Gemeinsamer Bundesausschuss

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

Asciminib (new therapeutic indication: chronic myeloid leukaemia, Ph+, chronic phase)

From 21 May 2026

Contents

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 active ingredient asciminib (Scemblix) was listed for the first time on 1 October 2022 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

Asciminib is approved as a medicinal product for the treatment of rare diseases under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999.

Within the previously approved therapeutic indication, the sales volume of asciminib with the statutory health insurance at pharmacy sales prices, including value-added tax exceeded € 30 million. Evidence must therefore be provided for asciminib in accordance with Section 5, paragraph 1 through 6 VerfO, and the additional benefit compared with the appropriate comparator therapy must be demonstrated.

A benefit assessment of asciminib has already been conducted according to Section 35 a SGB V in the therapeutic indication: "Treatment of adult patients with Philadelphia chromosome-

positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) previously treated with two or more tyrosine kinase inhibitors" and, in this regard, an amendment to Annex XII was made by resolution of 20 November 2025 (benefit assessment procedure for the active ingredient asciminib (reassessment of orphan drug > 30 million: chronic myeloid leukaemia, Ph+, following ≥ 2 prior therapies)). This therapeutic indication is not covered by the present benefit assessment. The present benefit assessment refers exclusively to those indications that have been added as a result of the marketing authorisation of the new therapeutic indication.

On 17 November 2025, asciminib 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 28 November 2025, 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 due time 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 asciminib with the new therapeutic indications "Treatment of adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) and for the treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a tyrosine kinase inhibitor.".

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 2 March 2026 on the G-BA website (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 asciminib compared with the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, and the statements submitted in the written statement and oral hearing procedure, as well of the addendum drawn up by the IQWiG on the benefit assessment. 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 the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of asciminib.

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

[1] General Methods, version 8.0 from 19.12.2025. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

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

2.1.1 Approved therapeutic indication of Asciminib (Scemblix) in accordance with the product information

Scemblix is indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP).

Therapeutic indication of the resolution (resolution of 21.05.2026):

Treatment of adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP).

Treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a tyrosine kinase inhibitor.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

Appropriate comparator therapy for asciminib:

- imatinib
  or
- nilotinib
  or
- dasatinib
  or
- bosutinib

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

Appropriate comparator therapy for asciminib:

An individualised therapy with selection of

- nilotinib,
- dasatinib,
- bosutinib and
- ponatinib

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 in 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 in 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.

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

On 1. The cytotoxic chemotherapies busulfan, cyclophosphamide, hydroxycarbamide and mitoxantrone as well as the tyrosine kinase inhibitors (TKI) bosutinib, ponatinib, dasatinib, imatinib und nilotinib are approved for the present therapeutic indication.

On 2. Non-medicinal treatment is not an option for newly diagnosed patients.

In principle, allogeneic stem cell transplantation is considered as non-medicinal treatment in the therapeutic indication for patients who have received TKI

pretreatment. For this therapeutic indication, it is assumed that patients are initially treated with BCR-ABL-TKIs as part of a remission-inducing therapy. Allogeneic stem cell transplantation can only be considered for some patients once they have achieved remission, and is therefore not part of the appropriate comparator therapy.

On 3. For the present therapeutic indication of asciminib, the following resolutions of the G-BA on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V are available:

- Asciminib (resolution of 20 November 2025; 3rd line)
- Bosutinib (resolution of 19 November 2021; newly diagnosed CML)
- Ponatinib (resolution of 20 November 2020; 2nd line)
- Bosutinib (resolution of 21 February 2019; 2nd line)

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"). A written statement from the Drugs Commission of the German Medical Association (AkdÄ) is available.

There are different therapy recommendations for patients with newly diagnosed Ph+ CML-CP and for patients who have previously been treated with a TKI. The G-BA therefore consider the formation of two distinct patient groups to be necessary for the determination of the appropriate comparator therapy.

On patient group a)

Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

Among the approved active ingredients listed under 1.), only certain active ingredients named below will be included in the appropriate comparator therapy, taking into account the evidence on therapeutic benefit, the guideline recommendations and the reality of care.

These guidelines as well as the written statement from the AkdÄ recommend the TKIs imatinib, dasatinib, nilotinib and bosutinib for the first-line treatment of Ph+ CML in chronic phase. While imatinib as the first representative of TKIs for the treatment of Ph+ CML in chronic phase is referred to as a TKI of the first generation, nilotinib, dasatinib and bosutinib are classified as TKIs of the second generation. The TKIs for first-line treatment should be selected on the basis of the range of side effects, taking risk factors and comorbidities into account.

With regard to the relative significance of TKIs, it can be inferred from the systematic review by Zhang et al.[2] that second-generation TKIs showed statistically significant

[2] Zhang JJ, Qian YL, Wu ZY, Li Y, Guan YJ, Sun C, et al. Comparative efficacy and safety of first-line tyrosine kinase inhibitors in chronic myeloid leukemia: a systematic review and network meta-analysis. Transl Cancer Res 2024;13(7):3783-3797.

advantages over imatinib in terms of molecular response. On the other hand, however, there were disadvantages in terms of adverse events and differing profiles of side effects associated with second-generation TKIs. To date, an advantage of one or more TKIs in terms of overall survival could not be demonstrated, a point also highlighted by the AkdÄ in their written statement. Current guidelines also highlight that large randomised phase III studies comparing imatinib with second-generation TKIs have shown similar results for the active ingredients mentioned.

Overall, there is no evidence that adequately demonstrates the significance of one of these TKIs.

Hydroxycarbamide is used exclusively in initial or palliative cytoreductive therapy. Hydroxycarbamide is therefore not considered to be an appropriate comparator therapy.

In the overall analysis, imatinib, nilotinib, dasatinib and bosutinib are considered to be equally appropriate therapy options for newly diagnosed patients in the present therapeutic indication.

On patient group b)

Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

According to the guidelines listed in the evidence synopsis and taking into account the authorisation status of the medicinal products, patients with Ph+ CML in chronic phase who have already been treated with a TKI may be treated with an alternative TKI or allogeneic stem cell transplantation, depending on their prior therapy, comorbidities and mutational status. In this regard, the TKIs imatinib, nilotinib, dasatinib, bosutinib and ponatinib may be considered. Once remission has been achieved, allogeneic stem cell transplantation may be considered for some patients. Allogeneic stem cell transplantation is not determined as a component of the appropriate comparator therapy since it is assumed with regard to the present therapeutic indication that the primary therapeutic goal is initially to achieve remission and that allogeneic stem cell transplantation is only considered for some of the patients who have achieved remission.

Patients with CP-CML who received second-generation TKIs as the first line of treatment but had to discontinue them due to toxicity may switch to imatinib among other TKIs as the second line of treatment. However, it is to be assumed that this only concerns very few patients in the therapeutic indication in the healthcare. Therefore, imatinib assumes minor significance in the second line of treatment and is not considered a treatment option in the appropriate comparator therapy for patients pretreated with a TKI.

The available evidence suggests that it is not possible - on the basis of patient-individual criteria - to derive a treatment option that is suitable for the entire patient population in the second line of treatment. The treatment decision is made, taking into account prior therapy, comorbidities and mutational status.

The G-BA therefore determine the appropriate comparator therapy to be an individualised therapy with selection of nilotinib, dasatinib, bosutinib and ponatinib, taking into account prior therapies, comorbidities and mutational status.

The relevant 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 asciminib is assessed as follows:

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

Hint for a considerable additional benefit

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

An additional benefit is not proven.

Justification:

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

For the benefit assessment relating to patient group a), the pharmaceutical company presented the results of the ASC4FIRST and ASC4START studies, which they summarised using meta-analysis based on patient-individual data. Both studies are ongoing, open-label, randomised controlled trials (RCTs) designed to investigate the efficacy and safety of asciminib in patients with newly diagnosed CML in chronic phase.

ASC4FIRST study

A total of 116 study sites across Europe, Asia, North America and Australia are involved in the ASC4FIRST study, which has been ongoing since October 2021.

A total of 405 patients with newly diagnosed CML in chronic phase, with a typical BCR-ABL1 transcript and an Eastern Cooperative Oncology Group Performance Status (ECOG-PS) of 0-1 were enrolled. Patients randomised to the comparator arm receive a TKI (imatinib, nilotinib, dasatinib or bosutinib) selected by the medical investigators. As bosutinib was not yet part of the appropriate comparator therapy at the time the benefit assessment dossier was prepared, the pharmaceutical company presented analyses in the dossier from which they excluded those patients who had been assigned to treatment with bosutinib prior to randomisation. As part of the written statement procedure, they presented analyses, taking these patients into account. These analyses are used for the benefit assessment.

The primary endpoint of the ASC4FIRST study is major molecular response (MMR) at week 48. Secondary endpoints are overall survival as well as endpoints in the categories of morbidity, health-related quality of life and side effects.

The results for the 2nd data cut-off from 22.10.2024 were used for the benefit assessment.

ASC4START study

A total of 120 study sites across Europe, Asia, South Africa as well as North and South America are involved in the ASC4START study, which has been ongoing since November 2022.

A total of 568 patients with newly diagnosed CML in chronic phase, with a typical BCR-ABL1 transcript and an ECOG-PS of 0 or 1, were enrolled. Nilotinib was used in the comparator arm of the ASC4START study.

The primary endpoint of the ASC4START study is therapy discontinuation due to adverse events. Secondary endpoints are overall survival as well as endpoints in the categories of morbidity, health-related quality of life and side effects.

The results for the 2nd data cut-off from 15.05.2025 were used for the benefit assessment.

Extent and probability of the additional benefit

Mortality

In the ASC4FIRST and ASC4START studies, overall survival is operationalised as the time period between randomisation and death from any cause.

For the endpoint of overall survival, neither the individual studies nor the meta-analysis of the ASC4FIRST and ASC4START studies showed any statistically significant difference between the treatment arms.

Morbidity

Progression to blast phase

In the ASC4FIRST and ASC4START studies, the endpoint "progression to blast phase" is operationalised as the time period between randomisation and the first occurrence of progression to blast phase, defined as ≥ 30% blasts in peripheral blood or bone marrow aspirate. Alternatively, a blast phase could be defined by biopsy as evidence of extramedullary involvement (excluding hepatosplenomegaly).

For the endpoint "progression to blast phase", neither the individual studies nor the meta-analysis showed any statistically significant difference between the treatment arms.

Major molecular response (MMR)

Major molecular response at week 48 is the primary endpoint of the ASC4FIRST study. Analyses are available for a sub-population, excluding patients who were assigned to treatment with bosutinib prior to randomisation.

The endpoint is based on the molecular genetic determination of BCR-ABL transcripts in peripheral blood and, thus, on haematological findings that are not directly relevant to the patient.

In clinical practice, the MMR represents a relevant prognostic factor and parameter for therapy planning.

As part of the written statement procedure, the clinical experts pointed out the importance of the MMR endpoint for therapy management, and the endpoint was assessed during the oral hearing as a suitable surrogate parameter for overall survival.

However, a validation of the MMR as a surrogate parameter for overall survival is not available. The MMR endpoint is neither assessed as a directly patient-relevant endpoint nor as a validated surrogate endpoint, and is therefore not used for the present assessment.

An overview of patient-reported endpoints

With regard to patient-reported endpoints on symptomatology and quality of life, each assessed using the EORTC QLQ-C30 and EORTC QLQ-CML24 as well as on health status, assessed using the EQ-5D visual analogue scale, a high percentage of patients were excluded from the analysis due to the absence of baseline values at the time of randomisation. In the ASC4FIRST study, a baseline value at randomisation for the patient-reported endpoints was available for only 54 – 56% of patients in the intervention arm and for only 53 – 56% of patients in the control arm. In the ASC4START study, a baseline value at randomisation was available for only 57 – 59% of patients in the intervention arm and for only 55 – 58% of patients in the control arm.

Against this background, the pharmaceutical company presented sensitivity analyses to investigate the reliability of results from the meta-analytic analysis of the ASC4FIRST and ASC4START studies with regard to patient-reported endpoints. In this benefit assessment, a statistically significant effect in the primary analysis was only used to derive an additional benefit if it was confirmed by both sensitivity analyses presented. If a statistically significant difference in the primary analysis was not confirmed by both sensitivity analyses, the results of the sensitivity analyses are presented.

Symptomatology

With regard to symptomatology, the meta-analysis presented showed statistically significant differences in favour of asciminib in the time to first deterioration on the EORTC QLQ-C30 symptom scales for fatigue, nausea and vomiting, as well as constipation, and in the time to first deterioration of disease-specific symptomatology, as assessed using the EORTC QLQ-CML24.

Health status

The health status endpoint was assessed exclusively in the ASC4FIRST study using the EQ-5D visual analogue scale. The primary analysis showed a statistically significant difference to the advantage of asciminib; however, this was not confirmed by both sensitivity analyses presented.

For the endpoint category of morbidity, an overall advantage of asciminib compared with the appropriate comparator therapy was therefore observed; this advantage is based on the positive effects of asciminib on the symptoms of fatigue, nausea and vomiting, as well as constipation and disease-specific symptomatology.

Quality of life

With regard to health-related quality of life, the meta-analysis of the ASC4FIRST and ASC4START studies showed a statistically significant advantage in favour of asciminib in terms of the time to first deterioration in social functioning, as assessed using the EORTC QLQ-C30, and in terms of the impact on daily life, as assessed using the EORTC QLQ-CML24.

An advantage of asciminib in terms of health-related quality of life can therefore be identified.

Side effects

Adverse events (AEs)

In the ASC4FIRST study, at least one adverse event occurred in 95.9% of patients in the intervention arm and 98.0% of patients in the comparator arm overall. In the ASC4START study, the overall rate of AEs was 87.7% in the intervention arm and 91.1% in the comparator arm. The results for the "adverse events" endpoint are presented additionally.

Serious adverse events (SAEs)

With regard to serious adverse events, the meta-analysis of the ASC4FIRST and ASC4START studies showed no statistically significant difference between the treatment arms.

Severe AEs (CTCAE grade ≥ 3), therapy discontinuations due to AEs

For the endpoints of severe AEs and therapy discontinuation due to AEs, the meta-analysis of the ASC4FIRST and ASC4START studies showed statistically significant differences to the advantage of asciminib.

Specific AEs

A detailed analysis of the severe AEs showed a statistically significant difference to the disadvantage of asciminib in the "vascular disorders" system organ class.

PRO-CTCAE

In the ASC4FIRST study, nine specific symptomatic AEs were also collected using the PRO-CTCAE tool. In the ASC4START study, two further symptomatic AEs were also collected.

The pharmaceutical company's approach to selecting the AEs is considered inappropriate overall to ensure that the side effects of asciminib, imatinib, nilotinib, dasatinib and bosutinib are shown with adequate certainty. Furthermore, it is unclear why additional symptomatic AEs were collected only in the ASC4START study.

Overall, the PRO-CTCAE endpoint is not used for the benefit assessment due to the reasons outlined above.

For the endpoint category of side effects, an overall improvement can be observed for asciminib compared with the appropriate comparator therapy; this improvement is based on the positive effects observed in terms of severe AEs and discontinuation due to AEs.

Overall assessment

For the assessment of the additional benefit of asciminib for the treatment of adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), the pharmaceutical company presented the results of a meta-analytic summary of the ASC4FIRST and ASC4START studies, which compared asciminib with other tyrosine kinase inhibitors (imatinib, nilotinib, dasatinib, bosutinib). Results on endpoints in the categories of mortality, morbidity, quality of life and side effects are available.

With regard to overall survival, there was no statistically significant difference between the treatment arms.

In the endpoint category of morbidity, advantages were observed for the endpoints of fatigue, nausea and vomiting as well as constipation, as assessed using the EORTC QLQ-C30. In addition, an advantage was observed in terms of disease-specific symptomatology, as assessed using the EORTC QLQ-CML24.

In the quality of life category, there was an advantage of asciminib due to improvements in social functioning, as assessed using the EORTC QLQ-C30, and in the impact on daily life, as assessed using the EORTC QLQ-CML24.

In the endpoint category of side effects, advantages of asciminib can be identified for the endpoints of severe AEs and therapy discontinuation due to AEs. Detailed analysis showed a disadvantage of asciminib in the system organ class of vascular disorders.

Overall analysis of the results on patient-relevant endpoints showed that asciminib led to a significant improvement in symptomatology, alongside a relevant improvement in quality of life and side effects.

As a result, a considerable additional benefit of asciminib over the appropriate comparator therapy for the treatment of adults with newly diagnosed Ph+ CML-CP is identified.

Reliability of data (probability of additional benefit)

This assessment is based on the meta-analytic analysis of the two open-label RCTs - ASC4FIRST and ASC4START. The risk of bias at the study level is rated as low.

Significant uncertainty is caused by the lack of blinding, which leads to a high risk of bias in patient-reported endpoints due to the subjective nature of the endpoint assessment, and in the endpoint of therapy discontinuation due to adverse events, due to the subjective decision on therapy discontinuation.

Further uncertainty regarding patient-reported endpoints is caused by the high percentage of patients excluded from the analysis due to missing baseline values at the time of randomisation, as well as by a declining return rate to questionnaires over the course of the study.

In principle, the percentage of patients included in the analyses would be too small to derive an additional benefit. The sensitivity analyses additionally presented by the pharmaceutical company nevertheless allow for an assessment of the direction and magnitude of any bias in an effect, which is why the patient-reported endpoints can be used to derive an additional benefit. The uncertainty is considered to be so relevant that

only a hint for the identified additional benefit can be derived, despite the availability of a meta-analysis.

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

For the benefit assessment relating to patient group b), the pharmaceutical company presented a literature research on pretreated patients in the dossier, with no restriction on the number of prior therapies, and identified no RCT involving patients who had received exactly one prior therapy. As part of the written statement procedure, the pharmaceutical company conducted a further systematic literature research on patients who had received exactly one prior therapy and identified the single-arm ASC2ESCALATE study. With regard to the appropriate comparator therapy, no literature research was presented as part of the written statement procedure to identify all potentially relevant investigations on the appropriate comparator therapy in the target population.

Furthermore, as part of the written statement procedure, the pharmaceutical company presented a descriptive comparison of data from studies involving newly diagnosed patients (first-line, ASC4FIRST and ASC4START studies), patients with exactly one pretreatment (second-line, ASC2ESCALATE study) and patients with at least two pretreatments (ASCEMBL study), on the basis of which they justify the transferability of the results on first-line treatment and subjects with at least two pretreatments to the second-line treatment setting. This comparison includes data on patient characteristics, the duration of exposure to asciminib, and results on selected endpoints.

A descriptive comparison of data on different lines of therapy is considered unsuitable for the assessment of the additional benefit of asciminib for patients who have received exactly one prior therapy.

An additional benefit of asciminib for adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), who have previously been treated with a TKI, 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 active ingredient asciminib.

The therapeutic indication assessed here covers adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), as well as adults with Ph+ CML-CP who have previously been treated with a tyrosine kinase inhibitor (TKI).

In the therapeutic indication to be considered, two patient groups were distinguished:

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy.

Patient group a)

The G-BA determined imatinib or nilotinib or dasatinib or bosutinib as the appropriate comparator therapy.

For this patient group, the pharmaceutical company presented a meta-analytical analysis of the open-label RCTs ASC4FIRST and ASC4START for the benefit assessment of asciminib.

With regard to overall survival, there was no statistically significant difference between the treatment arms.

In terms of the morbidity endpoints of fatigue, nausea and vomiting, constipation, as well as disease-specific symptomatology, an advantage of asciminib over the appropriate comparator therapy was observed overall. In addition, advantages of asciminib in the endpoints of social functioning and impact on daily life were observed.

Furthermore, advantages in the endpoints of severe adverse events and therapy discontinuation due to adverse events were observed. Detailed analysis showed a disadvantage in the system organ class of vascular disorders.

Uncertainty remains regarding patient-reported endpoints and the endpoint of therapy discontinuation due to adverse events due to the lack of blinding in the subjective endpoint assessment or the subjective decision on therapy discontinuation.

In the overall analysis, the G-BA identified a considerable additional benefit of asciminib, based on the significant improvement in symptomatology, alongside a relevant improvement in quality of life and side effects.

The reliability of data of the identified additional benefit is classified as a hint.

Patient group b)

The appropriate comparator therapy was determined to be an individualised therapy with selection of
nilotinib, dasatinib, bosutinib and ponatinib, taking into account previous therapies as well as comorbidities and mutational status.

For the benefit assessment, the pharmaceutical company presented a descriptive comparison of data from studies involving newly diagnosed patients, patients with exactly one pretreatment and patients with at least two pretreatments, on the basis of which they justify the transferability of the results on first-line treatment and subjects with at least two pretreatments to the second-line treatment setting. This comparison is considered unsuitable for the assessment of the additional benefit of asciminib for patients who have received exactly one prior therapy.

An additional benefit of asciminib for adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), who have previously been treated with a TKI, 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).

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

For newly diagnosed patients, the resolution is based on the information provided by the pharmaceutical company in the benefit assessment dossier. This information is subject to significant uncertainty. This uncertainty stems in particular from the data on the total number of new cases underlying the calculation, which is based on an analysis commissioned by the pharmaceutical company from the German Analysis Database for Evaluation and Healthcare Research (DADB) at Leipzig health forums. Compared with the patient numbers, which were most recently found in the resolution on the benefit assessment of bosutinib (resolution of 19 November 2021) and are based on data from the Centre for Cancer Registry Data at the Robert Koch Institute, the patient numbers submitted in the present procedure are significantly higher, and an overestimation must be assumed overall. Further uncertainty stems from the unclear timing of the start of treatment for some of the patients in the DADB analysis and the resulting allocation to a line of therapy.

Despite the uncertainties described, this resolution is based on the data from the pharmaceutical company's dossier in order to ensure a consistent data basis for the number of patients with newly diagnosed Ph+ CML-CP (patient group a) and patients who have received prior therapy (patient group b). For patient group b), there is no calculation of patient numbers based on anything other than the DADB analysis.

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

For the patient group that has received prior TKI therapy, the resolution is based on the IQWiG's calculation, which is based on the information provided by the pharmaceutical company in the dossier concerning patients with pretreated Ph^+ CML-CP, including those with the T315I mutation and without restriction to exactly one prior therapy. This represents the difference between the number of pretreated patients from the DADB analysis and the number of patients identified in the previous benefit assessment of asciminib for the treatment of patients who had previously been treated with ≥ 2 TKIs (resolution of 20 November 2025). The patient numbers for the second line of therapy presented by the pharmaceutical company as part of the written statement procedure are not regarded as a better estimate, as they were reduced by the percentage of pretreated patients with a T315I mutation.

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 Scemblix (active ingredient: asciminib) at the following publicly accessible link (last access: 9 February 2026):

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

Treatment with asciminib should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with chronic myeloid leukaemia.

2.4 Treatment costs

The treatment costs are based on the requirements in the product information and the information listed in the LAUER-TAXE® (last revised: 15 March 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

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.

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or comorbidities) are not taken into account when calculating the annual treatment costs.

Treatment period:

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Asciminib	Continuously, 1 – 2 x daily	365.0	1	365.0
Appropriate comparator therapy				
imatinib	Continuously, 1 x daily	365.0	1	365.0
nilotinib	Continuously, 2 x daily	365.0	1	365.0
dasatinib	Continuously, 1 x daily	365.0	1	365.0
bosutinib	Continuously, 1 x daily	365.0	1	365.0

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Asciminib	Continuously, 1 – 2 x daily	365.0	1	365.0
Appropriate comparator therapy				
An individualised therapy with selection of				
nilotinib	Continuously, 2 x daily	365.0	1	365.0
dasatinib	Continuously, 1 x daily	365.0	1	365.0
bosutinib	Continuously, 1 x daily	365.0	1	365.0
ponatinib	Continuously, 1 x daily	365.0	1	365.0

Consumption:

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

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					
Asciminib	40 mg – 80 mg	80 mg	2 x 40 mg	365.0	730 x 40 mg
Appropriate comparator therapy					
Imatinib	400 mg	400 mg	1 x 400 mg	365.0	365 x 400 mg
Nilotinib	300 mg	600 mg	4 x 150 mg	365.0	1,460 x 150 mg
Dasatinib	100 mg	100 mg	1 x 100 mg	365.0	365 x 100 mg
Bosutinib	400 mg	400 mg	4 x 100 mg	365.0	1,460 x 100 mg

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

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					
Asciminib	40 mg – 80 mg	80 mg	2 x 40 mg	365.0	730 x 40 mg
Appropriate comparator therapy					
An individualised therapy with selection of					
Nilotinib	400 mg	800 mg	4 x 200 mg	365.0	1,460 x 200 mg
Dasatinib	100 mg	100 mg	1 x 100 mg	365.0	365 x 100 mg
Bosutinib	500 mg	500 mg	5 x 100 mg	365.0	1,825 x 100 mg
Ponatinib	45 mg	45 mg	1 x 45 mg	365.0	365 x 45 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.

Costs of the medicinal products:

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

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					
Asciminib 40 mg	180 FCT	€ 15,780.78	€ 1.77	€ 897.95	€ 14,881.06
Appropriate comparator therapy					
Bosutinib 100 mg	28 FCT	€ 370.39	€ 1.77	€ 17.04	€ 351.58
Dasatinib 100 mg	30 FCT	€ 822.56	€ 1.77	€ 38.50	€ 782.29
Imatinib 400 mg[3]	90 FCT	€ 538.33	€ 1.77	€ 41.68	€ 494.88
Nilotinib 150 mg	112 HC	€ 2,294.56	€ 1.77	€ 109.50	€ 2,183.29
Nilotinib 200 mg	112 HC	€ 3,047.14	€ 1.77	€ 146.34	€ 2,899.03
Ponatinib 45 mg	30 FCT	€ 6,694.06	€ 1.77	€ 379.01	€ 6,313.28
Abbreviations: FCT = film-coated tablets; HC = hard capsules					

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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.

[3] Fixed reimbursement rate

2.5 Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

According to Section 35a, paragraph 3, sentence 4, the G-BA designate all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act.

Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

A designation is also not considered if the G-BA have decided on an exemption as a reserve antibiotic for the assessed medicinal product in accordance with Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the G-BA have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the G-BA. Due to the lack of an assessment mandate by the G-BA following the resolution on an exemption according to Section 35a, paragraph 1c, sentence 1 SGB V with regard to the extent of the additional benefit and the therapeutic significance of the reserve antibiotic to be assessed, there is a limitation due to the procedural privileging of the pharmaceutical companies to the effect that neither the proof of an existing nor an expected at least considerable additional benefit is possible for exempted reserve antibiotics in the procedures according to Section 35a paragraph 1 or 6 SGB V and Section 35a paragraph 1d SGB V. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V must therefore also be taken into account at the level of designation according to Section 35a, paragraph 3, sentence 4 SGB V in order to avoid valuation contradictions.

With regard to the further examination steps, a differentiation is made between a "determined" or "undetermined" combination, which may also be the basis for a designation.

A "determined combination" exists if one or more individual active ingredients which can be used in combination with the assessed medicinal product in the assessed therapeutic indication are specifically named.

An "undetermined combination" exists if there is information on a combination therapy, but no specific active ingredients are named. An undetermined combination may be present if the information on a combination therapy:

- names a product class or group from which some active ingredients not specified in detail can be used in combination therapy with the assessed medicinal product, or

- does not name any active ingredients, product classes or groups, but the assessed medicinal product is used in addition to a therapeutic indication described in more detail in the relevant product information, which, however, does not include data from the product information on active ingredients within the scope of this therapeutic indication.

Concomitant active ingredient

The concomitant active ingredient is a medicinal product with new active ingredients that can be used in combination therapy with the assessed medicinal product for the therapeutic indication to be assessed.

For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2 paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

Based on an "undetermined combination", the concomitant active ingredient must be attributable to the information on the product class or group or the therapeutic indication according to the product information of the assessed medicinal product in the assessed therapeutic indication, whereby the definition of a product class or group is based on the corresponding requirements in the product information of the assessed medicinal product.

In addition, there must be no reasons for exclusion of the concomitant active ingredient from a combination therapy with the assessed medicinal product, in particular no exclusive marketing authorisation as monotherapy.

In addition, all sections of the currently valid product information of the eligible concomitant active ingredient are checked to see whether there is any information that excludes its use in combination therapy with the assessed medicinal product in the assessed therapeutic indication under marketing authorisation regulations. Corresponding information can be, for example, dosage information or warnings. In the event that the medicinal product is used as part of a determined or undetermined combination which does not include the assessed medicinal product, a combination with the assessed medicinal product shall be excluded.

Furthermore, the product information of the assessed medicinal product must not contain any specific information that excludes its use in combination therapy with the eligible concomitant active ingredient in the assessed therapeutic indication under marketing authorisation regulations.

Medicinal products with new active ingredients for which the G-BA have decided on an exemption as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V are ineligible as concomitant active ingredients. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V also applies accordingly to the medicinal product eligible as a concomitant active ingredient.

Designation

The medicinal products which have been determined as concomitant active ingredients in accordance with the above points of examination are named by indicating the relevant active ingredient and the invented name. The designation may include several active ingredients,

provided that several medicinal products with new active ingredients may be used in the same combination therapy with the assessed medicinal product or different combinations with different medicinal products with new active ingredients form the basis of the designation.

If the present resolution on the assessed medicinal product in the assessed therapeutic indication contains several patient groups, the designation of concomitant active ingredients shall be made separately for each of the patient groups.

Exception to the designation

The designation excludes combination therapies for which - patient group-related - a considerable or major additional benefit has been determined by resolution according to Section 35a, paragraph 3, sentence 1 SGB V or it has been determined according to Section 35a, paragraph 1d, sentence 1 SGB V that at least considerable additional benefit of the combination can be expected. In this context, the combination therapy that is excluded from the designation must, as a rule, be identical to the combination therapy on which the preceding findings were based.

In the case of designations based on undetermined combinations, only those concomitant active ingredients - based on a resolution according to Section 35a, paragraph 3, sentence 1 SGB V on the assessed medicinal product in which a considerable or major additional benefit had been determined - which were approved at the time of this resolution are excluded from the designation.

Legal effects of the designation

The designation of combinations is carried out in accordance with the legal requirements according to Section 35a, paragraph 3, sentence 4 and is used exclusively to implement the combination discount according to Section 130e SGB V between statutory health insurance funds and pharmaceutical companies. The designation is not associated with a statement as to the extent to which a therapy with the assessed medicinal products in combination with the designated medicinal products corresponds to the generally recognised state of medical knowledge. The examination was carried out exclusively on the basis of the possibility under Medicinal Products Act to use the medicinal products in combination therapy in the assessed therapeutic indication based on the product information; the generally recognised state of medical knowledge or the use of the medicinal products in the reality of care were not the subject of the examination due to the lack of an assessment mandate of the G-BA within the framework of Section 35a, paragraph 3, sentence 4 SGB V.

The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

Justification for the findings on designation in the present resolution:

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

References:
Product information for asciminib (Scemblix); Scemblix 20 mg film-coated tablets, Scemblix 40 mg
film-coated tablets; last revised: November 2025.

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

References:
Product information for asciminib (Scemblix); Scemblix 20 mg film-coated tablets, Scemblix 40 mg
film-coated tablets; last revised: November 2025.

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 6 February 2024, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

A review of the appropriate comparator therapy took place once the positive opinion was granted. At their session on 9 December 2025, the Subcommittee on Medicinal Products newly determined the appropriate comparator therapy.

On 28 November 2025, the pharmaceutical company submitted a dossier for the benefit assessment of asciminib to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 2 VerfO.

By letter dated 1 December 2025 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 asciminib.

The dossier assessment by the IQWiG was submitted to the G-BA on 26 February 2026, and the written statement procedure was initiated with publication on the G-BA website on 2 March 2026. The deadline for submitting statements was 23 March 2026.

The oral hearing was held on 7 April 2026.

By letter dated 8 April 2026, the IQWiG was commissioned with a supplementary assessment of data submitted in the written statement procedure. The addendum prepared by IQWiG was submitted to the G-BA on 30 April 2026.

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 12 May 2026, and the draft resolution was deliberated.

At their session on 21 May 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	6 February 2024	Determination of the appropriate comparator therapy
Subcommittee on Medicinal Products	9 December 2025	New determination of the appropriate comparator therapy
Working group Section 35a	1 April 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	7 April 2026	Conduct of the oral hearing, commissioning of the IQWiG with the supplementary assessment of documents
Working group Section 35a	15 April 2026; 6 May 2025	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	12 May 2026	Concluding discussion of the draft resolution
Plenum	21 May 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 21 May 2026

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

Prof. Hecken