Justification

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 Niraparib (new therapeutic indication: ovarian carcinoma, fallopian tube carcinoma or primary peritoneal carcinoma, FIGO stages III and IV, maintenance therapy)

of 20 May 2021

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 studies 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:

1st Approved therapeutic indications,

2nd Medical benefit,

3rd Additional medical benefit in relation to the appropriate comparator therapy,

4th Number of patients and patient groups for whom there is a therapeutically significant additional benefit,

5th Treatment costs for statutory health insurance funds,

6th 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 is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient Niraparib (Zejula) was listed for the first time on 15 December 2017 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 27 October 2020, Niraparib received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2 number 2 letter a to Regulation (EC) No. 1234/2008 of the commission of 24 November 2008 concerning the examination of amendments to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12 December 2008, p. 7).

On 24 November 2020, i.e. at the latest within four weeks after the disclosure of the pharmaceutical company on the approval of a new therapeutic indication, the pharmaceutical company has submitted a dossier in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA on the active ingredient Niraparib with the new therapeutic indication (ovarian carcinoma, fallopian tube carcinoma or primary peritoneal carcinoma, FIGO stages III and IV, maintenance therapy).

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 01 March 2021 on the website of the G-BA (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA came to a resolution on whether an additional benefit of Niraparib compared to the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, the statements submitted in the written statement and oral hearing procedure, and the addenda to the benefit assessment prepared by the IQWiG. In order to determine the extent of the additional benefit, the G-BA has evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of Niraparib.

In the light of the above and taking into account the statements received and the oral hearing, the G-BA has come to the following assessment:

2.1 Additional benefit of the medicinal product in relation to the appropriate comparator therapy

2.1.1 New indication for Niraparib (Zejula) according to the product information

Zejula is used as monotherapy for maintenance treatment in adult patients with advanced epithelial (FIGO stages III and IV) high-grade carcinoma of the ovaries, fallopian tubes or with primary peritoneal carcinoma who have a response (complete or partial) after first-line platinum-based chemotherapy.

Therapeutic indication of the resolution (resolution of 20/05/2021):

see approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adult patients with advanced epithelial (stages III and IV), high-grade carcinoma of the ovaries, fallopian tubes or with primary peritoneal carcinoma who are in remission (complete or partial) following completed first-line platinum-based chemotherapy; maintenance therapy

A therapy according to the doctor's instructions taking into account
- Monitoring wait-and-see approach (after previous therapy with carboplatin in combination with paclitaxel)
- Bevacizumab (only after previous therapy with carboplatin in combination with paclitaxel and bevacizumab)

Criteria according to Chapter 5, Section 6 of the Rules of Procedure of the G-BA:

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication in accordance with the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

[1] General Methods, version 6.0 from 5.11.2020. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5, Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.
3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the Federal Joint Committee shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

Justification based on the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO:

on 1. Medicinal products with the following active ingredients are approved for the present therapeutic indication: Bevacizumab, carboplatin, cisplatin, cyclophosphamide, doxorubicin, epirubicin, melphalan, olaparib, paclitaxel and treosulfan.

Medicinal products with explicit approval for the maintenance therapy of patients with a platinum-sensitive relapse and for second-line or follow-up therapy were not included.

on 2. In the present therapeutic indication, no non-medicinal treatments can be considered.

on 3. For the present therapeutic indication, the G-BA has passed resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V for the active ingredients olaparib, on the 16.1.2020.

on 4. The generally accepted state of medical knowledge for the indication was established by means of a systematic search for guidelines and reviews of clinical studies.

Accordingly, there is limited evidence for the maintenance treatment of advanced high-grade epithelial ovarian carcinoma, fallopian tube carcinoma or primary peritoneal carcinomatosis after previous platinum-based first-line chemotherapy. It cannot be deduced from the present guidelines that maintenance therapy is regularly recommended in the present indication. Specifically, the national S3 guideline for the primary treatment of patients in the present indication strongly recommends first-line chemotherapy. With regard to possible chemotherapeutic maintenance treatment, the guideline states that these should not be carried out after completion of the primary therapy. The additional administration of bevacizumab in combination with primary chemotherapy and henceforth as maintenance treatment can be considered according to the S3 guideline. According to the approval status, maintenance treatment with bevacizumab can be considered if the primary therapy also included the use of bevacizumab.

PARP inhibitor olaparib is also available and is approved for the maintenance treatment of advanced BRCA1/2-mutated high-grade epithelial ovarian cancer (with response after completion of first-line platinum-based chemotherapy). In its resolution of 16 January 2020, the G-BA did not determine any additional benefit in the benefit assessment of olaparib in this indication compared to monitoring wait-and-see approach. The resolution is valid until 1 April 2024. The therapeutic value of olaparib cannot be conclusively assessed at present.

The recently approved combination of olaparib with bevacizumab as maintenance treatment in adult patients with advanced high-grade epithelial ovarian cancer,

fallopian tube carcinoma, or primary peritoneal carcinoma who have a response (complete or partial) following completed first-line platinum-based chemotherapy in combination with bevacizumab and whose tumour is associated with positive homologous recombination deficiency (HRD) status is also currently undergoing benefit assessment.

In the overall view, the G-BA, therefore, determines a therapy according to the physician's discretion, taking into account monitoring wait-and-see approach (after previous therapy with carboplatin in combination with paclitaxel) and bevacizumab (only after previous therapy with carboplatin in combination with paclitaxel and bevacizumab) as appropriate comparative therapy in the present therapeutic indication.

The findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment order.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of Niraparib is assessed as follows:

For maintenance treatment in adult patients with advanced epithelial (FIGO stages III and IV) high-grade carcinoma of the ovaries, fallopian tubes or with primary peritoneal carcinoma who have a response (complete or partial) after first-line platinum-based chemotherapy, an additional benefit is not proven.

Justification:

For the proof of additional benefit of Niraparib as maintenance therapy for the treatment of patients with advanced epithelial (stages III and IV), high-grade carcinoma of the ovaries, fallopian tubes or primary peritoneal carcinoma who are in remission (complete or partial) after completed first-line platinum-based chemotherapy, the pharmaceutical company has submitted the results of the PRIMA study.

PRIMA is a multicentre, double-blind, randomised study comparing Niraparib to placebo. The global study, which is currently ongoing and started in August 2016, enrolled adult patients with advanced (FIGO stages III and IV) high-grade serious or endometrioid carcinoma of the ovaries, fallopian tubes, or with primary peritoneal carcinoma who had a response after platinum-containing chemotherapy.

The 733 included patients were randomised 2:1 to the Niraparib arm (N=487) and to the placebo arm (N=246). Treatment with Niraparib was administered according to the approval with the exception of the individual starting dose. For the benefit assessment, the subpopulation of patients who received the dosing regimen recommended in the SmPC with an individual starting dose (ISD) for Niraparib based on body weight, and baseline platelet counts (ISD subpopulation) is used. This is particularly due to the better side effect profile of Niraparib in the ISD subpopulation. This results in a total of 352 patients in the pivotal ISD subpopulation with 228 patients in the Niraparib arm and 124 in the placebo arm.

The PRIMA study is being conducted in 220 study centres in Europe and the USA.

The pharmaceutical company presents results on the endpoint categories Mortality, Morbidity, Health-related quality of life and Adverse events in the dossier.

On the usability of the study results presented in the dossier:

IQWiG stated in the dossier assessment that the results of the PRIMA study presented by the pharmaceutical company in the dossier were incomplete and inadequately prepared. As a

result, IQWiG was unable to adequately assess the study data, so that the results of the PRIMA study as a whole were not considered usable for the benefit assessment.

In IQWiG's dossier assessment, the overall deficiencies in the dossier are considered to be serious. The finding of incompleteness of content is based specifically on the following deficiencies, described in summary here.

Health-related quality of life was assessed in the PRIMA study using the EORTC QLQ-C30 instrument and the EORTC QLQ-OV28. The EORTC QLQ-C30 consists of a global health status scale and, in addition to symptom scales, other health-related quality of life function scales. In the dossier, the pharmaceutical company omits to fully present the evaluations of the EORTC questionnaire QLQ-C30 and only presents results on the scale "global health status". There is no justification for this selective reporting in the dossier. Due to the incomplete presentation of results of the core module EORTC QLQ-C30, the results of the disease-specific additional module EORTC QLQ-OV28 cannot be assessed either. The additional analyses submitted by the pharmaceutical company (Appendix 4-G of the dossier) could also not be used to evaluate the results on the missing scales, as the necessary information was not available. Therefore, extensive information on patient-reported outcomes was missing for the dossier evaluation, and no evaluations of health-related quality of life were available, although these data were collected.

Furthermore, the information in the pharmaceutical company's dossier on adverse events (AEs) is not complete. Only selected adverse events are presented for the endpoint category Adverse events. Of the common AEs, only those SOCs and PTs for which a significant treatment difference has been identified (hazard ratio or relative risk) are presented by the pharmaceutical company. Furthermore, it indicates the AEs that occurred in at least 10 patients taking Niraparib but not placebo and for which no HR or RR could be calculated. Regarding the further UE required according to the dossier submission, the pharmaceutical company refers to Annex 4-G prepared by the pharmaceutical company, in which, however, only Kaplan-Meier curves are available without indication of absolute frequencies or treatment effects.

In conclusion, IQWiG states that, overall, due to the incomplete data, an adequate weighing of the benefits and harms and thus an assessment of the additional benefit of Niraparib compared to the appropriate comparator therapy is not possible. A presentation of the usable study results contained in the dossier was also omitted.

After detailed consideration of IQWiG's discussion of the deficiencies in the dossier, the G-BA concurs with IQWiG's assessment and, for its part, states that according to Chapter 5, Section 18 (1) of the G-BA's Regulations, the preparation of the documents in the dossier deviates to an extent from the requirements specified in Chapter 5, Section 9 of the G-BA's Regulations, which is contrary to a proper assessment of the additional benefit.

In accordance with the regulation in Chapter 5, Section 18 of the G-BA's Regulation, the benefit assessment examines whether there is evidence of an additional benefit for the medicinal product compared to the appropriate comparator therapy. The validity and completeness of the information in the dossier is also checked. The dossier template in Annex II must be used for compiling the dossier. The data according to Chapter 5, Section 9 (1), (4) to (8) of the G-BA's Regulation must be prepared and submitted in accordance with the requirements specified in Modules 1 to 5. Even if the pharmaceutical company objects to the publication of documents in Module 5 with reference to Chapter 5, Section 10 of the G-BA's Regulation, it must nevertheless ensure, in accordance with Chapter 5, Section 9(3), Sentence 1 of the Regulation, that all information on study methodology and results is made available in full for publication in the dossier in Modules 1 to 4 in accordance with the second sentence of Paragraph 2.

The preparation of the pharmaceutical company's data presented here does not comply with the requirements laid down in Chapter 5, Section 9 of the Regulation and proves to be inadequate and incomplete, so that it obstacled a proper assessment of the additional benefit. Subsequently, the G-BA determines in accordance with Chapter 5, Section 18, Sentence 4, of the G-BA's Regulation that an additional benefit has not been proven.

In the written statement procedure, the pharmaceutical company submitted comprehensive evaluations of study results. In this regard, it was discussed at the oral hearing that IQWiG's main substantive criticisms from the dossier assessment were not addressed. Irrespective of the fact that the pharmaceutical company has the right according to chapter 5 § 19 paragraph 1 and 2 of the G-BA's Regulation to comment on the benefit assessment of the medicinal product both in writing and orally upon publication of the benefit assessment on the website of the Federal Joint Committee and that the written and oral comments are included in the resolution on the adoption of the benefit assessment according to § 92 paragraph 1 sentence 2 number 6 of the German Social Code, Book V, it is the sole responsibility of the pharmaceutical entrepreneur according to § 5 paragraph 1 sentence 1 of the AM-NutzV to prove the additional benefit of the medicinal product concerned with a new active substance in the dossier. According to Section 5 (1) sentence 2 AM-NutzV, the G-BA has no official duty to investigate.

The comprehensive evaluations of study results, which were only submitted subsequently with the written statement, were not suitable for an appropriate assessment of the additional benefit, at least in consideration of the pharmaceutical company's obligation to present the results in the proceedings. As a result, it must be concluded that the additional benefit is not proven.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient Niraparib.

Niraparib is used as monotherapy for maintenance treatment in adult patients with advanced epithelial (FIGO stages III and IV) high-grade carcinoma of the ovaries, fallopian tubes or with primary peritoneal carcinoma who have a response (complete or partial) after first-line platinum-based chemotherapy.

The G-BA determined the appropriate comparator therapy to be therapy as determined by the physician, taking into account the monitoring wait-and-see approach (after previous therapy with carboplatin in combination with paclitaxel) or bevacizumab (only after prior therapy with carboplatin in combination with paclitaxel and bevacizumab).

For the proof of additional benefit, results from the PRIMA study comparing Niraparib to placebo were presented.

IQWiG stated in the dossier assessment that the presented results of the PRIMA study are incomplete in terms of content and inadequately prepared. As a result, IQWiG was unable to adequately assess the study data, so that the results of the PRIMA study as a whole were not considered usable for the benefit assessment.

In the dossier, the evaluations of the EORTC questionnaire QLQ-C30 are incomplete. As a result, the disease-specific additional module QLQ-OV28 cannot be assessed. Furthermore, only selected adverse events are presented for the endpoint category Adverse events.

The preparation of the pharmaceutical company's data presented here does not comply with the requirements laid down in Chapter 5, Section 9 of the Regulation and proves to be inadequate and incomplete, so that it obstacled a proper assessment of the additional benefit.

Subsequently, the G-BA determines in accordance with Chapter 5, Section 18, Sentence 4, of the G-BA's Regulation that an additional benefit has not been proven.

The comprehensive evaluations of study results, which were only submitted subsequently with the written statement, were not suitable for an appropriate assessment of the additional benefit, at least under consideration of the pharmaceutical company's obligation to present the results in the proceedings.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The information on the number of patients is based on the target population in statutory health insurance (SHI).

The G-BA bases its resolution on the information from the dossier of the pharmaceutical company. An underestimation is to be assumed for this figure. This is due to the inadequate operationalisation of response after first-line platinum-based chemotherapy via platinum sensitivity. Furthermore, patients with carcinoma of the fallopian tubes or primary peritoneal carcinoma were not included.

2.3 Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Zejula (active ingredient: Niraparib) at the following publicly accessible link (last access: 24 February 2021):

https://www.ema.europa.eu/en/documents/product-information/zejula-epar-product-information_de.pdf

Treatment with Niraparib should only be initiated and monitored by specialists in internal medicine, haematology and oncology, specialists in gynaecology and obstetrics and others, and specialists participating in the Oncology Agreement who are experienced in the treatment of patients with ovarian carcinoma.

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 1 May 2021).

If no maximum treatment duration is specified in the product information, the treatment duration is assumed to be one year (365 days), even if the actual treatment duration is patient-individual and/or is shorter on average. The time unit "days" is used to calculate the "number of treatments/patient/year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

The use of bevacizumab in the present indication is limited to a maximum of 15 months (including previous therapy with carboplatin in combination with paclitaxel and bevacizumab). In 15 months, a total of 21.7 cycles every three weeks is possible. After deduction of the 6 cycles of bevacizumab that are administered together with the platinum-based first-line chemotherapy according to the technical information of bevacizumab, 15.7 cycles of bevacizumab remain as maintenance treatment in the present therapy situation. Only these are used for the calculation of the annual treatment costs.

Treatment duration:

Name of therapy	Treatment mode	Number of treatments/patient/year	Treatment duration/treatment (days)	Days of treatment/patient/ year
Medicinal product to be assessed				
Niraparib	Once daily	365	1	365
Appropriate comparator therapy				
A therapy according to the doctor's instructions taking into account				
monitoring wait-and-see approach	incalculable			
Bevacizumab	Once per 21 day cycle	15.7	1	15.7

Consumption:

For dosages depending on body weight, the average body measurements from the official representative statistics "Microcensus 2017 – body measurements of the population" were applied. Taking into account the therapeutic application, an average body weight of adult women is used for the calculation of consumption (68.7 kg).[2]

Name of therapy	Dosage/ application	Dosage/ patient/days of treatment	Usage by strength/day of treatment	Days of treatment / patient/ year	Average annual consumption by strength
Medicinal product to be assessed					
Niraparib	200 mg	200 mg	twice 100 mg	365	730 x 100 mg
Appropriate comparator therapy					
A therapy according to the doctor's instructions taking into account					
monitoring wait-and-see approach	incalculable				
Bevacizumab	15 mg/kg = 1,030.5 mg	1,030,5 mg	twice 400 mg + 3 x 100 mg	15.7	31.4 x 400 mg + 47.1 x 100 mg

Costs:

[2] Statistisches Bundesamt (Federal Statistic Office), Wiesbaden 2018: http://www.gbe-bund.de/

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Sections 130 and 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular strength was first determined on the basis of consumption. Having determined the number of packs of a particular strength, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates.

Costs of the medicinal product:

Name of therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Niraparib	84 HKP	€ 6,628.48	€ 1.77	€ 377.97	€ 6,248.74
Appropriate comparator therapy					
monitoring wait-and-see approach	incalculable				
Bevacizumab 400 mg	1 IFC	€ 1,553.06	€ 1.77	€ 85.42	€ 1,465.87
Bevacizumab 100 mg	1 IFC	€ 396.75	€ 1.77	€ 21.35	€ 373.63
Abbreviations: HKP = hard capsules; IFK = concentrate for the preparation of an infusion solution					

LAUER-TAXE® last revised: 1 May 2021

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be taken into account as costs for additionally required SHI services.

Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

Because there are no regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, no costs for additionally required SHI services had to be taken into account.

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe)(Sections 4 and 5 of the Pharmaceutical Price Ordinance) from 1.10.2009 is not fully used to calculate costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131 paragraph 4 SGB V is a suitable basis for a standardised calculation.

According to special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe), all surcharges for the production of parenteral preparations containing cytostatic drugs a maximum of € 81 per ready-to-use preparation and for the production of parenteral solutions containing monoclonal antibodies a maximum of € 71 per ready-to-use unit are to be payable. These additional costs are not added to the pharmacy sales price but rather follow the rules for calculating in the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe). The cost representation is based on the pharmacy retail price and the maximum surcharge for the preparation and is only an approximation of the treatment costs. This presentation does not take into account, for example, the rebates on the pharmacy sales price of the active ingredient, the invoicing of discards, the calculation of application containers, and carrier solutions in accordance with the regulations in Annex 3 of the special agreement on contractual unit costs retail pharmacist services (Hilfstaxe).

3. Bureaucratic cost 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

The Subcommittee on Medicinal Products determined the appropriate comparator therapy at its session on 25 August 2020.

On 24 November 2020, the pharmaceutical company submitted a dossier for the benefit assessment of Niraparib to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 26 November 2020 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefits of medicinal products with new active ingredients in accordance with Section 35a SGB V, the G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient Niraparib.

The dossier assessment by the IQWiG was submitted to the G-BA on 25 February 2021, and the written statement procedure was initiated with publication on the website of the G-BA on 1 March 2021. The deadline for submitting written statement procedures was 22 March 2021.

The oral hearing was held on 7 April 2021.

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 11 May 2021, and the draft resolution was approved.

At its session on 20 May 2021, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	25 August 2020	Determination of the appropriate comparator therapy
Working group Section 35a	30 March 2021	Information on written statement procedures received; preparation of the oral hearing
Subcommittee Medicinal products	7 April 2021	Conduct of the oral hearing
Working group Section 35a	13 April 2021 20 April 2021	Consultation on the dossier assessment by the IQWiG, evaluation of the written statement procedure
Subcommittee Medicinal products	27 April 2021	Consultation on the dossier assessment by the IQWiG, evaluation of the written statement procedure
Working group Section 35a	4 May 2021	Consultation on the dossier assessment by the IQWiG, evaluation of the written statement procedure
Subcommittee Medicinal products	11 May 2021	Concluding consultation of the draft resolution
Plenum	20 May 2021	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 20 May 2021

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

Prof. Hecken