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
Burosumab (new therapeutic indication: FGF23-related hypophosphatemia in tumour-induced osteomalacia, ≥ 1 year)

of 16 February 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. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for 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 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 active ingredient burosumab (Crysvita) was listed for the first time on 15 April 2018 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 25 July 2022, Crysvita 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, 12.12.2008, p. 7).

On 22 August 2022, i.e. at the latest within four weeks after the notification of the pharmaceutical company of the approval of a new therapeutic indication, the pharmaceutical company has 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 burosumab with the new therapeutic indication (FGF23-related hypophosphatemia in tumour-induced osteomalacia, ≥ 1 year).

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 December 2022 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 burosumab compared to the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, 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 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 burosumab.

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

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

2.1.1 Approved therapeutic indication of Burosumab (Crysvita) in accordance with the product information

Crysvita is indicated for the treatment of FGF23-related hypophosphataemia in tumour-induced osteomalacia associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised in children and adolescents aged 1 to 17 years and in adults.

Therapeutic indication of the resolution (resolution of 16.02.2023):

See new therapeutic indication according to marketing authorisation.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Patients aged 1 year and above with FGF23-related hypophosphatemia in tumour-induced osteomalacia associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised

Appropriate comparator therapy for burosumab:

a phosphate replacement and active vitamin D (calcitriol or alfacalcidol) in combination

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

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

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

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.

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

on 1. In addition to burosumab, the following medicinal products are approved in the present therapeutic indication: Phosphate, calcitriol and alfacalcidol.

As the present indication concerns hypophosphataemic osteomalacia, the use of active vitamin D (active ingredients calcitriol and alfacalcidol) is approved for the present indication.

on 2. A non-medicinal treatment paid by the SHI is not considered as an appropriate comparator therapy in the present therapeutic indication.

on 3. Approved exceptions to the legal prescription exclusion according to Section 34, para. 1, sentence 2 SGB V (OTC overview) according to Annex I of the AM-RL are: "*38. Phosphate compounds in hypophosphataemia that cannot be remedied by appropriate nutrition*".

on 4. The generally state of medical knowledge was illustrated by a systematic search for guidelines as well as 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".

For patients aged 1 and above with FGF23-related hypophosphatemia in tumour-induced osteomalacia associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised, phosphate replacement and the additional administration of active vitamin D (calcitriol or alfacalcidol) are recommended as medicinal therapy on the basis of the available evidence. The additional administration of active vitamin D should also prevent a secondary hyperparathyroidism.

Also according to the approved exception to the legal prescription exclusion according to Section 34, para. 1, sentence 2 SGB V (so-called OTC overview) according to Annex I of the AM-RL ("*38. Phosphate compounds for hypophosphataemia that cannot be remedied by an appropriate nutrition")*, the treatment of hypophosphataemia by a phosphate compound is indicated and can be provided at the expense of the SHI. This OTC overview mainly refers to adults.

In special clinical situations, phosphate replacement is not indicated in subjects with FGF23-related hypophosphatemia in tumour-induced osteomalacia. For example, subjects with marked parathyroid hormone elevation or with secondary hyperparathyroidism or with nephrocalcinosis are not eligible for a phosphate replacement. However, this patient population does not represent the rule in the present indication.

Therefore, based on the available evidence in the present therapeutic indication, phosphate replacement and active vitamin D (calcitriol or afacalcidol) in combination is determined as an appropriate comparator therapy for the treatment of "patients aged 1 year and above with FGF23-related hypophosphataemia in tumour-induced osteomalacia associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised".

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

A change in the appropriate comparator therapy requires a resolution by the G-BA linked to the prior review of the criteria according to Chapter 5, Section 6, paragraph 3 Rules of Procedure.

2.1.3 Extent and probability of the additional benefit

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

Patients aged 1 year and above with FGF23-related hypophosphatemia in tumour-induced osteomalacia associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised

An additional benefit is not proven.

Justification:

For the assessment of the additional benefit of burosumab for patients aged 1 year and above with FGF23-related hypophosphataemia in tumour-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised, the two pivotal, open-label, single-arm phase II studies UX023T-CL201 and KRN23-002 were submitted by the pharmaceutical company.

In the single-arm study UX023T-CL201, adult patients with TIO and patients with epidermal nevus syndrome (ENS)-associated osteomalacia. According to the pharmaceutical company,

14 of the total of 17 patients enrolled in the study had TIO. The UX023T-CL201 study included a treatment phase of 48 weeks and a subsequent extension phase of up to 252 weeks.

A total of 14 adult patients with TIO were enrolled in the single-arm study KRN23-002. The KRN23-002 study included a treatment phase of 48 weeks and a subsequent extension phase of up to 96 weeks.

Patients in the studies UX023T-CL201 and KRN23-002 had to discontinue an existing phosphate replacement or a vitamin D metabolites replacement or their analogues at least 2 weeks before screening.

In the UX023T-CL201 and KRN23-002 studies, patients received burosumab subcutaneously every 4 weeks. During the course of the study, the burosumab dose could be gradually increased or decreased, starting from 0.3 mg/kg burosumab at week 0, to achieve a fasting serum phosphate target value for patients in the range of 2.5 to 4.0 mg/dl.

The single-arm studies UX023T-CL201 and KRN23-002 are not relevant for the present benefit assessment, as no data are available for an assessment of burosumab compared with the appropriate comparator therapy.

Overall, for the present therapeutic indication, the pharmaceutical company did not present any study that would have been suitable for the assessment of the additional benefit of burosumab compared with the appropriate comparator therapy.

An additional benefit of burosumab compared to the appropriate comparator therapy is therefore not proven.

Burosumab may represent a relevant therapeutic alternative in specific cases in the present therapeutic indication.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient burosumab (Crysvita). Crysvita was approved as an orphan drug but has exceeded the EUR 50 million turnover limit.

The G-BA defined phosphate replacement and active vitamin D (calcitriol or alfacalcidol) in combination as an appropriate comparator therapy.

For the assessment of the additional benefit of burosumab for patients aged 1 year and above with FGF23-related hypophosphataemia in tumour-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised, the two pivotal, open-label, single-arm phase II studies UX023T-CL201 and KRN23-002 were submitted by the pharmaceutical company. The single-arm studies UX023T-CL201 and KRN23-002 are not relevant for the present benefit assessment, as no data are available for an assessment of burosumab compared with the appropriate comparator therapy.

Overall, for the present therapeutic indication, the pharmaceutical company did not present any study that would have been suitable for the assessment of the additional benefit of

burosumab compared with the appropriate comparator therapy. An additional benefit of burosumab compared to the appropriate comparator therapy is therefore not proven.

Burosumab may represent a relevant therapeutic alternative in specific cases in the present therapeutic indication.

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

Patients aged 1 year and above with FGF23-related hypophosphatemia in tumour-induced osteomalacia associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised

The number of patients is the target population in statutory health insurance (SHI). The information is based on patient numbers based on the information provided by the pharmaceutical company in the dossier.

However, the number of patients in the statutory health insurance target population stated by the pharmaceutical company is subject to uncertainties overall due to the methodological procedure. Since the methodological procedure of the pharmaceutical company includes aspects of both overestimation and underestimation, no reliable statement can be made on the basis of the available data as to whether the stated patient numbers have been overestimated or underestimated.

The pharmaceutical company's restriction to adult patients is not observed as this restriction is not apparent from the present therapeutic indication.

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 Crysvita (active ingredient: burosumab) at the following publicly accessible link (last access: 2 January 2023):

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

Treatment with burosumab should only be initiated and monitored by doctors experienced in the therapy of metabolic bone diseases.

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 February 2023).

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. 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.

For dosages depending on body weight (BW), the average body measurements from the official representative statistics "Microcensus 2017 – body measurements of the population" are used as a basis. The range of annual treatment costs is calculated using the average body weight of children at 1 year (11.6 kg), 4 years (18.5 kg), 12 years (47.1 kg), 13 years (52.4 kg) and 17 years (67 kg), and the average body weight of adults aged 18 years and above (77 kg).

The burosumab dose range lower limit of 4.64 mg is derived from the recommended starting dose of 0.4 mg/kg and the average body weight of children at 1 year (11.6 kg). The upper limit of 154 mg is derived from the recommended maximum dose of 2.0 mg/kg and the average body weight of adults aged 18 years and above (77 kg). The maximum limit of 180 mg mentioned in the PI is not reached, taking into account the average weight of 77 kg, and is therefore not taken into account in the cost representation. According to the product information, the calculated dosages are to be rounded up or down to the nearest 10 mg.

For the dose ranges of phosphate and vitamin D supplementation, the lower dosage recommendations are shown for the youngest age group and the highest dosage recommendations for the oldest age group.

According to the calcitriol product information, as of August 2020, no dosage recommendation can be given for children and adolescents due to the limited data basis available. For this reason, the costs of calcitriol treatment are only presented for adults.

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Burosumab	Children and adolescents			
	Continuously, 1 x every 14 days	26.1	1	26.1
	Adults			
	Continuously, 1 x every 14 or 28 days	13.0 – 26.1	1	13.0 – 26.1
Appropriate comparator therapy				
Phosphate replacement and active vitamin D (calcitriol or alfacalcidol) in combination				

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Phosphate	continuously, daily at mealtimes	365	1	365
Active vitamin D				
Calcitriol	Adults[2]			
	Continuously, every 1 - 2 days	182.5 - 365	1	182.5 - 365
or				
Alfacalcidol	Continuously, 1 x daily	365	1	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					
Burosumab	Children aged between 1 and 12 years				
	0.4 mg/ kg BW = 4.64 mg - 90 mg	10 mg - 90 mg	1 x 10 mg 3 x 30 mg	26.1	26.1 x 10 mg - 78.3 x 30 mg
	Adolescents aged between 13 and 17 years				
	0.3 mg/ kg BW = 15.72 mg - 2 mg/ kg BW = 134 mg	20 mg - 130 mg	1 x 20 mg 4 x 30 mg + 1 x 10 mg	26.1	26.1 x 20 mg - 104.4 x 30 mg + 26.1 x 10 mg
	Adults				
	0.3 mg / kg BW = 23.1 mg - 2 mg/ kg BW = 154 mg	20 mg - 150 mg	1 x 20 mg 5 x 30 mg	13.0 – 26.1	13.0 x 20 mg -26.1 x 20 mg - 65.0 x 30 mg - 130.5 x 30 mg

[2] According to the calcitriol product information, as of August 2020, no dosage recommendation can be given for children and adolescents due to the limited data basis available.

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Appropriate comparator therapy					
Phosphate replacement and active vitamin D (calcitriol or alfacalcidol) in combination					
Phosphate	1-year-olds				
	50 mg / kg = 580 mg	580 mg	1 x 612.2 mg	365	365 x 612.2 mg
	17-year-olds				
	50 mg / kg = 3,350 mg	3,350 mg	5 x 612.2 mg	365	1,825 x 612.2 mg
	Adults				
	3,061 mg -	3,061 mg	5 x 612.2 mg -	365	1,825 x 612.2 mg -
	4,897.6 mg	4,897.6 mg	8 x 612.2 mg	365	2,920 x 612.2 mg
Active vitamin D					
Calcitriol	Adults[2]				
	0.25 µg -	0.25 µg -	1 x 0.25 µg -	182.5 - 365	182.5 x 0.25 µg -
	1 µg	1 µg	2 x 0.5 µg		730 x 0.5 µg
or					
Alfacalcidol	Children with a body weight below 20 kg (2 to 4-year-olds)				
	0.05 µg/kg = 0.58 µg -	0.58 µg -	1 x 0.5 µg	365	365 x 0.5 µg -
	0.05 µg/kg = 0.925 µg	0.93 µg	1 x 1 µg	365	365 x 1 µg
	Adults and children with a body weight above 20 kg (5 years and above)				
	1 µg - 3 µg	1 µg - 3 µg	1 x 1 µg - 3 x 1 µg	365	365 x 1 µg - 1095 x 1 µg

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.

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					
Burosumab 10 mg	1 SFI	€ 2,842.90	€ 2.00	€ 277.31	€ 2,563.59
Burosumab 20 mg	1 SFI	€ 5,675.36	€ 2.00	€ 554.62	€ 5,118.74
Burosumab 30 mg	1 SFI	€ 8,507.83	€ 2.00	€ 831.92	€ 7,673.91
Appropriate comparator therapy					
Phosphate 602 mg	100 CTA	€ 23.98	€ 1.20	€ 1.47	€ 21.31
Calcitriol 0.25 µg [3]	100 SC	€ 45.18	€ 2.00	€ 2.68	€ 40.50
Calcitriol 0.5 µg[3]	100 SC	€ 77.66	€ 2.00	€ 5.25	€ 70.41
Alfacalcidol 0.5 µg[3]	100 SC	€ 57.72	€ 2.00	€ 3.67	€ 52.05
Alfacalcidol 1 µg[3]	100 SC	€ 96.81	€ 2.00	€ 6.76	€ 88.05
Abbreviations: SFI = solution for injection, CTA = coated tablets, SC = soft capsules					

LAUER-TAXE® last revised: 1 February 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.

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

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) (Sections 4 and 5 of the Pharmaceutical Price Ordinance) from 01.10.2009 is not fully used to calculate costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131 paragraph 4 SGB V is a suitable basis for a standardised calculation.

[3] Fixed reimbursement rate

According to the currently valid version of the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe), surcharges for the production of parenteral preparations containing cytostatic drugs a maximum amount of € 100 per ready-to-use preparation, and for the production of parenteral solutions containing monoclonal antibodies a maximum of € 100 per ready-to-use unit are to be payable. These additional other costs are not added to the pharmacy sales price but rather follow the rules for calculating in the Hilfstaxe. The cost representation is based on the pharmacy retail price and the maximum surcharge for the preparation and is only an approximation of the treatment costs. This presentation does not take into account, for example, the rebates on the pharmacy purchase price of the active ingredient, the invoicing of discards, the calculation of application containers, and carrier solutions in accordance with the regulations in Annex 3 of the Hilfstaxe.

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 Burosumab

According to Section 35a, paragraph 3, sentence 4, the G-BA designates 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.

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

At its session on 22 June 2021, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 22 August 2022 the pharmaceutical company submitted a dossier for the benefit assessment of burosumab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

By letter dated 22 August 2022 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 burosumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 17 November 2022, and the written statement procedure was initiated with publication on the G-BA website on 1 December 2022. The deadline for submitting written statements was 22 December 2022.

The oral hearing was held on 9 January 2023.

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 February 2023, and the proposed resolution was approved.

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

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	22 June 2021	Determination of the appropriate comparator therapy
Working group Section 35a	4 January 2023	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal products	9 January 2023	Conduct of the oral hearing
Working group Section 35a	18 January 2023 1 February 2023	Consultation on the dossier assessment by the IQWiG, assessment of the written statement procedure
Subcommittee Medicinal products	7 February 2023	Concluding discussion of the draft resolution
Plenum	16 February 2023	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 16 February 2023

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

Prof. Hecken