Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL):
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Fedratinib (myelofibrosis);
Restriction of the Authority to Supply Care

of 3 November 2022

At its session on 3 November 2022, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of Fedratinib in accordance with the resolution of 2 September 2021:

Fedratinib

Resolution of: 3 November 2022
Entry into force on: 3 November 2022
Federal Gazette, BAnz AT DD MM YYYY Bx

Restriction of the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V

For the active ingredient fedratinib in the treatment of:

"Disease-related splenomegaly or symptoms in adults with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis who are not pretreated with a Janus Associated Kinase (JAK) inhibitor and for whom ruxolitinib is the patient-individual appropriate comparator therapy"

the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V is limited to those care providers who participate in the required routine practice data collection.

Care providers within the meaning of this resolution are physicians participating in SHI-accredited medical care, medical care centres and facilities according to Section 95 SGB V as well as hospitals approved for care provision according to Section 108 SGB V.

Care providers who are not authorised to supply the medicinal product may exceptionally prescribe the medicinal product at the expense of the statutory health insurance, provided that the prescription is made exclusively for the purpose of further prescribing the medicinal product and ensuring the success of the therapy after prior consultation with the care provider authorised to supply care and the same continues to be responsible for data collection, thus not jeopardising the purpose of the restriction of the authority to supply care, namely to obtain valid data from the supply of medicinal products to insured persons.

Participation in the required routine practice data collection is ensured by the proper (proven in writing) participation of the (approved) healthcare provider in the data collection for the required routine practice data collection on the basis of the confirmed study protocol of the pharmaceutical company.

The coordination of the unauthorised care provider with the authorised care provider should be documented in the patient record of the unauthorised care provider.

II. Entry into force

The resolution will enter into force on the day of its publication on the internet on the G-BA website on 3 November 2022.

The restriction of the authority to supply care to those care providers who participate in the required routine practice data collection, as regulated in the resolution, only takes effect with the start of the routine practice data collection, which is determined in a separate resolution.

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

Berlin, 3 November 2022

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

Prof. Hecken