Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on the discontinuation of the benefit assessment procedure according to Section 35a SGB V Bulevirtide (reassessment after the deadline: hepatitis delta virus (HDV) infection, HDV-RNA positive)

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 after expiry of the deadline according to Section 35a, paragraph 1, sentence 11 SGB V in conjunction with Section 3, paragraph 1, no. 5 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) and Chapter 5 Section 1, paragraph 2, no. 7 in conjunction with Section 12, no. 1 of the Rules of Procedure of the G-BA on the active ingredient bulevirtide in the therapeutic indication "for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult patients 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

Courtesy translation – only the German version is legally binding.