Gemeinsamer Bundesausschuss

Justification

to 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
Rimegepant (acute treatment of migraine)

of 20 November 2025

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical studies the pharmaceutical company have conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application,
7. number of study participants who participated in the clinical studies at study sites within the scope of SGB V, and total number of study participants.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

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

2. Key points of the resolution

The relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient rimegepant on 1 June 2025 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 28 May 2025.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 September 2025 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 rimegepant 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 have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5 Section 5, paragraph 7 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of rimegepant.

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

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

2.1.1 Approved therapeutic indication of Rimegepant (Vydura) in accordance with the product information

VYDURA is indicated for the

- Acute therapy of migraine with or without aura in adults;
- Preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month.

Therapeutic indication of the resolution (resolution of 20.11.2025):

Acute therapy of migraine with or without aura in adults.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults with migraine with or without aura who require acute therapy for the treatment of migraine headaches

Appropriate comparator therapy for rimegepant:

An individualised therapy with selection of

- selective serotonin 5HT1 receptor agonists (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan), and
- non-steroidal anti-inflammatory drugs (acetylsalicylic acid, diclofenac, ibuprofen)

[1] General Methods, version 7.0 from 19.09.2023. 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 and Section 6 paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication 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.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved in the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved in the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

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

On 1. In addition to the active ingredient rimegepant to be assessed, the following active ingredients from the product class of selective serotonin 5-HT1 receptor agonists (triptans) are approved in the present therapeutic indication for acute therapy of

migraine attacks: Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan. In addition, some non-steroidal anti-inflammatory drugs (NSAIDs), including acetylsalicylic acid, diclofenac and ibuprofen, the selective Cox-2 inhibitor celecoxib, as well as the active ingredients lasmiditan, paracetamol (as monotherapy or in a fixed combination with caffeine) and phenazone are approved for the acute therapy of migraine.

On 2. A non-medicinal treatment cannot be considered in the present therapeutic indication.

On 3. The following resolution of the G-BA on the early benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V is available for the therapeutic indication to be assessed for the acute therapy of migraine:

- Lasmiditan from 5 October 2023.

The provisions of the Pharmaceuticals Directive (AM-RL) Annex III concerning prescription restrictions and exclusions in the supply of medicinal products must be taken into account. According to No. 36 Annex III, medicinal product combinations for migraine are excluded from the prescription.

On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as systematic reviews of clinical studies in the present indication and is presented in the "Research and synopsis of the evidence to determine the appropriate comparator therapy according to Section 35a SGB V".

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present therapeutic indication according to Section 35a, paragraph 7 SGB V.

The available evidence on the acute therapy of migraine headaches is clear overall. The guidelines recommend both medicinal products of the product class of triptans and certain active ingredients of the group of non-steroidal anti-inflammatory drugs (NSAIDs).

The efficacy and safety of triptans for the treatment of acute migraine attacks with or without aura have been sufficiently proven and the therapy is already established in healthcare. Benefit-related differences between the individual triptans have not been proven, so that the active ingredients almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan can be regarded as equivalent to each other. Based on existing evidence, treatment with triptans is one of the pillars in the therapy of migraine attacks. Triptans are particularly recommended for severe migraine headaches and for subjects with an inadequate response to analgesics.

In addition to triptans, acetylsalicylic acid, diclofenac and ibuprofen from the NSAID product class are considered to be therapy options that are generally accepted in clinical practice for the treatment of mild-to-moderate migraine headaches. The above-mentioned NSAIDs are also recommended in the guidelines. Paracetamol and phenazone play a subordinate role in the German healthcare context and are not considered as the appropriate comparator therapy.

There is currently only limited evidence on the use of the selective Cox-2 inhibitor celecoxib for the acute treatment of migraine attacks. In addition, the significance in

the German healthcare context cannot be conclusively assessed, which is why celecoxib is not considered as the appropriate comparator therapy.

In the benefit assessment of the new active ingredient lasmiditan, no additional benefit thereof over the appropriate comparator therapy was demonstrated. In addition, high significance of lasmiditan compared to the already established therapy options in the therapeutic indication cannot be deduced from the available evidence. Based on the generally accepted state of medical knowledge, lasmiditan is not determined to be the appropriate comparator therapy for the present resolution.

In the overall assessment, the G-BA therefore consider it appropriate in the present therapeutic indication to determine the appropriate comparator therapy for rimegepant to be an individualised therapy with selection of selective serotonin 5-HT1 receptor agonists (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan) and non-steroidal anti-inflammatory drugs (acetylsalicylic acid, diclofenac, ibuprofen).

Individualised therapy is based on the assumption that several treatment options, which allow an individualised medical treatment decision, are available. Taking into account the available evidence, any pretreatment given, the severity of the attack and any existing concomitant diseases must in particular be taken into account for making the treatment decision.

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

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.

Editorial note: The term "individualised therapy" is used instead of previously used terms such as "patient-individual therapy" or "therapy according to doctor's instructions". This harmonises the terms used in the European assessment procedures (EU-HTA).

2.1.3 Extent and probability of the additional benefit

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

Adults with migraine with or without aura who require acute therapy for the treatment of migraine headaches

An additional benefit is not proven.

Justification:

The pharmaceutical company additionally presented the placebo-controlled BHV3000-301, BHV3000-302 and BHV3000-303 approval studies for the assessment of the additional benefit of rimegepant for use in the acute therapy of migraine headaches with or without aura. In addition, further studies on rimegepant were cited in the dossier as supporting evidence, without the results of these studies being presented. However, the pharmaceutical company did not submit any relevant studies comparing rimegepant with the appropriate comparator therapy.

Due to the lack of comparison of rimegepant with the appropriate comparator therapy, the studies presented are unsuitable for the assessment of the additional benefit. An additional benefit of rimegepant compared with the appropriate comparator therapy is therefore not proven.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product VYDURA with the active ingredient rimegepant, which is approved for the acute therapy of migraine with or without aura in adults and for the preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month.

The therapeutic indication assessed here is the acute therapy of migraine with or without aura in adults. The appropriate comparator therapy was determined to be an individualised therapy with selection of selective serotonin 5-HT1 receptor agonists (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan) and non-steroidal anti-inflammatory drugs (acetylsalicylic acid, diclofenac, ibuprofen).

No suitable studies that would allow a comparison of rimegepant with the appropriate comparator therapy were presented for the assessment of the additional benefit of rimegepant. An additional benefit of rimegepant for use in the acute therapy of migraine is therefore not proven.

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

The information on the number of patients is based on the target population in statutory health insurance (SHI). The resolution is based on the patient numbers stated in the pharmaceutical company's dossier. It is however assumed that the information given is underestimated. For the calculation of patient numbers, the pharmaceutical company restricts the information based on health insurance data. In principle, however, patients who are receiving non-prescription medicinal products and are not yet undergoing medical treatment for their migraine are also eligible in the present therapeutic indication. Therefore, the patient numbers stated do not include all patients in the SHI target population.

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 Vydura (active ingredient: rimegepant) at the following publicly accessible link (last access: 14 November 2025):

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

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 September 2025).

The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

The annual treatment costs are different from patient to patient depending on the frequency of attacks. For the purpose of comparability, the costs are calculated for an exemplary range of 1 to 60 migraine attacks per year. A shelf-life-related discard is taken into account for the cost representation.

The appropriate comparator therapy comprises pharmacy-only, non-prescription medicinal products. These are excluded from care according to Section 31 SGB V. An exceptional circumstance according to Section 34, paragraph 1, sentence 2 SGB V does not exist. Thus, the prescription of these medicinal products is not allowed at the expense of the statutory health insurance. Therefore, the cost representation for these preparations is omitted in the resolution according to Section 35a paragraph 3 SGB V.

A prescription-only proprietary medicinal product specifically approved for migraine has been identified for the active ingredient diclofenac. As this prescription-only proprietary medicinal product differs from over-the-counter proprietary medicinal products with the active ingredient diclofenac in terms of the therapeutic indication, potency and the recommended dosage, it must be taken into account when calculating the annual treatment costs.

Both prescription-only and pharmacy-only, non-prescription medicinal products are available for the active ingredients almotriptan, naratriptan and sumatriptan. The annual treatment costs are represented with a lower limit of € 0, taking into account the availability of non-prescription, non-reimbursable alternatives in accordance with Section 34 SGB V and Section 12 Pharmaceuticals Directive.

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.

Adults with migraine with or without aura who require acute treatment of migraine headaches

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				
Rimegepant	1 x per migraine attack	1 – 60	1	1 – 60
Appropriate comparator therapy				
An individualised therapy with selection of – selective serotonin 5HT1 receptor agonists (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan), and – non-steroidal anti-inflammatory drugs (acetylsalicylic acid, diclofenac, ibuprofen)				
Almotriptan	1-2 x per migraine attack	1 – 60	1	1 – 60
Eletriptan	1-2 x per migraine attack	1 – 60	1	1 – 60
Frovatriptan	1-2 x per migraine attack	1 – 60	1	1 – 60
Naratriptan	1-2 x per migraine attack	1 – 60	1	1 – 60
Rizatriptan	1-2 x per migraine attack	1 – 60	1	1 – 60
Sumatriptan	1-2 x per migraine attack	1 – 60	1	1 – 60
Zolmitriptan	1-2 x per migraine attack	1 – 60	1	1 – 60
Diclofenac	1-4 x per migraine attack	1 – 60	1	1 – 60

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					
Rimegepant	75 mg	75 mg	1 x 75 mg	1 – 60	1 x 75 mg – 60 x 75 mg
Appropriate comparator therapy					
An individualised therapy with selection of – selective serotonin 5HT1 receptor agonists (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan), and – non-steroidal anti-inflammatory drugs (acetylsalicylic acid, diclofenac, ibuprofen)					
Almotriptan	12.5 mg	12.5 – 25 mg	1 x 12.5 mg – 2 x 12.5 mg	1 – 60	1 x 12.5 mg – 120 x 12.5 mg
Eletriptan	40 mg	40 – 80 mg	1 x 40 mg – 2 x 40 mg	1 – 60	1 x 40 mg – 120 x 40 mg
Frovatriptan	2.5 mg	2.5 – 5 mg	1 x 2.5 mg – 2 x 2.5 mg	1 – 60	1 x 2.5 mg – 120 x 2.5 mg
Naratriptan	2.5 mg	2.5 – 5 mg	1 x 2.5 mg – 2 x 2.5 mg	1 – 60	1 x 2.5 mg – 120 x 2.5 mg
Rizatriptan	10 mg	10 – 20 mg	1 x 10 mg – 2 x 10 mg	1 – 60	1 x 10 mg – 120 x 10 mg
Sumatriptan	50 mg – 100 mg	50 – 200 mg	1 x 50 mg – 2 x 100 mg	1 – 60	1 x 50 mg – 120 x 100 mg

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Zolmitriptan	2.5 mg – 5 mg	2.5 – 10 mg	1 x 2.5 mg – 2 x 5 mg	1 – 60	1 x 2.5 mg – 120 x 5 mg
Diclofenac (50 mg/ml)	50 mg (≙ 1 ml)	50 – 200 mg (≙ 1 – 4 ml)	1 x 50 mg – 4 x 50 mg (≙ 1 x 1 ml – 1 x 4 ml)	1 – 60	1 x 50 mg – 240 x 50 mg (≙ 1 x 1 ml – 60 x 4 ml)

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

Costs of the medicinal products:

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					
Rimegepant 75 mg	16 ODL	€ 483.26	€ 1.77	€ 26.13	€ 455.36
Appropriate comparator therapy					
Almotriptan 12.5 mg[2]	14 FCT	€ 33.68	€ 1.77	€ 1.77	€ 30.14
Eletriptan 40 mg[2]	6 FCT	€ 21.79	€ 1.77	€ 0.83	€ 19.19
Eletriptan 40 mg[2]	12 FCT	€ 31.02	€ 1.77	€ 1.56	€ 27.69
Frovatriptan 2.5 mg[2]	3 FCT	€ 16.80	€ 1.77	€ 0.43	€ 14.60
Frovatriptan 2.5 mg[2]	12 FCT	€ 30.74	€ 1.77	€ 1.54	€ 27.43
Naratriptan 2.5 mg[2]	12 FCT	€ 30.74	€ 1.77	€ 1.54	€ 27.43
Rizatriptan 10 mg[2]	3 TAB	€ 16.89	€ 1.77	€ 0.44	€ 14.68
Rizatriptan 10 mg[2]	18 TAB	€ 39.87	€ 1.77	€ 2.26	€ 35.84
Sumatriptan 100 mg[2]	12 TAB	€ 31.31	€ 1.77	€ 1.58	€ 27.96
Zolmitriptan 2.5 mg[2]	3 ODT	€ 16.49	€ 1.77	€ 0.41	€ 14.31
Zolmitriptan 5 mg[2]	12 FCT	€ 31.56	€ 1.77	€ 1.60	€ 28.19
Diclofenac 50 mg/ml	10 OD	€ 27.86	€ 1.77	€ 0.78	€ 25.31

[2] Fixed reimbursement rate

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
Diclofenac 50 mg/ml	30 OD	€ 61.40	€ 1.77	€ 2.38	€ 57.25
Abbreviations: FCT = film-coated tablet; ODL = orally disintegrating lyophilisate; TAB = tablets; ODT = orally disintegrating tablets; OD = oral drops					

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Costs for additionally required SHI services:

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

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

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

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

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

Basic principles of the assessed medicinal product

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

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

A designation is also not considered if the G-BA have decided on an exemption as a reserve antibiotic for the assessed medicinal product in accordance with Section 35a, paragraph 1c,

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

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

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

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

- names a product class or group from which some active ingredients not specified in detail can be used in combination therapy with the assessed medicinal product, or
- does not name any active ingredients, product classes or groups, but the assessed medicinal product is used in addition to a therapeutic indication described in more detail in the relevant product information, which, however, does not include information on active ingredients within the scope of this therapeutic indication.

Concomitant active ingredient

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

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

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

In addition, there must be no reasons for exclusion of the concomitant active ingredient from

a combination therapy with the assessed medicinal product, in particular no exclusive marketing authorisation as monotherapy.

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

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

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

Designation

The medicinal products which have been determined as concomitant active ingredients in accordance with the above points of examination are named by indicating the relevant active ingredient and the invented name. The designation may include several active ingredients, provided that several medicinal products with new active ingredients may be used in the same combination therapy with the assessed medicinal product or different combinations with different medicinal products with new active ingredients form the basis of the designation.

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

Exception to the designation

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

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

Legal effects of the designation

The designation of combinations is carried out in accordance with the legal requirements

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

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

Justification for the findings on designation in the present resolution:

Adults with migraine with or without aura who require acute therapy for the treatment of migraine headaches

No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.
References:

Product information for rimegepant (Vydura); VYDURA® 75 mg orally disintegrating lyophilisate; last revised: April 2025

2.6 Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product Vydura is a medicinal product placed on the market from 1 January 2025. In accordance with Section 35a, paragraph 3, sentence 5 SGB V, the G-BA must determine whether a relevant percentage of the clinical studies on the medicinal product were conducted within the scope of SGB V. This is the case if the percentage of study participants who have participated in the clinical studies on the medicinal product to be assessed in the therapeutic indication to be assessed at study sites within the scope of SGB V is at least five per cent of the total number of study participants.

The calculation is based on all studies that were submitted as part of the benefit assessment dossier in the therapeutic indication to be assessed in accordance with Section 35a, paragraph 1, sentence 3 SGB V in conjunction with Section 4, paragraph 6 AM-NutzenV.

Approval studies include all studies submitted to the regulatory authority in section 2.7.3 (Summary of Clinical Efficacy) and 2.7.4 (Summary of Clinical Safety) of the authorisation dossier in the therapeutic indication for which marketing authorisation has been applied for. In addition, studies, which were conducted in whole or in part within the therapeutic indication described in this document, and in which the company was a sponsor or is otherwise financially involved, must also be indicated.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is <

5% (0.62%) of the total number of study participants according to the information in the dossier.

In the dossier, the pharmaceutical company provided information on a total of 15 studies in the present therapeutic indication, with a total percentage of 0.62% study participants at German study sites. For the BHV3000-310 and BHV3000-406 studies, no information on the number of study participants was available in the dossier. The information on the BHV3000-201 and BHV3000-301 studies in the dossier differed from IQWiG's calculation. In addition, the BHV3000-318 study was identified as a further study, which was sponsored by the pharmaceutical company, for which a study registry entry is available, recruitment has been completed and is therefore to be included in the calculation, but was not considered in the dossier.

In the written statement of the pharmaceutical company, information on the BHV300-310 and BHV3000-406 studies was subsequently submitted and the deviations in the BHV3000-201 and BHV3000-301 studies addressed by IQWiG were reviewed.

Overall, taking into account the written statement and the BHV3000-318 study, it is determined that the percentage of study participants at study sites within the scope of SGB V remains < 5%.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant extent within the scope of SGB V.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

At their session on 3 March 2023, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

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

By letter dated 30 May 2025 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit 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 rimegepant.

The dossier assessment by the IQWiG was submitted to the G-BA on 28 August 2025, and the written statement procedure was initiated with publication on the G-BA website on 1 September 2025. The deadline for submitting written statements was 22 September 2025.

The oral hearing was held on 6 October 2025.

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 11 November 2025, and the proposed draft resolution was approved.

At their session on 20 November 2025, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	3 March 2023	Determination of the appropriate comparator therapy
Working group Section 35a	30 September 2025	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	6 October 2025	Conduct of the oral hearing
Working group Section 35a	14 October 2025 4 November 2025	Consultation on the dossier evaluation by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	11 November 2025	Concluding discussion of the draft resolution
Plenum	20 November 2025	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 20 November 2025

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

Prof. Hecken