Justification

Gemeinsamer Bundesausschuss

to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Amendment of Information on the Period of Validity of a Resolution on the Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Niraparib (Ovarian Carcinoma,Tubal Carcinoma, or Primary Peritoneal Carcinoma)

of 20 August 2020

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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. 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 decides 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

At its session on 2 April 2020, the G-BA passed a resolution on the benefit assessment of niraparib in accordance with Section 35a SGB V. The period of validity of the resolution is limited to 1 October 2020. This was a reassessment of niraparib in accordance with § 35a SGB V after the € 50 million turnover limit of an oprhan drug is exceeded.

In accordance with the justification for the resolution, the limitation was because a small number of events on overall survival from the NOVA study were available at the time of the assessment.

Against the background that clinical data on overall survival as well as on all other patient-relevant endpoints of the NOVA study were expected at a later stage, which may be relevant for the assessment of the benefit of the medicinal product, the resolution was limited in time. The limitation should allow the expected final results from the NOVA study to be included in the benefit assessment of the medicinal product according to Section 35a SGB V. For this purpose, the G-BA considered a limitation of the resolution until 1 October 2020 to be appropriate.

The pharmaceutical company informed the G-BA that the defined threshold value for a final evaluation of the survival data of the NOVA study for a new data cut-off had not yet been reached. According to the current state of knowledge of the pharmaceutical company, this is not expected before August 2020 at the earliest.

In order to allow the inclusion of the final results of the NOVA study in the benefit assessment of niraparib after expiry of the limitation, the period of validity of the resolution, originally limited to 1 October 2020, is extended. It was decided to prolong the limitation of the resolution until 1 February 2021.

The issues upon which the limitation was based regarding the assessment of the additional benefit are hereby not prejudiced.

In accordance with Section 3, number 5 AM-NutzenV in conjunction with Chapter 5, Section 1, paragraph 2, number 7 VerfO, the procedure for the benefit assessment for the active ingredient niraparib shall recommence when the limitation has expired. For this purpose, the pharmaceutical company must submit a dossier on the benefit assessment of niraparib to the G-BA at the latest on the day of expiry of the deadline (Section 4, paragraph 3, No. 5 AM-NutzenV in conjunction with Chapter 5, Section 8, No. 5 VerfO).

The possibility that a benefit assessment for niraparib can be carried out at an earlier point in time because of other reasons (*cf* Chapter 5, Section 1, paragraph 2, no. 2, 3, 5, and 6 VerfO) remains unaffected hereof.

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

The matter was discussed in the Subcommittee on Medicinal Products, and an amendment resolution was passed.

At its session on 20 August 2020, the plenum decided to amend the limitation of the period of validity of the resolution.

Berlin, 20 August 2020

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken