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
Elbasvir/ grazoprevir (new therapeutic indication: chronic hepatitis C, 12 to < 18 years)

of 5 May 2022

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1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) 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

The combination of active ingredients elbasvir/ grazoprevir (Zepatier) was listed for the first time on 15 December 2016 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 22 October 2021, Zepatier 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 European 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 12 November 2021, i.e. at the latest within four weeks after informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company has submitted a dossier in due time in accordance with Section 4, paragraph 3, number 2 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA on the combination of active ingredients elbasvir/ grazoprevir with the new therapeutic indication (treatment of chronic hepatitis C (CHC) in adolescents and children aged 12 years and above and weighing at least 30 kg).

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 15 February 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 elbasvir/ grazoprevir 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. 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 elbasvir/ grazoprevir.

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 Elbasvir/ grazoprevir (Zepatier) in accordance with the product information

Zepatier is indicated for the treatment of chronic hepatitis C (CHC) in adult and paediatric patients 12 years of age and older who weigh at least 30 kg.

Therapeutic indication of the resolution (resolution of 5 May 2022):

Zepatier is indicated for the treatment of chronic hepatitis C (CHC) in adolescents aged 12 to < 18 years and who weigh at least 30 kg.

For specific activity against the different genotypes of the hepatitis C virus (HCV), see sections 4.4 and 5.1 of the product information.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adolescents aged 12 to < 18 years with chronic hepatitis C (genotypes 1 and 4):

Appropriate comparator therapy for Elbasvir/ grazoprevir:

Ledipasvir/ sofosbuvir or glecaprevir/ pibrentasvir or sofosbuvir/ velpatasvir

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.

[1] General Methods, version 6.0 from 05.11.2020. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

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. Peginterferon alfa-2a, peginterferon alfa-2b, interferon alfa-2b - each in combination with ribavirin - are approved for the treatment of chronic hepatitis C in previously untreated subjects aged below 18 years. Ledipasvir/ sofosbuvir is approved for therapy naïve and pretreated adolescents aged 3 years and older with treatment recommendations for genotypes 1, 4, 5 or 6 and - only in combination with ribavirin and only in the presence of cirrhosis in treatment naïve subjects - for genotype 3. Sofosbuvir is approved in adolescents aged 12 to below 18 years with treatment recommendations for genotypes 2 and 3 in combination with ribavirin. The combinations of active ingredients glecaprevir/ pibrentasvir, sofosbuvir/ velpatasvir and sofosbuvir/ velpatasvir/ voxilaprevir are approved across genotypes in adolescents aged 12 to below 18 years.

on 2. Non-medicinal treatments are not considered for the therapeutic indication.

on 3. In the therapeutic indication, there are resolutions of the G-BA on the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a SGB V on active ingredients/ combinations of active ingredients for the treatment of chronic hepatitis C. In the therapeutic indication for adolescents aged 12 to < 18 years, there are resolutions on the combination of active ingredients ledipasvir/ sofosbuvir dated 15 February 2018, sofosbuvir dated 5 April 2018, glecaprevir/ pibrentasvir dated 17 October 2019, sofosbuvir/ velpatasvir dated 1 April 2021 and sofosbuvir/ velpatasvir/ voxilaprevir dated 7 April 2022.

on 4. The generally recognised 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 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 therapeutic indication according to Section 35a, paragraph 7 SGB V.

It can be stated that the data basis for medicinal therapies and treatment cascades in the present therapeutic indication is limited overall, but the approved DAAs sofosbuvir in combination with ribavirin, ledipasvir/ sofosbuvir, glecaprevir/ pibrentasvir and sofosbuvir/ velpatasvir have already been considered in the current guidelines.

In previously untreated adolescents, the combination of peginterferon and ribavirin still represents an alternative to the other combinations of active ingredients, but is no longer recommended as a priority. Therapy with non-pegylated interferon is not

recommended. Avoiding the side effects of interferon-containing therapy (especially growth retardation and weight loss) is of particular importance in the present patient population, which is why peginterferons - although approved - were not determined as an alternative appropriate comparator therapy.

The combinations of active ingredients glecaprevir/ pibrentasvir and sofosbuvir/ velpatasvir are an appropriate treatment option for all adolescents aged 12 to < 18 years. Due to their pan-genotypic marketing authorisation, high SVR rates and positive side-effect profiles, they have proven their worth in care and are also regarded as standard therapy by both the guidelines and clinical experts. In addition, the G-BA identified a hint for a non-quantifiable additional benefit for patients with genotypes 1, 4, 5 or 6 for the combination of active ingredients ledipasvir/ sofosbuvir.

In addition, the treatment option sofosbuvir/ velpatasvir/ voxilaprevir is available. However, due to the recent resolution on the early benefit assessment, it is not yet considered sufficiently established in everyday care and is currently not considered an appropriate comparator therapy.

In summary, the options glecaprevir/ pibrentasvir, sofosbuvir/ velpatasvir and ledipasvir/ sofosbuvir are thus determined as equally appropriate comparator therapies.

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

Change of the appropriate comparator therapy

Until now, the combination of active ingredients sofosbuvir/ velpatasvir was not included in the options of the appropriate comparator therapy.

Taking into account the clinical treatment setting, the G-BA considers it appropriate to expand the specific appropriate comparator therapies to include the option of sofosbuvir/ velpatasvir and thus to adapt them to the current state of medical knowledge.

In addition, the observed virological response rates of sofosbuvir/ velpatasvir are comparable to those of the specific appropriate comparator therapies ledipasvir/ sofosbuvir and glecaprevir/ pibrentasvir.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of elbasvir/ grazoprevir is assessed as follows:

An additional benefit is not proven for adolescents aged 12 to < 18 years with chronic hepatitis C of genotypes 1 and 4.

Justification:

The pharmaceutical company presents results of the non-randomised, open-label, multicentre, single-arm MK-5172-079 study for patients aged 12 to below 18 years.

The age cohort of the study included 22 patients with chronic hepatitis C infection of genotype 1 (n=21) and 4 (n=1) without liver cirrhosis.

The study examined mortality, sustained virological response (SVR) as the endpoints of morbidity and side effects. These endpoints are fundamentally patient-relevant. Data on health-related quality of life were not collected.

Due to the lack of a comparison, the single-arm study is not suitable for assessing an additional benefit; this would only be possible with very large effects compared to the appropriate comparator therapy.

Mortality

No deaths occurred.

Morbidity

A sustained virological response 12 (SVR12) and 24 weeks (SVR24) after the end of the treatment was achieved with elbasvir/ grazoprevir in all 22 patients (100%). The results of the MK-5172-079 study are in a similar order of magnitude as those of the appropriate comparator therapy.

For ledipasvir/ sofosbuvir, SVR12 and SVR 24 of 95-100% were observed (see G-BA resolution of 21 January 2021). For sofosbuvir/ velpatasvir, SVR12 and SVR 24 of approximately 93% was observed for children aged 6 to < 12 years (see G-BA resolution of 1 April 2021). For glecaprevir/ pibrentasvir, SVR12 of 90-98.3% was observed for children aged 6 to < 12 years (see G-BA resolution of 16 December 2021).

Great effects compared to the appropriate comparator therapy can therefore not be assumed.

Quality of life

No data on health-related quality of life are available.

Side effects

In the MK-5172-079 study, one serious adverse event (SAE) and no therapy discontinuations due to AEs occurred.

Overall assessment

The presented single-arm MK-5172-079 study is not suitable for the assessment of an additional benefit due to the lack of a comparison with the respective appropriate comparator therapy; this would only be possible with very large effects compared to the appropriate comparator therapy. A sustained virological response 12 (SVR12) and 24 weeks (SVR24) after the end of the treatment was achieved with elbasvir/ grazoprevir in all 21 patients (100%). The results of the MK-5172-079 study are in the same order of magnitude as those of the appropriate comparator therapy.

There were no deaths, one serious adverse event and no adverse events leading to therapy discontinuation. No data on health-related quality of life are available.

Overall, no additional benefit can be derived on the basis of the data presented.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the medicinal product Zepatier with the combination of active ingredients elbasvir/ grazoprevir.

The therapeutic indication assessed here is as follows: Zepatier is indicated for the treatment of chronic hepatitis C (CHC) in adolescents aged 12 to < 18 years and who weigh at least 30 kg. For specific activity against the different genotypes of the hepatitis C virus (HCV), see sections 4.4 and 5.1 of the product information.

The G-BA determined the combinations of active ingredients glecaprevir/ pibrentasvir or sofosbuvir/ velpatasvir or ledipasvir/ sofosbuvir to be the appropriate comparator therapy for adolescents aged 12 to < 18 years with chronic hepatitis C (genotypes 1 and 4).

For the benefit assessment of elbasvir/ grazoprevir for the treatment of adolescents aged 12 to < 18 years with chronic hepatitis C, only data from the single-arm, non-comparator MK-5172-079 study were presented. Due to the lack of comparison, the data are not suitable for the derivation of an additional benefit compared to the appropriate comparator therapy. In addition, the observed virological response rates are in the same order of magnitude as for the respective appropriate comparator therapies.

An additional benefit of elbasvir/ grazoprevir versus the appropriate comparator therapy 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.

The G-BA bases its resolution on the patient numbers from the dossier submitted by the pharmaceutical company.

These patient numbers submitted by the pharmaceutical company for the age group relevant here are each fraught with uncertainty due to the exclusive consideration of newly reported patients within a 1-year period with a known age, unclear percentage values of acute HCV infections as well as the non-inclusion of cases not yet diagnosed or not reported.

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 Zepatier (active ingredient: elbasvir/ grazoprevir) at the following publicly accessible link (last access: 15 April 2022):

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

Treatment with elbasvir/ grazoprevir should only be initiated and monitored by specialists who are experienced in the treatment of adolescents with chronic hepatitis C virus infection.

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: 15 April 2022).

According to the product information, the following therapy options are available:

Designation of the therapy	Duration of the treatment cycle	Use according to product information:
Medicinal product to be assessed		

Designation of the therapy	Duration of the treatment cycle	Use according to product information:
Elbasvir/ grazoprevir	12 weeks	Patients with genotype 1, 4 with or without compensated cirrhosis.
Elbasvir/ grazoprevir + ribavirin	16 weeks	Patients with genotype 1, 4 with or without compensated cirrhosis.
Appropriate comparator therapy		
Ledipasvir/ sofosbuvir	8 weeks	Can be considered in genotype 1 patients without cirrhosis.
Ledipasvir/ sofosbuvir	12 weeks	Patients with genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis, a low risk of progression and retreatment option.
Ledipasvir/ sofosbuvir	24 weeks	Patients with genotype 1, 4, 5 or 6 and compensated cirrhosis.
Glecaprevir/ pibrentasvir	8 weeks	Therapy naïve patients with genotype 1, 4, 5 or 6 with or without cirrhosis
Glecaprevir/ pibrentasvir	8 weeks	Pretreated patients with genotype 1, 4-6 without cirrhosis
Glecaprevir/ pibrentasvir	12 weeks	Pretreated patients with genotype 1, 4-6 with cirrhosis
Sofosbuvir/ velpatasvir	12 weeks	Patients aged 3 years and older regardless of HCV genotype

Treatment period

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.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Elbasvir/ grazoprevir	1 x daily for 12 weeks	84	1	84
Elbasvir/ grazoprevir + ribavirin	1 x daily + 2 x daily for 16 weeks	112	1	112
Appropriate comparator therapy				
Ledipasvir/ sofosbuvir	1 x daily for 8 weeks	56	1	56
Ledipasvir/ sofosbuvir	1 x daily for 12 weeks	84	1	84
Ledipasvir/ sofosbuvir	1 x daily for 24 weeks	168	1	168
Glecaprevir/ pibrentasvir	1 x daily for 8 weeks	56	1	56

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Glecaprevir/ pibrentasvir	1 x daily for 12 weeks	84	1	84
Sofosbuvir/ velpatasvir	1 x daily for 12 weeks	84	1	84

Consumption:

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.

The average body measurements were applied for dosages depending on body weight or body surface area (BSA) (average height and weight of a 12-year-old: 1.56 m and 47.1 kg; average height of a 17-year-old: 1.74 m, average body weight: 67.0 kg)[2].

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					
Elbasvir/ grazoprevir					
Elbasvir/ grazoprevir	50 mg/100 mg	50 mg/100 mg	1 x 50 mg/100 mg	84	84 x 50 mg/100 mg
Elbasvir/ grazoprevir in combination with ribavirin					
Elbasvir/ grazoprevir	50 mg/100 mg	50 mg/100 mg	1 x 50 mg/100 mg	112	112 x 50 mg/100 mg
Ribavirin	Patients 12 to under 13 years				
	400 mg	800 mg	2 x 400 mg	112	224 x 400 mg
	Patients 17 to under 18 years				
	400 or 600 mg	1,000 mg	1 x 200 mg + 2 x 400 mg	112	112 x 200 + 224 x 400 mg
Appropriate comparator therapy					
Ledipasvir/ sofosbuvir	90 mg/ 400 mg	90 mg/ 400 mg	1 x 90 mg/400 mg	56	56 x 90 mg/400 mg
Ledipasvir/ sofosbuvir	90 mg/ 400 mg	90 mg/ 400 mg	1 x 90 mg/400 mg	84	84 x 90 mg/400 mg

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

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Ledipasvir/ sofosbuvir	90 mg/ 400 mg	90 mg/ 400 mg	1 x 90 mg/400 mg	168	168 x 90 mg/400 mg
Glecaprevir/ pibrentasvir	300 mg/ 120 mg	300 mg/120 mg	3 x 100 mg/40 mg	56	168 x 100 mg/40 mg
Glecaprevir/ pibrentasvir	300 mg/ 120 mg	300 mg/120 mg	3 x 100 mg/40 mg	84	252 x 100 mg/40 mg
Sofosbuvir/ velpatasvir	400 mg/ 100 mg	400 mg/ 100 mg	1 x 400 mg/100 mg	84	84 x 400 mg/100 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.

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					
Elbasvir/ grazoprevir 50/100 mg	28 FCT	€ 8,666.97	€ 1.77	€ 0.00	€ 8,665.20
Ribavirin 200 mg	112 FCT	€ 538.89	€ 1.77	€ 36.00	€ 501.12
Ribavirin 400 mg	56 FCT	€ 538.89	€ 1.77	€ 25.04	€ 512.08
Appropriate comparator therapy					
Glecaprevir/ pibrentasvir 100/40 mg	84 FCT	€ 14,995.30	€ 1.77	€ 0.00	€ 14,993.53
Ledipasvir/ sofosbuvir 45/200 mg and 90/400 mg	28 FCT	€ 14,995.30	€ 1.77	€ 0.00	€ 14,993.53
Sofosbuvir/ velpatasvir 400/100 mg	28 FCT	9,996.95	€ 1.77	€ 0.00	€ 9,995.18
Abbreviations: FCT = film-coated tablets					

LAUER-TAXE® last revised: 15 April 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.

HCV RNA testing is not listed because it can be assumed that this is a part of all active therapies by default.

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 12 October 2021, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 12 November 2021, the pharmaceutical company submitted a dossier for the benefit assessment of elbasvir/ grazoprevir to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

By letter dated 15 November 2021 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 elbasvir/ grazoprevir.

The dossier assessment by the IQWiG was submitted to the G-BA on 11 February 2022, and the written statement procedure was initiated with publication on the website of the G-BA on 15 February 2022. The deadline for submitting written statements was 9 March 2022.

The oral hearing was held on 28 March 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 26 April 2022, and the proposed resolution was approved.

At its session on 5 May 2022, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	12 October 2021	Determination of the appropriate comparator therapy
Working group Section 35a	15 March 2022	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal products	28 March 2022	Conduct of the oral hearing,
Working group Section 35a	5 April 2022 19 April 2022	Consultation on the dossier assessment by the IQWiG, assessment of the written statement procedure
Subcommittee Medicinal products	26 April 2022	Concluding discussion of the draft resolution
Plenum	5 May 2022	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 5 May 2022

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

Prof. Hecken