

Justification

for the Resolution of the Federal Joint Committee (G-BA) on
an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with
New Active Ingredients according to Section 35a SGB V
Niraparib/ abiraterone acetate (new therapeutic indication:
metastatic hormone-sensitive prostate cancer, BRCA 1/2
mutations, in combination with prednis(ol)one and
androgen deprivation therapy)

From 3 September 2026

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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) assess the benefit of all 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 have 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 the 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 decide 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 combination of active ingredients niraparib/ abiraterone acetate (Akeega) was listed for the first time on 15 November 2023 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 6 March 2026, niraparib/ abiraterone acetate 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 variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 from 12.12.2008, sentence 7).

On 13 March 2026, i.e. at the latest within four weeks of informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company 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 combination of active ingredients niraparib/ abiraterone acetate with the new therapeutic indication

"Niraparib/ abiraterone acetate with prednisone or prednisolone is indicated for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations (germline and/or somatic) in combination with androgen deprivation therapy (ADT)."

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 15 June 2026 on the G-BA website at (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

Based on the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, the statements submitted in the written statement and oral hearing procedure as well as the addendum to the benefit assessment prepared by IQWiG, the G-BA decided on the question on whether an additional benefit of pembrolizumab compared with the appropriate comparator therapy could be determined – Annex XII - Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V. In order to determine the extent of the additional benefit, the G-BA have 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 IQWiG according to the General Methods was not used in the benefit assessment of niraparib/ abiraterone – Annex XII - Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V.

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

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

2.1.1 Approved therapeutic indication for Niraparib/ abiraterone acetate (Akeega) in accordance with the product information

Akeega is indicated with prednisone or prednisolone:

- in combination with androgen deprivation therapy (ADT) for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations (germline and/or somatic).

Therapeutic indication of the resolution (resolution of 03.09.2026):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) with BRCA 1/2 mutations (germline and/or somatic)

Appropriate comparator therapy:

- conventional androgen deprivation in combination with apalutamide
or
- conventional androgen deprivation in combination with enzalutamide
or
- conventional androgen deprivation in combination with abiraterone acetate and prednisone or prednisolone (only for patients with newly diagnosed, high-risk prostate cancer)
or
- conventional androgen deprivation in combination with darolutamide and docetaxel

Criteria according to Chapter 5, Section 6 of the Rules of Procedure of the G-BA and Section 6, paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication according to 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.

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 G-BA 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.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of

medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved for the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved for the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

Justification based on the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:

- On 1. Medicinal products with the active ingredients bicalutamide, cyproterone acetate, flutamide, degarelix, relugolix, buserelin, goserelin, leuprorelin, triptorelin, abiraterone acetate, apalutamide, darolutamide, enzalutamide and docetaxel are approved in the present therapeutic indication.
- On 2. As a non-medicinal treatment option, an orchiectomy, in addition to the use of GnRH agonists or GnRH antagonists, is one way to implement conventional androgen deprivation (ADT).
- On 3. The following resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V are available:
- Abiraterone acetate: resolution of 07.06.2018
 - Apalutamide: resolution of 20.08.2020
 - Enzalutamide: resolution of 19.11.2021
 - Relugolix: resolution of 06.04.2023
 - Darolutamide: resolutions of 21.09.2023 and 19.02.2026
- On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as systematic reviews of clinical studies in the present indication and is presented in the "Research and synopsis of the evidence to determine the appropriate comparator therapy according to Section 35a SGB V".

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present indication according to Section 35a, paragraph 7 SGB V (see "Information on Appropriate Comparator Therapy"). In this regard, there is a joint written statement from the German Society for Haematology and Medical Oncology (DGHO) and the German Society for Urology (DGU).

In the present therapeutic indication, it is assumed that combination therapy – additional therapy to conventional androgen deprivation therapy (ADT) – is usually an option for the patients, taking into account any comorbidities and the general condition. In the context of the present therapeutic indication, conventional ADT refers to surgical or medicinal castration by therapy with GnRH agonists or GnRH antagonists. The disease of metastatic hormone-sensitive prostate cancer (mHSPC) constitutes a palliative treatment setting. Therefore, maintaining quality of life and symptom control are of particular importance.

The present guidelines unanimously recommend therapy with abiraterone acetate in combination with prednisone or prednisolone, apalutamide, enzalutamide or darolutamide in combination with docetaxel in addition to ADT. The rationale behind these recommendations is that relevant advantages in the therapeutic benefit could be shown for abiraterone acetate in combination with prednisone or prednisolone, apalutamide and enzalutamide compared with ADT alone as well as for darolutamide in combination with docetaxel and ADT compared with docetaxel and ADT.

The guidelines also include recommendations for combination therapy (in addition to ADT) consisting of abiraterone acetate in combination with prednisone or prednisolone and docetaxel. However, this combination is not approved and therefore not considered as an appropriate comparator therapy. In their written statement, the scientific-medical societies follow the recommendations set out in the guidelines on the individual active ingredients or combinations of active ingredients.

The benefit assessment of abiraterone acetate gave an indication of a considerable additional benefit of the combination therapy with ADT and prednisone or prednisolone compared to conventional ADT (resolution of 07.06.2018). In this context, the underlying therapeutic indication was restricted to patients with newly diagnosed high-risk mHSPC. The relevant recommendations for the use of combination therapy with abiraterone acetate are set out in the S3 guideline (modified recommendation from 2025) and in the written statement issued by the scientific-medical societies.

The benefit assessment of apalutamide in combination with ADT showed no additional benefit in the indirect comparison for patients with distant metastases (M1 stage) and good general condition (0 to 1 according to ECOG/ WHO or $\geq 70\%$ according to Karnofsky index), compared to docetaxel in combination with prednisolone and ADT (resolution of 20.08.2020). Likewise, the G-BA did not identify any additional benefit of enzalutamide in combination with ADT over docetaxel in combination with prednisolone and ADT in the indirect comparison for patients with distant metastases (M1 stage) and good general condition (0 to 1 according to ECOG/ WHO or $\geq 70\%$ according to Karnofsky index) (resolution of 15.12.2021). By the resolution of 21.09.2023, an indication of a considerable additional benefit of darolutamide in combination with docetaxel and ADT compared with ADT in combination with docetaxel with or without prednisone or prednisolone could be found. Furthermore, the G-BA found no additional benefit of darolutamide in combination with ADT compared with apalutamide in combination with ADT (resolution of 19.02.2026).

In the overall analysis, the treatment options of apalutamide, enzalutamide and darolutamide in combination with docetaxel - all treatment options, each in combination with ADT - are considered equally appropriate comparator therapies. Abiraterone acetate in combination with prednisone or prednisolone and ADT also represents another equally appropriate comparator therapy for patients with newly diagnosed high-risk mHSPC.

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

Any change to the appropriate comparator therapy requires a decision by the G-BA based on a prior review of the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of niraparib/ abiraterone acetate is assessed as follows:

Adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) with BRCA 1/2 mutations (germline and/or somatic)

a) Adult patients with newly diagnosed metastatic hormone-sensitive prostate cancer (mHSPC) with BRCA 1/2 mutations (germline and/or somatic) and a high-risk profile

An additional benefit is not proven.

b) Adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations who are not newly diagnosed and/or do not have a high-risk profile

An additional benefit is not proven.

Justification:

For the benefit assessment, the pharmaceutical company submitted the results of the AMPLITUDE study:

The AMPLITUDE study is an ongoing, double-blind, randomised, controlled phase III study comparing niraparib/ abiraterone acetate in combination with placebo, prednisone and ADT against the combination of placebo, abiraterone acetate, prednisone and ADT. Adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and homologous recombination repair (HRR) mutations were enrolled in the study.

A total of 696 patients were randomised to receive either treatment with niraparib/ abiraterone acetate in combination with placebo, prednisone and ADT, or the combination of placebo, abiraterone acetate, prednisone and ADT. Randomisation was carried out in a 1:1 ratio, stratified by HRR mutational status (BRCA2 versus CDK12 versus other pathogenic alterations), prior docetaxel treatment (yes versus no) and tumour volume (high versus low). The study has been ongoing since 2020 at 205 study sites in Asia, Europe (three in Germany), North America, South America, Africa, Australia and New Zealand.

The dosage of the comparator therapy was administered without any significant deviations from the relevant product information. Treatment was continued until disease progression,

defined as radiological or clinical progression, until the occurrence of unacceptable toxicity, the withdrawal of consent by the patient, or the termination of the study by the sponsor.

The primary endpoint of the study is radiographic progression-free survival (rPFS). Patient-relevant secondary endpoints in the categories of mortality, morbidity, health-related quality of life and side effects were also assessed.

Two pre-specified data cut-offs were intended for the AMPLITUDE study: a first interim analysis on 07.01.2025 and a second interim analysis on 03.10.2025. As regards the interim analysis dated 07.01.2025, the dossier contains results for rPFS only. The relevant results for this benefit assessment are based on data from the second interim analysis (data cut-off from 03.10.2025). The final analysis of overall survival is still pending and is due to be carried out once 389 events have occurred in the total population of patients with the HRR mutation.

Relevant sub-population:

Given the approved therapeutic indication for niraparib/ abiraterone acetate in combination with prednisone and ADT, only the sub-population of patients with BRCA 1/2 mutations is relevant for the benefit assessment. Furthermore, the choice of abiraterone acetate in combination with prednisone and a conventional ADT as the appropriate comparator therapy results in the study population being restricted to patients with newly diagnosed, high-risk mHSPC.

In the dossier, the pharmaceutical company presented data from the assessment-relevant sub-population of patients with newly diagnosed, high-risk mHSPC and BRCA 1/2 mutations from the AMPLITUDE study. Patients were considered newly diagnosed if they were diagnosed with mHSPC within 3 months prior to randomisation. This criterion formed the basis of the LATITUDE approval study on abiraterone acetate. Based on the LATITUDE criteria, the pharmaceutical company also defined the high-risk prognosis as the presence of ≥ 2 of the following risk factors: 1. Gleason score of ≥ 8 , 2. Presence of ≥ 3 lesions on skeletal scintigraphy, 3. Presence of measurable visceral metastases.

The assessment-relevant sub-population of the AMPLITUDE study comprises 58 versus 50 patients with newly diagnosed, high-risk mHSPC and BRCA 1/2 mutations.

Extent and probability of the additional benefit

Mortality

Overall mortality

In the AMPLITUDE study, overall survival is defined as a secondary endpoint and as the time from randomisation to death from any cause.

For the endpoint of overall survival, there was no statistically significant difference between the treatment groups.

Morbidity

Symptomatic progression

The composite endpoint of symptomatic progression was defined, in accordance with Protocol Amendment 4 of 28.08.2023, as the time from randomisation to the first documented occurrence of any of the following events:

- administration of radiotherapy for skeletal or pelvic symptoms
- necessity of a tumour-related orthopaedic surgical intervention
- cancer-related morbidity events (for example: [symptomatic and/or pathological] fractures, spinal cord compression, urinary tract obstructions)
- initiation of new systemic cancer therapy due to cancer symptoms
- performance of other cancer-related procedures (for example, insertion of a nephrostomy, insertion of a urinary catheter or surgery to manage tumour symptoms)

These are, in principle, patient-relevant events. This documentation of events and individual components is considered suitable for adequately reflecting the symptomatic progression throughout the course of the illness and treatment in question.

With regard to the interpretation of the analyses of this endpoint presented in the dossier, the IQWiG considered these analyses to be unsuitable in their benefit assessment, in particular due to a high number of censoring events in the intervention arm, the majority of which were attributable to deaths. According to the IQWiG, given the current data basis, the failure to take account of the relevant percentage of deaths as competing events in the endpoint of symptomatic progression means that the results for this endpoint cannot be interpreted meaningfully.

In their written statement and following the oral hearing, the pharmaceutical company provided further data and analyses of the endpoint of symptomatic progression in response to this and other points of criticism.

Consequently, there are several analyses based on different methodological approaches, which differ primarily in how they account for deaths and are listed as follows:

Analysis A1) Time-to-event analysis using the Cox proportional hazards model; including the subcomponent of death from any cause.

Analysis A2) Time-to-event analysis using the Cox proportional hazards model; excluding the subcomponent of death from any cause.

Analysis A3) Time-to-event analysis using the Cox proportional hazards model; including death due to asymptomatic progression.

Analysis B1) Stratified Fine Gray model; deaths from any cause without prior symptomatic progression are considered competing events.

Analysis B2) Stratified Fine Gray model; deaths attributable to asymptomatic (in particular, radiographically detected) progression are recorded as events in the subcomponent; all other deaths without prior asymptomatic progression are considered competing events.

The data on the number of qualifying events for the individual subcomponents show that death is the most common qualifying event (16 out of 24 events (67%) in the intervention arm, 12 out of 30 events (40%) in the control arm). In addition to the high overall percentage of total events, there are also differences between the study arms in the percentages of events attributable to death from any cause.

Following careful consideration of the arguments for and against including the subcomponent of death or death from any cause in the analyses, and taking into account the statements in which this rationale is also reflected, the G-BA consider it appropriate, in the present assessment situation, to base the interpretation of the results primarily on an analysis that excludes the subcomponent of death from any cause.

In this regard, the analysis A2), which demonstrates a statistically significant advantage of niraparib/ abiraterone acetate in combination with prednisone and ADT, is used for the present assessment. This finding is supported by the analysis B1), in which deaths from any cause without prior symptomatic progression were considered competing events, and which also demonstrates a statistically significant advantage. Furthermore, the analysis A1), which includes the subcomponent of death from any cause, shows a similar result; however, this is not statistically significant (hazard ratio [95% CI]; p value: 0.67 [0.39; 1.15]; p value: 0.143).

In summary, an improvement in the endpoint of symptomatic progression can be observed, and thus an advantage of niraparib/ abiraterone acetate in combination with prednisone and ADT compared with abiraterone acetate in combination with prednisone and ADT. However, uncertainties regarding the inclusion of the subcomponent of "death from any cause" remain. Taking into account the total number of events, the absolute difference between the treatment groups and the number of events in the respective individual components, the results for the endpoint of symptomatic progression are rated as a relevant, yet minor, improvement, based on the available data.

Worst pain (BPI-SF item 3), impairment due to pain (BPI-SF item 9a–g) and health status (EQ-5D VAS)

For the endpoints of worst pain (BPI-SF item 3), impairment due to pain (BPI-SF item 9a–g) and health status, as assessed using the VAS component of the EQ-5D questionnaire, there was no statistically significant difference between the treatment groups.

Quality of life

In the AMPLITUDE study, patients' quality of life was assessed using the FACT-P total score.

There was no statistically significant difference between the treatment groups.

Overall, there was neither an advantage nor a disadvantage of niraparib/ abiraterone acetate in combination with placebo, prednisone and ADT with regard to health-related quality of life.

Side effects

Total adverse events

Adverse events (AEs) occurred in almost all patients. The results for the endpoint "Total adverse events" are only presented additionally.

Serious AEs (SAEs), severe AEs (CTCAE grade ≥ 3)

For the endpoints of serious AEs (SAEs) and severe AEs (CTCAE grade ≥ 3), there was a statistically significant difference in each case to the disadvantage of niraparib/ abiraterone acetate in combination with placebo, prednisone and ADT.

Discontinuation due to AEs (≥ 1 active ingredient component)

For the endpoint of discontinuation due to AEs (≥ 1 active ingredient component), there was no statistically significant difference between the treatment groups.

PRO-CTCAE

No suitable data are available for the PRO-CTCAE questionnaire.

Specific AEs

MDS and AML (both AEs)

No data on the endpoints of MDS and AML (both AEs) are available for the relevant sub-population.

Anaemia and hypertension (both severe AEs)

For the endpoints of anaemia and hypertension (both PTs and severe AEs), there was a statistically significant difference to the disadvantage of niraparib/ abiraterone acetate in combination with placebo, prednisone and ADT.

In summary, within the endpoint category of side effects, there was a significant disadvantage of treatment with niraparib/ abiraterone acetate in combination with prednisone and ADT, substantiated by a marked increase in SAEs and severe AEs (CTCAE grade ≥ 3). With regard to the specific AEs, detailed analysis showed a marked increase in severe anaemia and severe hypertension cases.

Overall assessment/conclusion

The results of the AMPLITUDE study are available for the assessment of the additional benefit of niraparib/ abiraterone acetate in combination with prednisone or prednisolone and ADT for the treatment of adult patients with newly diagnosed, metastatic hormone-sensitive prostate cancer (mHSPC).

Given the approved therapeutic indication for niraparib/ abiraterone acetate in combination with prednisone and ADT, and the selection of abiraterone acetate in combination with prednisone and ADT as the comparator therapy, the pharmaceutical company identified a corresponding sub-population from the AMPLITUDE study: patients with newly diagnosed mHSPC who have BRCA 1/2 mutations (germline and/or somatic) and a high-risk profile.

On the basis of this sub-population from the AMPLITUDE study, data are therefore available only for a subset of the total patient population covered by the present therapeutic indication. In this respect, the sub-population from the AMPLITUDE study is distinguished from the rest of the patient population by the clinically relevant "newly diagnosed" and "high-risk profile" characteristics. Against this background, the relevant sub-populations within the scope of this therapeutic indication are considered separately in the assessment of the additional benefit.

a) Adult patients with newly diagnosed metastatic hormone-sensitive prostate cancer (mHSPC) with BRCA 1/2 mutations (germline and/or somatic) and a high-risk profile

Results on mortality, morbidity, health-related quality of life and side effects are available for the sub-population from the AMPLITUDE study comparing niraparib/ abiraterone acetate in combination with placebo, prednisone and ADT against abiraterone acetate in combination with prednisone and ADT.

For the endpoint of overall survival, there was no statistically significant difference between the treatment groups.

For the composite endpoint "symptomatic progression", which includes various clinically relevant events based on symptoms, there was an overall improvement, and thus an advantage of niraparib/ abiraterone acetate in combination with prednisone and ADT compared with abiraterone acetate in combination with prednisone and ADT. However, uncertainties regarding the inclusion of the subcomponent of "death from any cause" remain. Taking into account the total number of events, the absolute difference between the treatment groups and the number of events in the respective individual components, the results for the endpoint of symptomatic progression are rated as a relevant, yet minor, improvement, based on the available data.

Treatment with niraparib/ abiraterone acetate in combination with prednisone and ADT had neither positive nor negative effects on health-related quality of life.

With regard to side effects, there was a significant disadvantage of treatment with niraparib/ abiraterone acetate in combination with prednisone and ADT, substantiated by a marked increase in SAEs and severe AEs (CTCAE grade ≥ 3). With regard to the specific AEs, detailed analysis showed a marked increase in severe anaemia and severe hypertension cases.

In the overall analysis, the improvement in the morbidity endpoint "symptomatic progression", which is rated as a relevant, yet minor, improvement, based on the available

data, is offset by significant disadvantages in terms of side effects. In a weighted decision, the G-BA concluded that an additional benefit of niraparib/ abiraterone acetate in combination with prednisone or prednisolone and ADT compared with abiraterone acetate in combination with prednisone or prednisolone and ADT is not proven.

b) Adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations who are not newly diagnosed and/or do not have a high-risk profile

No data are available for the group of patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations who are not newly diagnosed and/or do not have a high-risk profile. An additional benefit of niraparib/ abiraterone acetate in combination with prednisone or prednisolone and ADT is therefore not proven.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the medicinal product "Akeega" with the active ingredient niraparib/abiraterone acetate. Akeega has been approved for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations (germline and/or somatic) in combination with androgen deprivation therapy (ADT).

The G-BA determined the appropriate comparator therapy to be a treatment – in each case in combination with ADT – with

- apalutamide *or*
- enzalutamide *or*
- abiraterone acetate in combination with prednisone or prednisolone (only for patients with newly diagnosed, high-risk prostate cancer) *or*
- darolutamide in combination with docetaxel.

The pharmaceutical company presented the randomised, controlled AMPLITUDE study, which compared niraparib/abiraterone acetate in combination with placebo, prednisone and ADT against the combination of placebo, abiraterone acetate, prednisone and ADT.

The AMPLITUDE study population comprises patients with mHSPC who have BRCA 1/2 mutations (germline and/or somatic). Given the approved therapeutic indication for niraparib/abiraterone acetate in combination with prednisone and ADT, and the selection of abiraterone acetate in combination with prednisone and ADT as the comparator therapy, the pharmaceutical company identified a corresponding sub-population from the AMPLITUDE study: Patients with newly diagnosed mHSPC who have BRCA 1/2 mutations (germline and/or somatic) and a high-risk profile. On the basis of this sub-population from the AMPLITUDE study, data are therefore available only for a subset of the total patient population covered by the present therapeutic indication.

The G-BA therefore carried out a separate assessment of the additional benefit for patients with newly diagnosed mHSPC with BRCA 1/2 mutations (germline and/or somatic) and a high-risk profile, and patients with mHSPC and BRCA 1/2 mutations who are not newly diagnosed and/or do not have a high-risk profile:

Adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) with BRCA 1/2 mutations (germline and/or somatic)

a) Adult patients with newly diagnosed metastatic hormone-sensitive prostate cancer (mHSPC) with BRCA 1/2 mutations (germline and/or somatic) and a high-risk profile

and

b) Adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations who are not newly diagnosed and/or do not have a high-risk profile

On a)

In the endpoint category of mortality, there was no statistically significant difference between the treatment groups.

For the endpoint "symptomatic progression", there was an overall improvement, and thus an advantage of niraparib/ abiraterone acetate in combination with prednisone and ADT compared with abiraterone acetate in combination with prednisone and ADT. However, uncertainties regarding the inclusion of the subcomponent of "death from any cause" remain. The results for the endpoint of symptomatic progression are rated as a relevant, yet minor, improvement.

Treatment with niraparib/ abiraterone acetate in combination with prednisone and ADT had neither positive nor negative effects on health-related quality of life.

With regard to side effects, there was a significant disadvantage of treatment with niraparib/ abiraterone acetate in combination with prednisone and ADT, substantiated by a marked increase in SAEs and severe AEs (CTCAE grade ≥ 3). With regard to the specific AEs, detailed analysis showed a marked increase in severe anaemia and severe hypertension cases.

In the overall analysis, the improvement in the morbidity endpoint "symptomatic progression" is offset by significant disadvantages in terms of side effects. In a weighted decision, the G-BA concluded that an additional benefit of niraparib/ abiraterone acetate in combination with prednisone or prednisolone and ADT compared with abiraterone acetate in combination with prednisone or prednisolone and ADT is not proven.

On b)

No data are available for the group of patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations who are not newly diagnosed and/or do not have a high-risk profile. An additional benefit of niraparib/ abiraterone acetate in combination with prednisone or prednisolone and ADT is therefore not proven.

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 base their resolution on the patient numbers from the dossier submitted by the pharmaceutical company. These are subject to uncertainties. Overall, it is assumed that the patient numbers are an underestimate, as, on the one hand, they do not take into account patients from previous years with mHSPC who are eligible for treatment in the analysis year. On the other, due to the short observation period of 6 weeks after the start of ADT, patients who only develop metastasis after this period following ADT are neglected.

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 Akeega (active ingredient: niraparib/ abiraterone acetate) at the following publicly accessible link (last access: 25 August 2026):

https://www.ema.europa.eu/en/documents/product-information/akeega-epar-product-information_en.pdf

Treatment with niraparib/ abiraterone acetate should only be initiated and monitored by specialists in internal medicine, haematology, oncology and urology who are experienced in the treatment of patients with prostate cancer, and other doctors from other specialist groups participating in the Oncology Agreement.

Medicinal castration with a GnRH agonist or antagonist should be continued during the treatment of patients who have not been surgically castrated.

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 July 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

Treatment period:

The costs for the first year of treatment are shown for the cost representation in the resolution.

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 different from patient to patient 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.

Orchiectomy

The costs of an orchiectomy are calculated on the basis of the case flat fee revenues, which result from the valuation ratios of the respective DRG multiplied by the federal base rate value of 2026 (€ 4,570.64). Furthermore, the nursing revenue is included in the inpatient costs. This is calculated from the average length of stay of the concerned DRG multiplied by the nursing fee Section 15 para. 2a KHEntgG (Act on Fees for Full and Semi-inpatient Hospital Services) (€ 250) and the treatment-specific nursing revenue valuation ratio.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed:				
Niraparib/ abiraterone acetate in combination with prednisone or prednisolone and ADT				
Niraparib/ abiraterone acetate	Continuously, 2 x daily	365	1	365
Prednisone	Continuously, 1 x daily	365	1	365
Prednisolone	Continuously, 1 x daily	365	1	365
ADT				
Buserelin	Continuously, every 3 months	4	1	4
Goserelin	Continuously, every 3 months	4	1	4
Leuprorelin	Continuously, every 3 months	4	1	4
Triptorelin	Continuously, every 6 months	2	1	2

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Degarelix	Continuously, 1 x monthly	12	1	12
Relugolix	Continuously, 1 x daily	365	1	365
Orchiectomy	Once		4.0 (average length of stay)	
Appropriate comparator therapy				
Conventional androgen deprivation in combination with apalutamide				
ADT				
Buserelin	Continuously, every 3 months	4	1	4
Goserelin	Continuously, every 3 months	4	1	4
Leuprorelin	Continuously, every 3 months	4	1	4
Triptorelin	Continuously, every 6 months	2	1	2
Degarelix	Continuously, 1 x monthly	12	1	12
Relugolix	Continuously, 1 x daily	365	1	365
Orchiectomy	Once		4.0 (average length of stay)	
Apalutamide	Continuously, 1 x daily	365	1	365
Conventional androgen deprivation in combination with enzalutamide				
ADT				
Buserelin	Continuously, every 3 months	4	1	4
Goserelin	Continuously, every 3 months	4	1	4
Leuprorelin	Continuously, every 3 months	4	1	4
Triptorelin	Continuously, every 6 months	2	1	2
Degarelix	Continuously, 1 x monthly	12	1	12
Relugolix	Continuously, 1 x daily	365	1	365

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Orchiectomy	Once		4.0 (average length of stay)	
Enzalutamide	Continuously, 1 x daily	365	1	365
Conventional androgen deprivation in combination with abiraterone acetate and prednisone or prednisolone				
<i>ADT</i>				
Buserelin	Continuously, every 3 months	4	1	4
Goserelin	Continuously, every 3 months	4	1	4
Leuprorelin	Continuously, every 3 months	4	1	4
Triptorelin	Continuously, every 6 months	2	1	2
Degarelix	Continuously, 1 x monthly	12	1	12
Relugolix	Continuously, 1 x daily	365	1	365
Orchiectomy	Once		4.0 (average length of stay)	
Abiraterone acetate	Continuously, 1 x daily	365	1	365
Prednisone	Continuously, 1 x daily	365	1	365
Prednisolone	Continuously, 1 x daily	365	1	365
Conventional androgen deprivation in combination with darolutamide and docetaxel				
<i>ADT</i>				
Buserelin	Continuously, every 3 months	4	1	4
Goserelin	Continuously, every 3 months	4	1	4
Leuprorelin	Continuously, every 3 months	4	1	4
Triptorelin	Continuously, every 6 months	2	1	2
Degarelix	Continuously, 1 x monthly	12	1	12
Relugolix	Continuously,	365	1	365

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
	1 x daily			
Orchiectomy	Once		4.0 (average length of stay)	
Darolutamide	Continuously, 2 x daily	365	1	365
Docetaxel	1 x every 21 days	6	1	6
If applicable, prednisone	2 x daily	6	21	126
If applicable, prednisolone	2 x daily	6	21	126

Consumption:

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements of adult males from the official representative statistics "2025 Microcensus – body measurements of the population" were applied (average body height: 1.79 m; average body weight: 86.5 kg)¹.

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed:					
Niraparib/ abiraterone acetate in combination with prednisone or prednisolone and ADT					
Niraparib/ abiraterone acetate	100 mg/ 500 mg	200 mg/ 1,000 mg	2 x 100 mg/ 1,000 mg	365	730 x 100 mg/ 1,000 mg
Prednisone	5 mg	5 mg	1 x 5 mg	365	365 x 5 mg
Prednisolone	5 mg	5 mg	1 x 5 mg	365	365 x 5 mg
<i>ADT</i>					
Buserelin	9.45 mg	9.45 mg	1 x 9.45 mg	4	4 x 9.45 mg
Goserelin	10.8 mg	10.8 mg	1 x 10.8 mg	4	4 x 10.8 mg
Leuprorelin	11.25 mg	11.25 mg	1 x 11.25 mg	4	4 x 11.25 mg
Triptorelin	22.5 mg	22.5 mg	1 x 22.5 mg	2	2 x 22.5 mg
Degarelix	80 mg	80 mg	1 x 80 mg	12	12 x 80 mg

¹ Federal Health Reporting. Average body measurements of the population (2025, both sexes), www.gbe-bund.de

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Relugolix	120 mg	120 mg	1 x 120 mg	365	365 x 120 mg
Orchiectomy	One-off intervention				
Appropriate comparator therapy					
Conventional androgen deprivation in combination with apalutamide					
ADT					
Buserelin	9.45 mg	9.45 mg	1 x 9.45 mg	4	4 x 9.45 mg
Goserelin	10.8 mg	10.8 mg	1 x 10.8 mg	4	4 x 10.8 mg
Leuprorelin	11.25 mg	11.25 mg	1 x 11.25 mg	4	4 x 11.25 mg
Triptorelin	22.5 mg	22.5 mg	1 x 22.5 mg	2	2 x 22.5 mg
Degarelix	80 mg	80 mg	1 x 80 mg	12	12 x 80 mg
Relugolix	120 mg	120 mg	1 x 120 mg	365	365 x 120 mg
Orchiectomy	One-off intervention				
Apalutamide	240 mg	240 mg	1 x 240 mg	365	365 x 240 mg
Conventional androgen deprivation in combination with enzalutamide					
ADT					
Buserelin	9.45 mg	9.45 mg	1 x 9.45 mg	4	4 x 9.45 mg
Goserelin	10.8 mg	10.8 mg	1 x 10.8 mg	4	4 x 10.8 mg
Leuprorelin	11.25 mg	11.25 mg	1 x 11.25 mg	4	4 x 11.25 mg
Triptorelin	22.5 mg	22.5 mg	1 x 22.5 mg	2	2 x 22.5 mg
Degarelix	80 mg	80 mg	1 x 80 mg	12	12 x 80 mg
Relugolix	120 mg	120 mg	1 x 120 mg	365	365 x 120 mg
Orchiectomy	One-off intervention				
Enzalutamide	160 mg	160 mg	4 x 40 mg	365	1,460 x 40 mg
Conventional androgen deprivation in combination with abiraterone acetate and prednisone or prednisolone					
ADT					
Buserelin	9.45 mg	9.45 mg	1 x 9.45 mg	4	4 x 9.45 mg
Goserelin	10.8 mg	10.8 mg	1 x 10.8 mg	4	4 x 10.8 mg
Leuprorelin	11.25 mg	11.25 mg	1 x 11.25 mg	4	4 x 11.25 mg
Triptorelin	22.5 mg	22.5 mg	1 x 22.5 mg	2	2 x 22.5 mg

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Degarelix	80 mg	80 mg	1 x 80 mg	12	12 x 80 mg
Relugolix	120 mg	120 mg	1 x 120 mg	365	365 x 120 mg
Orchiectomy	One-off intervention				
Abiraterone acetate	1,000 mg	1,000 mg	1 x 1,000 mg	365	365 x 1,000 mg
Prednisone	5 mg	5 mg	1 x 5 mg	365	365 x 5 mg
Prednisolone	5 mg	5 mg	1 x 5 mg	365	365 x 5 mg
Conventional androgen deprivation in combination with darolutamide and docetaxel					
<i>ADT</i>					
Buserelin	9.45 mg	9.45 mg	1 x 9.45 mg	4	4 x 9.45 mg
Goserelin	10.8 mg	10.8 mg	1 x 10.8 mg	4	4 x 10.8 mg
Leuprorelin	11.25 mg	11.25 mg	1 x 11.25 mg	4	4 x 11.25 mg
Triptorelin	22.5 mg	22.5 mg	1 x 22.5 mg	2	2 x 22.5 mg
Degarelix	80 mg	80 mg	1 x 80 mg	12	12 x 80 mg
Relugolix	120 mg	120 mg	1 x 120 mg	365	365 x 120 mg
Orchiectomy	One-off intervention				
Darolutamide	600 mg	1,200 mg	4 x 300 mg	365	1,460 x 300 mg
Docetaxel	75 mg/m ² = 154.5 mg	154.5 mg	1 x 160 mg	6	6 x 160 mg
If applicable, prednisone	5 mg	10 mg	2 x 5 mg	126	252 x 5 mg
If applicable, prednisolone	5 mg	10 mg	2 x 5 mg	126	252 x 5 mg

Costs:

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 Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

Inpatient costs

Calculation year	DRG	Average length of stay [d]	DRG valuation ratio (main department)	Federal case value	Nursing revenue valuation ratio	Nursing fee	Case flat fee revenue	Nursing revenue	Total case flat fee revenue and nursing revenue
Orchiectomy									
2026	M04B	4	0.872	€ 4,570.64	0.8243	€ 250	€ 3,985.60	€ 824.30	€ 4,809.90

Costs of the medicinal products:

Designation of the 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/ abiraterone acetate in combination with prednisone or prednisolone and ADT					
Niraparib/ abiraterone acetate 100 mg/ 500 mg	56 FCT	€ 4,597.17	€ 1.77	€ 0.00	€ 4,595.40
Buserelin 9.45 mg	2 PS	€ 1,294.28	€ 1.77	€ 70.99	€ 1,221.52
Degarelix 80 mg	3 PSI	€ 605.42	€ 1.77	€ 32.85	€ 570.80
Goserelin 10.8 mg	2 IMP	€ 1,298.64	€ 1.77	€ 71.24	€ 1,225.63
Leuprorelin 11.25 mg	2 IMP	€ 731.55	€ 1.77	€ 86.93	€ 642.85
Prednisolone 5 mg ²	100 TAB	€ 16.21	€ 1.77	€ 0.33	€ 14.11
Prednisone 5 mg ²	100 TAB	€ 17.52	€ 1.77	€ 0.43	€ 15.32
Relugolix 120 mg	95 FCT	€ 573.13	€ 1.77	€ 31.06	€ 540.30
Triptorelin 22.5 mg	1 DSS	€ 1,188.75	€ 1.77	€ 65.15	€ 1,121.83
Appropriate comparator therapy					
Abiraterone acetate 1,000 mg ²	28 FCT	€ 136.87	€ 1.77	€ 9.87	€ 125.23
Apalutamide 240 mg	28 FCT	€ 2,684.84	€ 1.77	€ 0.00	€ 2,683.07
Buserelin 9.45 mg	2 PS	€ 1,294.28	€ 1.77	€ 70.99	€ 1,221.52
Darolutamide 300 mg	112 FCT	€ 3,527.16	€ 1.77	€ 0.00	€ 3,525.39
Degarelix 80 mg	3 PSI	€ 605.42	€ 1.77	€ 32.85	€ 570.80
Docetaxel 160 mg	1 CIS	€ 516.56	€ 1.77	€ 23.94	€ 490.85
Enzalutamide 40 mg	112 FCT	€ 3,123.98	€ 1.77	€ 0.00	€ 3,122.21
Goserelin 10.8 mg	2 IMP	€ 1,298.64	€ 1.77	€ 71.24	€ 1,225.63
Leuprorelin 11.25 mg	2 IMP	€ 731.55	€ 1.77	€ 86.93	€ 642.85
Prednisone 5 mg ²	100 TAB	€ 16.21	€ 1.77	€ 0.33	€ 14.11
Prednisolone 5 mg ²	100 TAB	€ 17.52	€ 1.77	€ 0.43	€ 15.32

² Fixed reimbursement rate

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Relugolix 120 mg	95 FCT	€ 573.13	€ 1.77	€ 31.06	€ 540.30
Triptorelin 22.5 mg	1 DSS	€ 1,188.75	€ 1.77	€ 65.15	€ 1,121.83
Abbreviations: FCT = film-coated tablets; PS = prefilled syringes; CIS = concentrate for the preparation of an infusion solution; IMP = implant; DSS = dry substance with solvent; PSI = powder and solvent for solution for injection; TAB = tablets					

LAUER-TAXE® last revised: 1 July 2026

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 01.10.2009 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 the currently valid version of the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe), surcharges for the production of parenteral preparations containing cytostatic agents a maximum amount of € 100 per ready-to-use preparation, and for the production of parenteral solutions containing monoclonal antibodies a maximum of € 100 per ready-to-apply unit are to be payable. These additional other costs are not added to the pharmacy sales price but rather follow the rules for calculating in the 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 purchase 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 Hilfstaxe.

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

At their session on 12 August 2025, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 13 March 2026, the pharmaceutical company submitted a dossier for the benefit assessment of niraparib/ abiraterone acetate to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

By letter dated 13 March 2026 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit 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/ abiraterone acetate.

The dossier assessment by the IQWiG was submitted to the G-BA on 10 June 2026, and the written statement procedure was initiated with publication on the G-BA website on 15 June 2026. The deadline for submitting written statements was 6 July 2026.

The oral hearing was held on 27 July 2026.

By letter dated 28 July 2026, the IQWiG was commissioned with a supplementary assessment of data submitted in the written statement procedure. The addendum prepared by the IQWiG was submitted to the G-BA on 14 August 2026.

On 28 July 2026, the IQWiG submitted a new version of IQWiG's dossier assessment to the G-BA. This version 1.1, dated 23 July 2026, replaces version 1.0 of the dossier assessment dated 10 June 2026. The assessment result was not affected by the changes in version 1.1 compared to version 1.0.

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 Subcommittee's session on 25 August 2026, and deliberation of the draft resolution was concluded.

At their session on 3 September 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	12 August 2025	Determination of the appropriate comparator therapy
Working group Section 35a	14 July 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	27 July 2026	Conduct of the oral hearing, commissioning of the IQWiG with the supplementary assessment of documents
Working group Section 35a	4 August 2026 18 August 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	25 August 2026	Concluding discussion of the draft resolution
Plenum	3 September 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 3 September 2026

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

Dr Optendrenk