# Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee on a Finding in the Procedure of Routine Practice Data Collection and Evaluations according to Section 35a, paragraph 3b SGB V:
Valoctocogene roxaparvovec (severe haemophilia A) – Review of the study protocol, statistical analysis plan and interim analyses

of 2 April 2026

At their session on 2 April 2026, the Federal Joint Committee (G-BA) decided the following in the procedure of routine practice data collection and evaluations according to Section 35a, paragraph 3b SGB V for the active ingredient Valoctocogene roxaparvovec (severe haemophilia A):

I. The routine practice data collection will not be carried out as it was found that the pharmaceutical company have not fulfilled their obligation - required by resolutions of 2 February 2023 and 18 July 2024 - to submit a revised statistical analysis plan and study protocol, and to provide details of the progress of data collection and interim analyses 18 months after the start of the routine practice data collection.

II. The resolution will enter into force on the day of its publication on the G-BA website on 2 April 2026.

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

Berlin, 2 April 2026

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

Prof. Hecken