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 (exceeding € 50 million turnover limit: X-linked hypophosphataemia, ≥ 18 years)

of 21 July 2022

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 on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

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. Crysvita for the treatment of X-linked hypophosphataemia (XLH) 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.

At its session on 15 April 2021, the G-BA decided on the benefit assessment of burosumab in the therapeutic indication "Treatment of X-linked hypophosphataemia in adults" according to Section 35a SGB V.

If the sales of the orphan drug through the statutory health insurance at pharmacy sales prices and outside the scope of SHI-accredited medical care, including value-added tax, exceed an amount of €50 million in the last twelve calendar months, the pharmaceutical company must submit evidence in accordance with Section 5, paragraphs 1 to 6 within three months of being

requested to do so by the Federal Joint Committee, and in this evidence must demonstrate the additional benefit compared to the appropriate comparator therapy.

By letter dated 21 October 2021, the pharmaceutical company was requested to submit a dossier for the benefit assessment according to Section 35a SGB V by 1 February 2022, due to exceeding the €50 million turnover limit within the period from August 2020 to July 2021. The pharmaceutical company has 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, paragraph1, number 6 VerfO on 31 January 2022.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on the website of the G-BA (www.g-ba.de) on 2 May 2022, 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 X-linked hypophosphataemia in adults.

Therapeutic indication of the resolution (resolution of 21.07.2022):

see therapeutic indication according to marketing authorisation

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults with X-linked hypophosphataemia (XLH)

Appropriate comparator therapy for burosumab:

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

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

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 XLH is a familial hypophosphataemic rickets, 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 for the treatment of XLH.

on 3. For the patient group to be considered in the present therapeutic indication, there are no resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V.

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".

The Haffner *et al.* 2019 guideline was included in the evidence synopsis for the treatment of XLH . This guideline provides recommendations for the treatment of children and adults with XLH.

For adult patients with XLH who are symptomatic and thus in need of treatment, the guideline recommends a phosphate replacement and the additional administration of active vitamin D (calcitriol or alfacalcidol) as medicinal therapy, in particular to reduce the occurrence of osteomalcia and its consequences and to improve the oral health of the patients. The additional administration of active vitamin D should also prevent a secondary hyperparathyroidism. However, routine treatment of asymptomatic patients is not recommended.

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.
As the disease progresses, adults with symptomatic XLH require treatment and individualised treatment with oral phosphate in combination with active vitamin D is indicated for this patient population based on the available evidence.

Patients in need of treatment whose pathologically low serum phosphate levels do not reach the normal range under conventional therapy also continue to receive a phosphate replacement in combination with active vitamin D in clinical practice, provided there are no clinical reasons to the contrary.

In special clinical situations, phosphate replacement of adults with XLH is not indicated. 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 for the treatment of "adults with XLH", a phosphate replacement and active vitamin D (calcitriol or afacalcidol) in combination is determined as an appropriate comparator therapy.

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

2.1.3 Extent and probability of the additional benefit

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

Adults with X-linked hypophosphataemia (XLH)

An additional benefit is not proven.

Justification:

For the assessment of the additional benefit of burosumab for adults with X-linked hypophosphatemia, the pharmaceutical company presented the multicentre, randomised, double-blind, placebo-controlled phase III UX023-CL303 study justifying the marketing authorisation with data cut-off at week 24. In the UX023- CL303 study, a total of 134 patients were randomised in a 1: 1 ratio to the intervention arm (burosumab; N = 68) or the comparator arm (placebo; N = 66).

The patient population enrolled in the UX023-CL303 study comprised adult patients aged 18 to 65 years whose XLH diagnosis was confirmed by clinical and biochemical or molecular biology criteria. The enrolled patients had to have at least one of the following characteristics: documented PHEX mutation and/or iFGF23 level in serum > 30 pg/ml according to Kainos assay. Another inclusion criterion was a reduced serum phosphate level (<2.5 mg / dL). The patient population enrolled in the UX023-CL303 study had to have symptomatology in the form of skeletal pain attributable to XLH and osteomalacia caused by it. Asymptomatic adult patients were not enrolled in the UX023-CL303 study.

In the UX023-CL303 study, patients were excluded if they had taken phosphate or vitamin D metabolites within 14 days prior to the 2nd screening visit. In addition, subjects with elevated serum calcium concentrations or elevated serum concentrations of the intact parathyroid hormone were excluded.

The UX023-CL303 study is divided into a screening and a 24 week treatment period. This was followed by a single-arm, open-label extension phase in which all study participants received burosumab until week 96. In the study sites in the USA, continuation of treatment was possible up to week 149.

Treatment with burosumab was carried out in the UX023-CL303 study according to the product information at a dose of 1.0 mg / kg every 4 weeks.

Primary endpoint in the UX023-CL303 study was reaching the mean serum phosphate level above the lower limit of the normal range at the middle of the dose cycle. In the UX023-CL303 study, more endpoints were collected in the category of mortality, morbidity and side effects.

The UX023-CL303 study cannot be used for the present benefit assessment because the appropriate comparator therapy was not implemented. The G-BA has defined a phosphate replacement and active vitamin D (calcitriol or alfacalcidol) in combination as the appropriate comparator therapy.

However, in the UX023-CL303 study, phosphate and active vitamin D supplementation was explicitly excluded.

Although the study participants had the option of receiving phosphate and active vitamin D as part of a rescue therapy, this was only provided for when an acute event occurred (e.g. a traumatic fracture or an unplanned surgical intervention) and did not represent a regular treatment option. The limited use of phosphate and active vitamin D does not correspond to everyday care. In addition, the study documents show that the administration of phosphate led to the discontinuation of the study medication.

Furthermore, in the UX023-CL303 study, there were no appropriate/ comprehensible clinical reasons for not administering a phosphate replacement (e.g. parathyroid hormone elevation, secondary hyperparathyroidism or nephrocalcinosis). Rather, symptomatic adults with XLH in need of treatment were enrolled. Subjects with a parathyroid hormone elevation of 2.5 times the upper reference value were excluded from the UX023-CL303 study and only 4.5% of adults in the comparator arm had undifferentiated hyperparathyroidism. Thus, administration of a phosphate replacement and active vitamin D would have been indicated for the majority of adult patients in the comparator arm of the UX023-CL303 study. Contraindication or clinical reasons for not administering a phosphate replacement and active vitamin D were not presented for the participants of the UX023-CL303 study, thus rendering it unusable for the benefit assessment because the appropriate comparator therapy was not implemented.

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 treatment option in specific cases in the present therapeutic indication.

2.1.4 Summary of the assessment

The present assessment is a new benefit assessment of the active ingredient burosumab due to the exceeding of the €50 million turnover limit. Crysvita was approved under "special conditions" as an orphan drug.

The present assessment refers to the therapeutic indication "for the treatment of X-linked hypophosphataemia (XLH) in adults".

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 adults with X-linked hypophosphatemia, the pharmaceutical company presented the multicentre, randomised, double-blind, placebo-controlled phase III UX023-CL303 study justifying the marketing authorisation with data cut-off at week 24. The UX023-CL303 study cannot be used for the present benefit assessment because the appropriate comparator therapy was not implemented.

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 treatment option in specific cases in the present therapeutic indication.

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

Adults with X-linked hypophosphataemia (XLH)

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.

The number of patients in the statutory health insurance target population specified by the pharmaceutical company is, however, fraught with uncertainties. In the source on prevalence used by the pharmaceutical company,[2] reference is made to a possible underestimation. In addition, a routine data analysis was identified for Germany that shows a higher number of adults with XLH. As a result, the specified range represents an underestimation of the number of patients.

The restriction made by the pharmaceutical company to patients who do not respond to a phosphate replacement within one year is not followed, as this restriction does not result 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: 5 May 2022):

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.

This medicinal product was authorised under "special conditions". The EMA will assess new information on this medicinal product at least annually and update the product information as necessary.

[2] Hawley S, Shaw NJ, Delmestri A, et al. Prevalence and Mortality of Individuals With X-Linked Hypophosphatemia: A United Kingdom Real-World Data Analysis. J Clin Endocrinol Metab 2020; 105(3): e871-e878.

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 1 July 2022).

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

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" were used as a [3]basis. The average body weight of adults aged 18 and over (77 kg) was used as the basis for calculating the annual treatment costs. The burosumab lower dose range limit of 77 mg is derived from the recommended starting dose of 1.0 mg/kg and the average body weight of adults aged 18 years and over (77 kg) rounded up to the nearest 10 mg. The upper limit corresponds to the maximum dose of 90 mg.

According to the most recent guideline for the treatment of hereditary hypophosphataemic rickets, 20 - 40 mg of elemental phosphate per kg body weight (BW) should be administered in at least 5 individual doses[4]. Medicinal products for phosphate replacement with the administration form infusion solution seem unsuitable when used 5 times a day. The remaining medicinal product is dispensed as a coated tablet containing 602 mg of active ingredient. The recommended lower limit of 20 mg/kg BW is 1,540 mg phosphate per day for the average adult (77 kg). This dose can be rounded up to 3 daily doses. With the upper limit of 3,080 mg phosphate per day (40 mg x 77 kg BW), a division into 5 single doses per day is possible (5 x 602 mg coated tablet).

According to the guideline for the treatment of hereditary hypophosphataemic rickets, 20-30 ng calcitriol per kg BW or 50 ng alfacalcidol per kg BW, divided into 1-2 single doses, should be administered[4].

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				

[3] Federal Statistical Office, Wiesbaden 2018: http://www.gbe-bund.de/

[4] DGKED e.V. S1 guideline 174-008: Hereditary hypophosphataemic rickets; last revised: 03.2016; https://www.awmf.org/uploads/tx_szleitlinien/174-008l_S1_Hereditaere_hypophosphataemische_Rachitiden_2016-05-abgelaufen.pdf

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Burosumab	continuously, every 28 days	13.0	1	13.0
Appropriate comparator therapy				
Phosphate replacement and active vitamin D (calcitriol or alfacalcidol) in combination				
Phosphate	continuously, 3-5 x daily	365	1	365
Active vitamin D				
Calcitriol	continuously, 1-2 x daily	365	1	365
or				
Alfacalcidol	continuously, 1-2 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	1.0 mg/kg BW = 77 mg 90 mg	80 mg - 90 mg	2 x 30 mg + 1 x 20 mg - 3 x 30 mg	13.0 13.0	26.0 x 30 mg + 13.0 x 20 mg - 39.0 x 30 mg
Appropriate comparator therapy					
Phosphate replacement and active vitamin D (calcitriol or alfacalcidol) in combination					
Phosphate	20 mg/kg BW = 1,540 mg - 40 mg/kg BW = 3,080 mg	1,806 mg - 3,010 mg	3 x 602 mg - 5 x 602 mg	365 365	1,095 x 602 mg - 1,825 x 602 mg
Active vitamin D					
Calcitriol	20 ng/kg = 1,540 ng - 30 ng/kg = 2,310 ng	1.5 µg - 2.5 µg	3 x 0.5 µg - 5 x 0.5 µg	365 365	1,095 x 0.5 µg - 1,825 x 0.5 µg
or					
Alfacalcidol	50 ng/kg BW = 3,850 ng	4 µg	4 x 1 µg	365	1460 x 1 µg

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					
Burosumab 20 mg	1 SFI	€ 5,675.36	€ 1.77	€ 323.53	€ 5,350.06
Burosumab 30 mg	1 SFI	€ 8,507.83	€ 1.77	€ 485.29	€ 8,020.77
Appropriate comparator therapy					
Phosphate 602 mg	100 CTA	€ 23.98	€ 1.77	€ 0.86	€ 21.35

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
Calcitriol 0.5 µg[5]	100 SC	€ 77.66	€ 1.77	€ 5.25	€ 70.64
Alfacalcidol 1 µg[5]	100 SC	€ 96.81	€ 1.77	€ 6.76	€ 88.28
Abbreviations: SFI = solution for injection, CTA = coated tablets, SC = soft capsules					

LAUER-TAXE® last revised: 1 July 2022

Costs for additionally required SHI services:

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

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

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

Other SHI services:

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

According to the currently valid version of the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe), surcharges for the production of parenteral preparations containing cytostatic drugs a maximum amount of € 81 per ready-to-use preparation, and for the production of parenteral solutions containing monoclonal antibodies a maximum of € 71 per ready-to-use unit are to be payable. These additional 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.

[5] Fixed reimbursement rate

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 10 March 2020, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 31 January 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 6 VerfO.

By letter dated 1 February 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 26 April 2022, and the written statement procedure was initiated with publication on the website of the G-BA on 2 May 2022. The deadline for submitting written statements was 23 May 2022.

The oral hearing was held on 7 June 2022.

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 12 July 2022, and the proposed resolution was approved.

At its session on 21 July 2022, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	10 March 2020	Determination of the appropriate comparator therapy
Working group Section 35a	31 May 2022	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal products	7 June 2022	Conduct of the oral hearing

Working group Section 35a	14.06.2022; 06.07.2022	Consultation on the dossier assessment by the IQWiG, assessment of the written statement procedure
Subcommittee Medicinal products	12 July 2022	Concluding discussion of the draft resolution
Plenum	21 July 2022	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 21 July 2022

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

Prof. Hecken