Justification

Gemeinsamer Bundesausschuss

to the Resolution of the Federal Joint Committee (G-BA) on the Discontinuation of the Benefit Assessment of Prasterone in Accordance with Section 35a SGB V – Prasterone

of 17 October 2019

Contents

1. Legal basis

According to Section 35a, paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. Approved therapeutic indications,
2. Medical benefit,
3. Additional medical benefit in relation to the appropriate comparator therapy,
4. Number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. Treatment costs for statutory health insurance funds,
6. Requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a, paragraph 3 SGB V, the G-BA shall pass a resolution on the benefit assessment within three months of its publication. The resolution is to be published on the internet and forms part of the Pharmaceuticals Directive.

2. Key points of the resolution

The medicinal product Intrarosa® with the active ingredient prasterone was placed on the market on 1 May 2019 in a packaging size that exceeds the largest packaging size specified by the German Packaging Size Ordinance in accordance with Section 31, paragraph 4, sentence 1 SGB V. According to Section 31, paragraph 4 sentence 2 SGB V, this means that according to Section 31, paragraph 1, sentence 1 SGB V, the medicinal product is not covered by and may not be supplied at the expense of statutory health insurance. Because Section 35a, paragraph 1, sentence 1 SGB V presupposes that a medicinal product must be reimbursable for the benefit assessment of a medicinal product with a new active ingredient and Intrarosa® did not fulfil this requirement, the procedure for the benefit assessment of prasterone is discontinued by resolution of 17 October 2019 (Federal Gazette, BAnz AT DD MM YYYY Bx).

If the medicinal product is placed on the market in a reimbursable packaging size, it is subject to the scope of the benefit assessment in accordance with Section 35a SGB V.

3. Bureaucratic costs

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

No dossier was submitted when the medicinal product Intrarosa® with the active ingredient prasterone was first placed on the market on 1 May 2019.

The G-BA prepared the benefit assessment.

The written statement procedure was initiated with the publication of the benefit assessment prepared by the G-BA on the G-BA website on 1 August 2019. The deadline for submitting written statements was 22 August 2019.

The oral hearing was held on 9 September 2019.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received and the oral hearing were discussed at the session of the subcommittee on 24 September 2019, and the proposed resolution was approved.

In its session on 17 October 2019, the plenum decided to discontinue the benefit assessment of prasterone in accordance with Section 35a SGB V.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal product	23 July 2019	Knowledge of the benefit assessment of the G-BA
Working group Section 35a	3 September 2019	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal product	9 September 2019	Conduct of the oral hearing
Working group Section 35a	17 September 2019	Advice on the obligation to carry out a benefit assessment in accordance with Section 35a SGB V
Subcommittee Medicinal product	24 September 2019	Concluding discussion of the proposed resolution
Plenum	17 October 2019	Adoption of the resolution on the amendment of Annex XII of the AM-RL

Berlin, 17 October 2019

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

Prof Hecken