Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) on the 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

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1. Legal basis

According to Section 35a, paragraph 3b, sentence 2 SGB V, the Federal Joint Committee may decide for a medicinal product that is or will be the subject of a resolution according Section 35a, paragraph 3b, sentence 1 SGB V that the authority to supply insured persons such a medicinal product at the expense of the statutory health insurance is restricted to those care providers who participate in the required routine practice data collection according to Section 35a, paragraph 3b SGB V (restriction of the care providers' authority to supply care). The resolution is to be published online and is part of the Pharmaceuticals Directive (AM-RL).

2. Key points of the resolution

At its session on 3 November 2022, the G-BA decided on the restriction of the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V for the use of fedratinib in myelofibrosis. The active ingredient fedratinib in myelofibrosis is the subject of a resolution on the requirement of routine practice data collection according to Section 35a, paragraph 3b, sentence 1 SGB V.

The restriction of the authority to supply care to those care providers who participate in the required routine practice data collection according to Section 35a, paragraph 3b SGB V aims to obtain complete and valid data from the care of insured persons with the medicinal product and to prevent only fragmentary data collection in order to obtain reliable, suitable data for the purposes of the benefit assessment.

The need for information for a benefit assessment of fedratinib has resulted in the question of a (long-term) additional benefit compared to the appropriate comparator therapy for the population of patients who have not been pretreated with a Janus Associated Kinase (JAK) inhibitor and for whom ruxolitinib is the patient-individual appropriate comparator therapy. As part of the concept development for routine practice data collection, a search was conducted for ongoing, planned and completed studies. No ongoing or planned data collections were identified in this search. Furthermore, the search revealed that the completed data collections (JAKARTA study) are not suitable to address the existing gaps in the evidence as they do not include data against the established comparator therapy. The question of routine practice data collection requires the collection of comparator data compared to the identified comparator therapy (ruxolitinib).

The expected eligible number of subjects who can be treated with fedratinib is small because treatment with fedratinib is not an option for all adults with disease-related splenomegaly or symptoms of primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and the present indication is a rare haematological disorder.

In order to ensure a sufficient data stock for the routine practice data collection, it is necessary that the data collection is as complete as possible, at least from the care context of insured persons with fedratinib.

Care providers within the meaning of Chapter 5, Section 60 of the G-BA's Rules of Procedure (VerfO) 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. In this context, efforts must also be made to ensure that the data transmission is as complete as possible.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

In order to hold consultations and prepare a recommendation for a resolution on the initiation of a written statement procedure for the restriction of the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V, the Subcommittee on Medicinal Products commissioned a working group (WG routine practice data collection (RPDC)) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and the representative(s) of the patient organisations. Representatives of the IQWiG also participate in the sessions. The working group discussed the amendment of the AM-RL in its session on 15 August 2022.

The draft resolution to initiate a written statement procedure was discussed at the session of the Subcommittee on Medicinal Products on 23 August 2022 and the draft resolution was consented to.

At its session on 23 August 2022, the Subcommittee unanimously decided to initiate the written statement procedure according to Chapter 1, Section 10, paragraph 1 of the G-BA's Rules of Procedure.

Statements were received during the written statement procedure. The oral hearing was held on 10 October 2022.

The evaluation of the written statements received and the oral hearing was discussed at the session of the subcommittee on 25 October 2022, and the proposed resolution was approved.

At its session on 3 November 2022, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
WG RPDC	15 August 2022	Consultation on the amendment of the AM-RL
Subcommittee Medicinal products	23 August 2022	Discussion and consensus on the draft resolution Resolution to initiate the written statement procedure on the amendment of the AM-RL Scheduling the oral hearing
WG RPDC	6 October 2022	Consultation on the statements received
Subcommittee Medicinal products	10 October 2022	Conduct of the oral hearing
WG RPDC	17 October 2022	Consultation on the draft resolution and evaluation of the written statement procedure
Subcommittee Medicinal products	25 October 2022	Concluding discussion of the draft resolution
Plenum	3 November 2022	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 3 November 2022

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

Prof. Hecken