Justification

Gemeinsamer Bundesausschuss

to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V – Olaratumab (Repeal of the Resolution of 18 May 2017)

of 16 January 2020

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 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

The active ingredient olaratumab was first approved as a medicinal product on 9 November 2016 (Lartruvo®). The marketing authorisation was granted for the therapeutic indication: “Lartruvo is indicated in combination with doxorubicin for the treatment of adult patients with advanced soft tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin”. This market authorisation was a conditional marketing authorisation for a medicinal product for the treatment of a rare disease (orphan drugs).

On 1 December 2016, the active ingredient olaratumab was marketed for the first time in Germany as the active ingredient of the medicinal product Lartruvo®.

The G-BA decided on the benefit assessment of olaratumab on 18 May 2017. Accordingly, the active ingredient olaratumab was added to Annex XII of the Pharmaceuticals Directive by the resolution of 18 May 2017.

The benefit assessment was based on the results of the "JGDG" Phase 2 study. Against the background that the medicinal product Lartruvo® was approved under "special conditions", the European Medicines Agency (EMA) required, among other things, that the results of the ongoing phase 3 "ANNOUNCE study be submitted as part of the evidence to be provided by the pharmaceutical company. The clinical study report on this study was expected to be submitted to the EMA by 31 January 2020.

The G-BA has limited the period of validity of its resolution on the benefit assessment of olaratumab to 1 May 2020 and made it a condition that the study results from the ongoing "ANNOUNCE" phase 3 study be presented for the renewed benefit assessment after the deadline expires.

On 26 April 2019, the EMA recommended that the marketing authorisation for the medicinal product Lartruvo® be revoked. This recommendation was based on the assessment of the results of the "ANNOUNCE" Phase 3 study according to which olaratumab in combination with doxorubicin did not lead to an increase in overall survival of patients compared with treatment with doxorubicin alone.

On 19 July 2019, the marketing authorisation for olaratumab as the active ingredient of the medicinal product Lartruvo® was revoked by the European Commission because of the facts described above. With this revocation of the marketing authorisation, the basis for the benefit assessment according to Section 35a, paragraph 1 SGB V by the G-BA no longer applies. Consequently, the resolution on olaratumab of 18 May 2017 (BAnz AT 27 July 2017 B1) is to be repealed.

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

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	7 January 2020	Consultation and consensus on the draft resolution to repeal the resolution.
Plenum	16 January 2020	Resolution on the repeal of the resolution.

Berlin, 16 January 2020

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

Prof. Hecken