Gemeinsamer Bundesausschuss

# Justification

of the resolution of the Federal Joint Committee on the discontinuation of the benefit assessment procedure according to Section 35a, para. 2 SGB V
Bulevirtide (hepatitis delta virus (HDV) infection, HDV-RNA positive, ≥ 3 to < 18 years, ≥ 10 kg BW)

of 18 June 2025

**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 all reimbursable medicinal products with new active ingredients.

For medicinal products for the treatment of rare diseases (orphan drugs) that are approved according to Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999, the additional medical benefit is considered to be proven through the grant of the marketing authorisation according to Section 35a, paragraph 1, sentence 11, half-sentence 1 SGB V. Evidence of the medical benefit and the additional medical benefit do not have to be submitted (Section 35a, paragraph 1, sentence 11, half-sentence 2 SGB V). Section 35a paragraph 1 sentence 11, half-sentence 1 SGB V thus guarantees an additional benefit for an approved orphan drug, although an assessment of the orphan drug in accordance with the principles laid down in Section 35a, paragraph 1, sentence 3, Nos. 2 and 3 SGB V in conjunction with Chapter 5 Sections 5 et seq. of the Rules of Procedure (VerfO) of the G-BA has not been carried out. Only the extent of the additional benefit has to be proven.

However, the restrictions on the benefit assessment of orphan drugs resulting from the statutory obligation to the marketing authorisation do not apply if the turnover of the medicinal product with the SHI at pharmacy sales prices, including VAT exceeds € 30 million in the last 12 calendar months.

According to Section 35a, paragraph 1, sentence 12 SGB V, the pharmaceutical company must then, within three months of being requested to do so by the G-BA, submit evidence according to Chapter 5 Section 5, paragraphs 1–6 VerfO, in particular regarding the additional medical benefit in relation to the appropriate comparator therapy as defined by the G-BA according to Chapter 5 Section 6 VerfO of the G-BA and prove the additional benefit in comparison with the appropriate comparator therapy.

## 2. Key points of the resolution

Hepcludex is approved as a medicinal product for the treatment of rare diseases in accordance with Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999.

According to Section 35a, paragraph 1, sentence 11 SGB V in conjunction with Chapter 5 Section 12, number 1 SGB V, evidence pursuant to Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V need not be submitted for medicinal products that are approved for the treatment of a rare disease [hereinafter: orphan drug]. This means that for these medicinal products, the dossier to be prepared by the pharmaceutical company need not contain any information on the medical benefit or the additional medical benefit in relation to the appropriate comparator therapy - as long as the privileging applies by law. In addition, the

additional medical benefit is considered proven owing to the marketing authorisation. If the turnover of the orphan drug with the statutory health insurance at pharmacy sales prices and outside the SHI-accredited medical care including VAT in the last twelve calendar months exceeds an amount of EUR 30 million, the G-BA requests the pharmaceutical company to submit a dossier for the initiation of a benefit assessment procedure in accordance with Section 35a, paragraph 1, sentence 12 SGB V in conjunction with Chapter 5 Section 12, number 2 VerfO with complete evidence in accordance with Section 35a, paragraph 1, sentence 3 SGB V. The procedural privileges under Section 35a, paragraph 1, sentence 11 SGB V in conjunction with Chapter 5 Section 12, number 1 SGB V no longer apply.

On 25 November 2024, bulevirtide received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, sentence 7).

On 19 December 2024, i.e. at the latest within four weeks after informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company has submitted a dossier in due time in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA on the active ingredient bulevirtide with the new therapeutic indication

"Hepcludex is indicated for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult and paediatric patients 3 years of age and older weighing at least 10 kg with compensated liver disease".

Bulevirtide exceeded the turnover limit of EUR 30 million by 28 February 2025 at the latest and has not yet been assessed by submitting evidence of the medical benefit and additional medical benefit in relation to the appropriate comparator therapy in accordance with Section 35a, paragraph 1, sentence 12 SGB V in conjunction with Chapter 5 Section 12, number 2 VerfO. The dossier submitted by the pharmaceutical company on the basis of the studies used for the marketing authorisation without proof of additional benefit in relation to the appropriate comparator therapy is unsuitable for the benefit assessment to be carried out now by the G-BA following the expiry of the procedural privileges as a result of the turnover limit being exceeded. By the present resolution, the G-BA therefore discontinues the ongoing benefit assessment procedure according to Section 35a, paragraph 1, sentence 11 SGB V in conjunction with Chapter 5 Section 12, number 1 VerfO on bulevirtide for the therapeutic indication "for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult and paediatric patients 3 years of age and older weighing at least 10 kg with compensated liver disease".

The G-BA has also requested the pharmaceutical company in accordance with Section 35a, paragraph 1, sentence 12 SGB V to submit evidence in accordance with sentence 3, numbers 2 and 3 and, in deviation from Section 35a, paragraph 1, sentence 11 SGB V, to demonstrate the additional benefit compared to the appropriate comparator therapy.

## 3. Bureaucratic costs calculation

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 11 June 2025, the Subcommittee on Medicinal Products discussed the discontinuation of the benefit assessment procedure that began on 1 January 2025.

Berlin, 18 June 2025

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

Prof. Hecken