Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on the discontinuation of the benefit assessment procedure according to Section 35a SGB V Iptacopan (new therapeutic indication: complement 3 glomerulopathy)

of 21 August 2025

The Federal Joint Committee (G-BA) decided the following at their session on 21 August 2025:

Following the finding that sales of the proprietary medicinal product Fabhalta with the active ingredient iptacopan 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 Rules of Procedure of the G-BA for the active ingredient iptacopan in the newly approved therapeutic indication "for the treatment of adult patients with complement 3 glomerulopathy (C3G) in combination with a renin-angiotensin system (RAS) inhibitor, or in patients who are RAS-inhibitor intolerant, or for whom a RAS inhibitor is contraindicated" is discontinued.

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

Berlin, 21 August 2025

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

Prof. Hecken