Gemeinsamer Bundesausschuss

Justification

of 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 (chronic myeloid leukaemia, Ph+, after ≥ 2 prior therapies)

of 16 March 2023

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of reimbursable medicinal products with new active ingredients.

For medicinal products for the treatment of rare diseases (orphan drugs) that are approved according to Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999, the additional medical benefit is considered to be proven through the grant of the marketing authorisation according to Section 35a, paragraph 1, sentence 11, 1st half of the sentence German Social Code, Book Five (SGB V). Evidence of the medical benefit and the additional medical benefit in relation to the appropriate comparator therapy do not have to be submitted (Section 35a, paragraph 1, sentence 11, 2nd half of the sentence SGB V). Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V thus guarantees an additional benefit for an approved orphan drug, although an assessment of the orphan drug in accordance with the principles laid down in Section 35a, paragraph 1, sentence 3, No. 2 and 3 SGB V in conjunction with Chapter 5 Sections 5 et seq. of the Rules of Procedure (VerfO) of the G-BA has not been carried out. In accordance with Section 5, paragraph 8 AM-NutzenV, only the extent of the additional benefit is to be quantified indicating the significance of the evidence.

However, the restrictions on the benefit assessment of orphan drugs resulting from the statutory obligation to the marketing authorisation do not apply if the turnover of the medicinal product with the SHI at pharmacy sales prices and outside the scope of SHI-accredited medical care, including VAT exceeds € 30 million in the last 12 calendar months. According to Section 35a, paragraph 1, sentence 12 SGB V, the pharmaceutical company must then, within three months of being requested to do so by the G-BA, submit evidence according to Chapter 5, Section 5, paragraphs 1–6 VerfO, in particular regarding the additional medical benefit in relation to the appropriate comparator therapy as defined by the G-BA according to Chapter 5, Section 6 VerfO and prove the additional benefit in comparison with the appropriate comparator therapy.

In accordance with Section 35a, paragraph 2 SGB V, the G-BA decides whether to carry out the benefit assessment itself or to commission the Institute for Quality and Efficiency in Health Care (IQWiG). Based on the legal requirement in Section 35a, paragraph 1, sentence 11 SGB V that the additional benefit of an orphan drug is considered to be proven through the grant of the marketing authorisation the G-BA modified the procedure for the benefit assessment of orphan drugs at its session on 15 March 2012 to the effect that, for orphan drugs, the G-BA initially no longer independently determines an appropriate comparator therapy as the basis for the solely legally permissible assessment of the extent of an additional benefit to be assumed by law. Rather, the extent of the additional benefit is assessed exclusively on the basis of the approval studies by the G-BA indicating the significance of the evidence.

Accordingly, at its session on 15 March 2012, the G-BA amended the mandate issued to the IQWiG by the resolution of 1 August 2011 for the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a, paragraph 2 SGB V to that effect that, in the case of orphan drugs, the IQWiG is only commissioned to carry out a benefit assessment in the case of a previously defined comparator therapy when the sales volume of the medicinal product concerned has exceeded the turnover threshold according to Section 35a, paragraph 1, sentence 12 SGB V and is therefore subject to an unrestricted benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment by the G-BA must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a paragraph 3 SGB V, the G-BA decides on the benefit assessment within three months of its publication. The resolution is to be published online and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient asciminib on 1 October 2022 in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure (VerfO) of the G-BA. The pharmaceutical company submitted the final dossier to the G-BA in accordance with Section 4, paragraph 3, number 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 1 VerfO on 26 September 2022.

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

In accordance with Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V, the additional benefit is considered to be proven through the grant of the marketing authorisation. The extent of the additional benefit and the significance of the evidence are assessed on the basis of the approval studies by the G-BA.

The G-BA carried out the benefit assessment and commissioned the IQWiG to evaluate the information provided by the pharmaceutical company in Module 3 of the dossier on treatment costs and patient numbers. The benefit assessment was published on 02 January 2023 together with the IQWiG assessment on the website of the G-BA (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA has adopted its resolution on the basis of the dossier of the pharmaceutical company, the dossier assessment carried out by the G-BA, the assessment of treatment costs and patient numbers (IQWiG G22-32) prepared by the IQWiG, and the statements submitted in the written statement and oral hearing procedure.

In order to determine the extent of the additional benefit, the G-BA has assessed the studies relevant for the marketing authorisation considering their therapeutic relevance (qualitative) in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7, sentence 1, numbers 1 – 4 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods 1 was not used in the benefit assessment of asciminib.

1 General Methods, version 6.1 from 24.01.2022. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

2.1 Additional benefit of the medicinal product

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) previously treated with two or more tyrosine kinase inhibitors (see section 5.1)

Therapeutic indication of the resolution (resolution of 25 August 2022):

see the approved therapeutic indication

2.1.2 Extent of the additional benefit and significance of the evidence

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

Indication of a minor additional benefit

Justification:

For the benefit assessment, the pharmaceutical company uses the ASCEMBL study. This is an open-label, randomised controlled trial comparing asciminib to bosutinib in the treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia in the chronic phase (Ph+ CML-CP). A total of 157 patients were randomised to the intervention arm and 76 patients to the control arm (2:1 randomisation). On average, the age of the patients in both the intervention and control groups was 51 years. The study ongoing since 2017 is being conducted at 87 study sites in 25 countries worldwide.

The primary endpoint of the study was major molecular response (MMR) at week 24. Patient-relevant secondary endpoints were collected for the endpoint categories of mortality, morbidity and adverse events (AEs).

The benefit assessment is based on the 3rd data cut-off of the ASCEMBL study from 6 October 2021.

<u>Mortality</u>
Overall survival is defined in the ASCEMBL study as the period between randomisation and the date of death from any cause.

For the endpoint on overall survival, no statistically significant difference was detected between the treatment arms.

<u>Morbidity</u>

Molecular response

Good molecular response (MMR) at week 24 was the primary endpoint of the ASCEMBL study. A secondary study objective was also the MMR rate at week 96. For this endpoint, there was a statistically significant advantage of treatment with asciminib compared to bosutinib at both week 24 and week 96.

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.

Two studies were submitted by the pharmaceutical company to validate the MMR endpoint as a surrogate parameter for survival in patients with CML in chronic phase who received imatinib as first-line therapy compared to treatment with no TKI or no TKI other than imatinib[2,3]. Due to the lack of use of another TKI in the control group, the studies investigating MMR as a surrogate parameter are considered unsuitable. In addition, correlation analyses necessary for surrogate validation are missing.

The endpoint MMR is neither assessed as a directly patient-relevant endpoint nor as a validated surrogate endpoint and is therefore not used for the present assessment.

Progression to the blast phase

Progression to the blast phase is defined in the ASCEMBL study as the period between randomisation and the date of the first occurrence of progression to the blast phase.

The endpoint is classified as patient-relevant because a transition to the blast phase is associated with a deterioration in health status that is directly perceptible to the patient. However, there was no statistically significant difference between the two treatment arms for this endpoint. Only a small number of events occurred in both arms.

Symptomatology (M. D. Anderson Symptom Inventory (MDASI) – CML)

Symptomatology was assessed in the ASCEMBL study using the patient-reported symptom questionnaire MDASI-CML prior to study-related measures at the beginning of each visit during the treatment phase until the end of treatment.

The recording of the severity of disease-related symptoms (20 items) and the impairment of daily life by the symptoms (6 items) via the MDASI-CML is considered patient-relevant.

The pharmaceutical company submits an MMRM model as well as responder analyses defined post hoc for the endpoint MDASI-CML. The median observation period for the endpoint in the intervention group is approximately twice as long compared to the control group. Return rates ≥ 70% were observed in both treatment arms only up to week 16 in the intervention arm and up to week 8 in the control arm in relation to the change from baseline. Due to the low return rate compared to the median observation periods, less data is included in the survival time analyses, which is why a risk of bias in the results cannot be ruled out. Therefore, the responder analyses defined post hoc are not used for the present assessment, but the prespecified evaluations on MMRM analyses.

[2] Hehlmann R, Lauseker M, Saußele S, Pfirrmann M, Krause S, Kolb HJ, et al. Assessment of imatinib as first-line treatment of chronic myeloid leukaemia: 10-year survival results of the randomised CML study IV and impact of non-CML determinants. Leukaemia 2017; 31(11):2398-2406.

[3] Hochhaus A, Larson RA, Guilhot F, Radich JP, Branford S, Hughes TP, et al. Long-term outcomes of Imatinib treatment for Chronic Myeloid Leukaemia. The New England journal of medicine 2017;376(10):917-927.

For the endpoint "severity of disease-related symptoms", the MMRM analyses show a statistically significant difference in the mean change at week 8 to the advantage of asciminib versus bosutinib. However, the 95% confidence interval of the standardised mean difference (Hedges' g) is not completely outside the irrelevance range of -0.2 to 0.2. Consequently, it cannot be inferred that the observed effect is clinically relevant.

General health status (EQ-5D, visual analogue scale)

General health status was assessed in the ASCEMBL study using the EQ-5D visual analogue scale prior to study-related measures at the beginning of each visit during the treatment phase until the end of treatment.

In addition to evaluations using MMRM, the pharmaceutical company submitted responder analyses defined post hoc for the time to permanent deterioration or to the first deterioration for the dossier.

The results of the responder analyses are classified as being biased due to the uncertainties described under the explanations on symptomatology (collected with MDASI-CML). Therefore, the prespecified evaluations for MMRM are also used for the endpoint of health status. For this evaluation, no statistically significant difference could be identified between the treatment arms at week 8.

PGI-C

The PGI-C questionnaire consists of a single question that records the patient's view of improvement or deterioration of symptomatology with treatment.

The survey in the ASCEMBL study was conducted prior to study-related measures at the beginning of each visit during the treatment phase until the end of treatment.

The pharmaceutical company submitted prespecification of an MMRM model as well as responder analyses defined post hoc for the endpoint PGI-C. Return rates ≥ 70% were observed in both treatment arms only up to week 16 in the intervention arm and up to week 12 in the control arm in relation to the change from baseline. The results of the responder analyses are classified as being biased due to the uncertainties described under the explanations on symptomatology (collected with MDASI-CML).

Therefore, the prespecified evaluations for MMRM are also used for the endpoint PGI-C. For this evaluation, no statistically significant difference could be identified between the treatment arms at week 12.

Conclusion on morbidity

As a result, in the endpoint category of morbidity for the endpoint "severe disease-related symptomatology", a statistically significant difference in the mean change to the advantage of asciminib over bosutinib was only seen at week 8 in the MMRM analysis on MDASI-CML. However, the 95% confidence interval of the standardised mean difference is not completely outside the irrelevance range of -0.2 to 0.2. Consequently, it cannot be inferred that the observed effect is clinically relevant. Overall, there are therefore no relevant differences between the treatment arms in terms of morbidity.

Quality of life
No data on quality of life were submitted.

Side effects
Adverse events (AEs) in total

In the ASCEMBL study, almost all randomised patients experienced at least one adverse event. The results were only presented additionally.

Serious adverse events (SAEs), severe AEs (CTCAE grade ≥ 3), discontinuation due to AEs

For the endpoints of serious adverse events (SAE), severe AEs (CTCAE grade ≥ 3) and discontinuation due to AEs, there is a statistically significant difference between the treatment arms in each case to the advantage of asciminib.

In terms of severe AEs, only advantages of asciminib compared to bosutinib are shown in detail for examinations, gastrointestinal disorders and skin and subcutaneous tissue disorders.

AEs of special interest

For AEs of special interest, there are statistically significant differences to the advantage of asciminib versus bosutinib for gastrointestinal tumours (severe AEs), hepatotoxicity (including laboratory parameters) (severe AEs) and hypersensitivity (severe AEs). For myelosuppression (thrombocytopenia) grade ≥ 3, there is a statistically significant difference to the disadvantage of asciminib compared to bosutinib.

Conclusion on side effects

In the overall analysis of side effects, there are advantages of asciminib over bosutinib in all overall categories (SAEs, severe AEs (CTCAE ≥ 3) and discontinuation due to AEs) as well as in the AEs of special interest, with the exception of myelosuppression. Overall, this is assessed as a significant improvement in side effects.

Overall assessment

For the assessment of the additional benefit of asciminib for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph^+ CML-CP) who were previously treated with two or more tyrosine kinase inhibitors, results are available from the randomised, controlled, open-label, multicentre phase III ASCEMBL study on the endpoint categories of mortality, morbidity and side effects compared to bosutinib.

For the endpoint on overall survival, there was no statistically significant difference between the treatments with asciminib and bosutinib, respectively.

With regard to morbidity, there was no statistically significant difference between the two treatment arms for the endpoint "progression to the blast phase". Only a small number of events occurred in both arms.

Symptomatology was assessed in the ASCEMBL study using the patient-reported MDASI-CML and PGI-C questionnaires. In addition, the general health status was assessed using the EQ-5D visual analogue scale. The results show no relevant differences between the treatment arms.

With regard to health-related quality of life, no data are available from the ASCEMBL study. Thus, the extent to which the treatment with asciminib has an effect on the patients' quality of life compared to bosutinib cannot be assessed. Data on health-related quality of life is given high priority in the present treatment setting.

With regard to adverse events, there are advantages for asciminib compared to bosutinib with regard to the occurrence of serious AEs, severe adverse events (CTCAE grade ≥ 3) as well as in the endpoint of discontinuations due to AEs, which are assessed as a significant improvement.

In summary, there is a significant improvement in side effects. There are no relevant differences in the patient-relevant endpoints of overall survival, symptomatology, general health status and progression to the blast phase. No data are available on health-related quality of life.

In the overall analysis, the G-BA concludes that there is a minor additional benefit of asciminib compared to bosutinib for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in the chronic phase (Ph^+ CML-CP) who were previously treated with two or more tyrosine kinase inhibitors.

Significance of the evidence

This assessment is based on the results of the open-label, randomised, controlled phase III ASCEMBL study comparing asciminib with bosutinib.

Basically, the risk of bias is classified as high due to the open-label study design.

Further uncertainties arise from the possibility of switching from the bosutinib to the asciminib arm and from the more intensive pretreatment of patients in the control arm compared to the intervention arm.

Furthermore, there are clear differences in the treatment and observation periods between the treatment arms.

The reliability of data on the side effect categories SAEs, severe AEs (CTCAE grade ≥ 3) is assessed as high, on the endpoint of discontinuation due to AEs as limited due to possible competing events (reasons for discontinuation other than AEs with different durations of treatment and observation).

Since the results on the side effects, from which the additional benefit is derived, predominantly show high reliability, an indication of an additional benefit can be derived overall on the available data basis despite the limitations described.

2.1.3 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product "Scemblix" with the active ingredient asciminib.

Scemblix was approved as an orphan drug.

Asciminib is approved for the 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.

For the benefit assessment, the pharmaceutical company submits the results of the data cut-off of 6 October 2021 from the randomised, controlled, open-label, multicentre phase III ASCEMBL study, in which asciminib was compared to bosutinib in the treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (PH^+ CML-CP) previously treated with two or more tyrosine kinase inhibitors.

For the endpoint on overall survival, there was no statistically significant difference between the treatments with asciminib and bosutinib, respectively.

With regard to morbidity, there was no statistically significant difference between the two treatment arms for the endpoint "progression to the blast phase". Only a small number of events occurred in both arms.

Symptomatology was assessed in the ASCEMBL study using the patient-reported MDASI-CML and PGI-C questionnaires. In addition, the general health status was assessed using the EQ-5D visual analogue scale. The results show no relevant differences between the treatment arms.

With regard to health-related quality of life, no data are available from the ASCEMBL study. Thus, the extent to which the treatment with asciminib has an effect on the patients' quality of life compared to bosutinib cannot be assessed. Data on health-related quality of life is given high priority in the present treatment setting.

With regard to adverse events, there are advantages for asciminib compared to bosutinib with regard to the occurrence of serious AEs, severe adverse events (CTCAE grade ≥ 3) as well as in the endpoint of discontinuations due to AEs, which are assessed as a significant improvement.

In summary, there is a significant improvement in side effects. There are no relevant differences in the patient-relevant endpoints of overall survival, symptomatology, general health status and progression to the blast phase. No data are available on health-related quality of life.

An indication can be derived regarding the reliability of data.

As a result, the G-BA found an indication of a minor additional benefit for asciminib compared to bosutinib on the basis of the ASCEMBL study.

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 resolution is based on the information from the dossier of the pharmaceutical company. The procedure of the pharmaceutical company is mathematically largely comprehensible. However, the calculation is subject to uncertainties and the number in the SHI target population could also be outside this range. This is especially due to the use of the 20-year

prevalence in conjunction with the incidence as a starting point and the percentage values transferred to it on the basis of newly ill patients.

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: 12 December 2022):

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 contents of the product information and the information listed in the LAUER-TAXE® (last revised: 1 March 2023).

Treatment period:

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 varies from patient to patient and/or is shorter on average.

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, 2 x daily	730	2	365

Consumption:

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	2 x 40 mg	365	730 x 40 mg

Costs:

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					
Asciminib	180 Pic	€ 24,272.49	€ 2.00	€ 2,370.72	€ 21,899.77
Abbreviations: FCT = film-coated tablets					

LAUER-TAXE® last revised: 1 March 2023

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.

No additionally required SHI services are taken into account for the cost representation.

2.5 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 Asciminib

According to Section 35a, paragraph 3, sentence 4, the Federal Joint Committee shall 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.

In accordance with Section 2, paragraph 1, sentence 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), only medicinal products containing active ingredients whose effects are not generally known in medical science at the time of initial marketing authorisation are to be considered within the framework of the designation of medicinal products with new active ingredients that can be used in a combination therapy. According to Section 2, paragraph 1, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), a medicinal product with a new active ingredient is considered to be a medicinal product with a new active ingredient for as long as there is dossier protection for the medicinal product with the active ingredient that was authorised for the first time.

The designation of the combination therapies is based solely on the specifications according to Section 35a, paragraph 3, sentence 4. The G-BA does not conduct a substantive review

based on the generally recognised state of medical knowledge. Thus, the designation is not associated with a statement as to the extent to which a therapy with the designated medicinal product with new active ingredient in combination with the medicinal product to be assessed corresponds to the generally recognised state of medical knowledge.

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

On 26 September 2022, 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 1, sentence 2 VerfO.

The benefit assessment of the G-BA was published on 02 January 2023 together with the IQWiG assessment of treatment costs and patient numbers on the website of the G-BA (www.g-ba.de), thus initiating the written statement procedure. The deadline for submitting written statements was 23 January 2023.

The oral hearing was held on 6 February 2023.

A new version of the G-BA's dossier assessment was prepared on 3 March 2023. This version 1.1 of 3 March 2023 replaces version 1.0 of the dossier assessment of 2 January 2023 and was brought to the attention of the Subcommittee on Medicinal Products at its session on 7 March 2023. 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 was discussed at the session of the subcommittee on 7 March 2023, and the proposed resolution was approved.

At its session on 16 March 2023, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	20 December 2022	Information of the benefit assessment of the G-BA
Working group Section 35a	31 January 2023	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal products	6 February 2023	Conduct of the oral hearing
Working group Section 35a	14 February 2023 28 February 2023	Consultation on the dossier assessment by the G-BA, the assessment of treatment costs and patient numbers by the IQWiG, and the evaluation of the written statement procedure
Subcommittee Medicinal products	7 March 2023	Concluding discussion of the draft resolution
Plenum	16 March 2023	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 16 March 2023

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

Prof. Hecken