Gemeinsamer Bundesausschuss

Justification

to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Casirivimab/ imdevimab (post-exposure prophylaxis of COVID-19 infection, ≥ 12 years; COVID-19, ≥ 12 years)
(repeal of the resolutions of 6 October 2022)

From 19 March 2026

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all 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. requirement 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 decide 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

On 18 March 2021, the G-BA decided on an exemption to temporarily suspend the obligation to submit the dossier in benefit assessment procedures of medicinal products for the treatment of COVID-19, which were in a so-called "rolling review" procedure of the European Medicines Agency (EMA) during the determination of an epidemic situation of national importance according to Section 5 of the Infection Protection Act (IPA). The pharmaceutical company demonstrated for the active ingredient casirivimab/ imdevimab that the suspension requirements according to the above-mentioned resolution are met. The obligation to submit the dossier for the active ingredient casirivimab/ imdevimab in accordance with Chapter 5 Section 11 Rules of Procedure by the relevant date specified in Chapter 5 Section 8, paragraph 1, number 1, sentence 1 VerfO has been temporarily suspended. In a letter dated 27 April 2021 and 9 November 2021, the G-BA requested the pharmaceutical company to submit a

complete dossier in accordance with Chapter 5 Section 11 VerfO after the expiry of the suspension period - in this case five months from the date of marketing authorisation. The pharmaceutical company submitted the final dossier to the G-BA on 14 April 2022.

On 6 October 2022, the G-BA passed a resolution on the benefit assessments of casirivimab/ imdevimab for treatment of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19, as well as for the prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg. Accordingly, Annex XII to the Pharmaceuticals Directive was amended to include the active ingredient casirivimab/ imdevimab.

Against the backdrop of a legal dispute and its settlement by way of a compromise, the pharmaceutical company and the G-BA have agreed to repeal the resolutions on the benefit assessments of casirivimab/ imdevimab dated 6 October 2022.

Consequently, the findings on the benefit assessments of the active ingredient casirivimab/ imdevimab in Annex XII of the Pharmaceuticals Directive in the version of the resolutions of 6 October 2022 (BAnz AT 03.11.2022 B1 and BAnz AT 03.11.2022 B2) must be deleted.

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

At their session on 10 March 2026, the Subcommittee on Medicinal Products discussed the repeal of the resolution on the benefit assessment of the active ingredient casirivimab/ imdevimab in the version of the resolution of 6 October 2022 and approved the draft resolution.

At their session on 19 March 2026, the plenum decided on the repeal of the resolution on the benefit assessment of the active ingredient casirivimab/ imdevimab in the version of the resolution of 6 October 2022.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal products	10 March 2026	Consultation on the draft resolution on the repeal of the resolution
Plenum	19 March 2026	Adoption of the repeal of the resolution

Berlin, 19 March 2026

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

Prof. Hecken