Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Amendment to the Information on the Period of Validity of a Resolution on the Benefit Assessment of Medicinal Products with New Active Ingredients Pursuant to Section 35a SGB V
Atezolizumab (Reassessment due to New Scientific Knowledge: Urothelial carcinoma)

of 6 April 2023

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 online and is 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 atezolizumab in accordance with Section 35a SGB V. The resolution of 20 June 2019 and thus, also the corresponding time limit referred exclusively to the sub-population a) urothelial carcinoma; patients who are unsuitable for treatment with cisplatin and whose tumours have a PD-L1 expression ≥ 5% (first-line). The period of validity of this resolution was limited to 1 October 2021. The period of validity of the resolution was extended until 1 May 2023 upon application of the pharmaceutical company by the resolutions of 15 April 2021 and 16 June 2022.

After reviewing again, the G-BA lifts the time limit on the validity of the resolution of 20 June 2019 on an amendment to the Pharmaceuticals Directive on the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a SGB V for the active ingredient atezolizumab.

The intended time limit for atezolizumab related to open medical-scientific questions, in particular with regard to the further clinical data of the IMvigor130 study expected at the time

of drafting the resolution to assess the additional benefit with regard to overall survival as well as other patient-relevant endpoints compared to the appropriate comparator therapy on which the resolution of 20 June 2019 was based.

Taking into account the further development of the generally recognised state of medical knowledge in the first-line treatment of adults with locally advanced or metastatic urothelial carcinoma who are considered unsuitable for treatment with cisplatin and whose tumours have a PD-L1 expression ≥ 5%, a new benefit assessment of atezolizumab compared with the appropriate comparator therapy on which the resolution of 20 June 2019 was based is no longer considered appropriate with regard to the questions addressed in the justification for the time limit.

The possibility that a benefit assessment of atezolizumab can be carried out due to other reasons (cf. Chapter 5, Section 1 paragraph 2, Nos. 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 issue was discussed in the Subcommittee on Medicinal Products and an amending resolution was agreed upon.

At its session on 6 April 2023, the plenum decided on the amendment to the limitation of the period of validity of the resolution.

Berlin, 6 April 2023

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

Prof. Hecken