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 Abemaciclib (Breast Cancer; in Combination with Fulvestrant)

of 5 December 2019

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 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 shall pass a resolution 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 2 May 2019, the G-BA discussed the benefit assessment of abemaciclib in combination with fulvestrant in accordance with Section 35a SGB V. The period of validity of this resolution was limited to 31 December 2020 for patient groups a1, b1, and b2.

In accordance with the justification for this resolution, the reason for the limitation was that the overall survival data available for assessment from the MONARCH-2 study were preliminary with a small number of events at the time of the data cut-off. The final results from the study, which was still ongoing at that time, were still outstanding.
Because further clinical data on overall survival from the MONARCH-2 study, which may be relevant for the assessment of the benefit of the medicinal product, were expected, it was justified to temporarily limit the resolution until further scientific evidence is available for the assessment of the additional benefit of abemaciclib in combination with fulvestrant.

The pharmaceutical company has informed the G-BA that current overall survival results are available earlier than expected and are already available. These are the results of the pre-specified, event-driven 3rd data cut-off of overall survival. The study was ended on the basis of these results. Thus, no further data on overall survival is expected from the originally planned event-driven 4th data cut-off (planned as the final analysis of overall survival).

In order to ensure that the new results of the MONARCH-2 study are included in the new benefit assessment of the medicinal product in accordance with Section 35a SGB V in a timely manner, the validity period of the resolution for patient groups a1, b1, and b2, originally limited until 31 December 2020, will be shortened. A shortening of the time limit until 15 March 2020 is considered appropriate for this purpose.

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 abemaciclib shall recommence when the deadline has expired.
For this purpose, the pharmaceutical company must submit a dossier on the benefit assessment of abemaciclib 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).

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 approved.

At its session on 5 December 2019, the plenum decided to amend the limitation of the period of validity of the resolution.

Berlin, 5 December 2019

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

Prof Hecken