Justification

Gemeinsamer Bundesausschuss

to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Amendment of Information on the Period of Validity of a Resolution on the Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Pembrolizumab (Urothelial Carcinoma)

of 5 March 2020

Contents

Courtesy translation – only the German version is legally binding.

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 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 forms part of the Pharmaceuticals Directive.

2. Key points of the resolution

At its session on 20 June 2019, the G-BA decided on the benefit assessment of pembrolizumab in accordance with Section 35a SGB V. The period of validity of the resolution is limited to 1 July 2020.

The subject matter of the resolution was a reassessment in accordance with Section 35a, paragraph 1 SGB V in conjunction with Section 3, paragraph 1, no. 4 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) and Chapter 5, Section 13 of the Rules of Procedure of the G-BA (VerfO). The reassessment was initiated on the basis of new scientific findings from the KEYNOTE-361 (NCT02853305) study and a related change in the approved therapeutic indication of pembrolizumab by resolution of the EU Commission dated 6 July 2018.

As described in the justification, the results of the ongoing KEYNOTE-361 study were not yet available when the resolution was passed. The rationale at this time for the limitation was that relevant clinical data for the benefit assessment of the medicinal product on patient-relevant outcomes, and in particular on overall survival, were outstanding. The limitation was intended to permit the upcoming results from the KEYNOTE-361 study to be promptly incorporated into the benefit assessment of the medicinal product in accordance with Section 35a SGB V.

Courtesy translation – only the German version is legally binding.

The pharmaceutical company has informed the G-BA that results of the KEYNOTE 361 study, whose final cut-off date is based on event numbers, will not be available when the limitation expires on 1 July 2020. To the best of the pharmaceutical company's current knowledge, these are not expected until the second half of 2020 at the earliest.

In order to allow the inclusion of the final results of the KEYNOTE-361 study in the benefit assessment of pembrolizumab after expiry of the limitation, the period of validity of the resolution, originally limited to 1 July 2020, is extended.
It was decided to extend the limitation of the resolution until 1 April 2021.

The questions underlying the limitation with regard to the assessment of the additional benefit remain unaffected by this.

In accordance with Section 3, number 5 AM-NutzenV in conjunction with Chapter 5, Section 1, paragraph 2, number 7 VerfO, the procedure for the benefit assessment for the active ingredient pembrolizumab shall recommence when the limitation has expired. For this purpose, the pharmaceutical company must submit a dossier on the benefit assessment of pembrolizumab to the G-BA at the latest on the day of expiry of the deadline (Section 4, paragraph 3, number 5 AM-NutzenV in conjunction with Chapter 5, Section 8, number 5 VerfO).

The possibility that a benefit assessment for pembrolizumab can be carried out at an earlier point in time because of other reasons (*cf* Chapter 5, Section 1, paragraph 2, no. 2, 3, 5, and 6 VerfO) remains unaffected hereof.

3. Bureaucratic costs

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

The matter was discussed in the Subcommittee on Medicinal Products, and an amendment resolution was passed.

At its session on 5 March 2020, the plenum decided to amend the limitation of the period of validity of the resolution.

Berlin, 5 March 2020

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken

Courtesy translation – only the German version is legally binding.