least 3 prior therapies. The benefit assessment procedure that began on 1 March 2024 will therefore be suspended.

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

Session	Date	Subject of consultation
Working group Section 35a	17 April 2024	Consultation on the draft resolution
Subcommittee Medicinal products	23 April 2024	Consultation and consensus on the draft resolution on suspension of the benefit assessment procedure
Plenum	2 May 2024	Resolution on the suspension of the benefit assessment procedure

Berlin, 2 May 2024

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

Prof. Hecken