Resolution

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

of 18 June 2025

The Federal Joint Committee (G-BA) decided the following at their session on 18 June 2025:

Following the finding that sales of the proprietary medicinal product Hepcludex with the active ingredient bulevirtide exceeded the turnover limit of EUR 30 million according to Section 35a, paragraph 1, sentence 12 SGB V, the ongoing benefit assessment procedure according to Section 35a, paragraph 1, sentence 11 SGB V in conjunction with Chapter 5 Section 12 No. 1 the Rules of Procedure of the G-BA for the active ingredient bulevirtide in the newly approved 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" is discontinued.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 18 June 2025

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

Prof. Hecken