Justification

Gemeinsamer Bundesausschuss

to the 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 Erenumab (patient numbers)

of 19 September 2019

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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. According to Section 35a, paragraph 6 SGB V, the G-BA may also arrange for a benefit assessment according to Section 35a, paragraph 1 SGB V for reimbursable medicinal products containing an active ingredient that is not a new active ingredient within the meaning of Section 35a, paragraph 1 SGB V if a new marketing authorisation with new data protection is granted for the medicinal product. 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.

According to Chapter 5, Section 20, paragraph 4 of the VerfO, the sub-committee on Medicinal Products may, in the event of a need for change in the sense of a factual and mathematical correction with regard to the information according to Chapter 5, Section 20, paragraph 3, no. 2 (Number of patients or demarcation of patient groups eligible for treatment) or no. 4 (Treatment costs) of the VerfO, make the corresponding changes by mutual consent.

2. Key points of the resolution

At its session on 2 May 2019, the G-BA passed a resolution on the benefit assessment of erenumab in accordance with Section 35a SGB V. Following publication of the resolution on the website of the G-BA, the G-BA concluded that there is a need to adapt the information on the number of patients presented in the resolution or the demarcation of patient groups eligible for treatment.

The resolution of 2 May 2019 was based on the estimate of the number of adult migraine patients derived from the dossier of the pharmaceutical company. The information on the number of patients is based on the target population in statutory health insurance (SHI).

Within the scope of the benefit assessment for galcanezumab, significantly different numbers were presented for the identical indication of migraine prophylaxis.

Based on the estimations of the IQWiG addendum of 3 September 2019 in the resolution on galcanezumab of 18 September 2019 a range of approx. 1,428,000–1,445,000 patients was derived for patient group a in deviation from the resolution on erenumab of 2 May 2019 with additional consideration of the criterion "patients with < 4 migraine days per month". In contrast to the resolution on erenumab of 2 May 2019, the lower limit for patient group b is the more plausible estimate of 1,400 patients because this takes into account the restriction to exactly the four active ingredient classes named by the G-BA. The upper limit, however, was the number of patients from the erenumab dossier (11,000 patients), which was considered more plausible. This is mainly due to the fact that in the dossier on galcanezumab, for the upper limit, the regulation was budgeted at only at least two (instead of four) prophylactics. Despite the fact that in the dossier on erenumab, patients with less than four migraine days per month were not also excluded for sub-populations b and c, based on the routine data analyses presented, it was assumed that the patients in question were severely affected and regularly suffer from at least four migraine days per month; a more plausible approximation of the care reality was ultimately assumed. For patient group b, the overall range was thus 1,400 to 11,000 patients.

In accordance with the resolution on galcanezumab of 19 September 2019, the ranges determined under consideration of the IQWiG addendum are to be used analogously for erenumab; these replace the previous data in the resolution of 2 May 2019 under "Number of patients or demarcation of patient groups eligible for treatment" for patient populations a and b. For patient group c, no need to adjust the patient numbers decided on 2 May 2019 is seen.

3. Written statement procedure according to Section 92, paragraph 3a SGB V

The amendment of the Pharmaceuticals Directive does not require the submission a written statement procedure according to Section 92, paragraph 3a of the German Social Code, Book Five. Pharmaceutical companies are not adversely affected by the correction of the costs of the active ingredient erenumab; the change for the reasons mentioned under 2. is legally necessary.

4. 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.

5. Process sequence

Following the adoption of the resolution, the necessity of the adjustment in the resolution with regard to the patient numbers in the resolution of 2 May 2019 on an amendment of the Pharmaceuticals Directive Annex XII – Resolutions on the benefit assessment of medicinal

products with new active ingredients according to Section 35a SGB V – active ingredient has become apparent.

The matter was discussed in the Working Group Section 35a as well as the medicinal products sub-committee.

At its session on 19 September 2019, the plenum unanimously adopted the amendment to the AM-RL with regard to an adjustment to the number of patients stated in the resolution of 2 May 2019.

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	3 September 2019	Consultation on the facts of the case
Subcommittee Medicinal product	10 September 2019	Consultation on an amendment to the resolution of 2 May 2019 regarding the indication of patient numbers
Plenum	19 September 2019	Resolution on an amendment to the resolution of 2 May 2019 regarding the indication of patient numbers

Berlin, 19 September 2019

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

Prof Hecken