GBA
Gemeinsamer
Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (GBA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Dupilumab (new therapeutic indication: chronic spontaneous urticaria (CSU), ≥ 2 years to < 12 years)

of 5 November 2026

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1. Legal basis

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

The GBA 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 GBA 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 active ingredient dupilumab (Dupixent) was listed for the first time on 1 December 2017 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 8 April 2026, dupilumab received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 from 12.12.2008, sentence 7).

On 5 May 2026, i.e. at the latest within four weeks of informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company submitted a dossier in due time in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the GBA concerning

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the active ingredient dupilumab with the new therapeutic indication "for the treatment of moderate to severe CSU in children (2 – 11 years) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU".

The GBA came to a decision on whether an additional benefit of dupilumab 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 GBA 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 dupilumab.

In the light of the above, and taking into account the statements received and the oral hearing, the GBA have made 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 dupilumab (Dupixent) in accordance with the product information

Dupixent is indicated for the treatment of moderate to severe chronic spontaneous urticaria in adults, adolescents and children (2 years and above) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU.

Therapeutic indication of the resolution (resolution of 05.11.2026):

Dupixent is indicated for the treatment of moderate to severe CSU in children (2–11 years) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Children ≥ 2 years to < 12 years of age with moderate to severe chronic spontaneous urticaria with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU

Appropriate comparator therapy for dupilumab:

- Omalizumab, in combination with H1 antihistamines of the 2nd generation

[1] General Methods, version 8.0 from 19.12.2025. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

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Criteria according to Chapter 5 Section 6 of the Rules of Procedure of the GBA 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 according to 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 GBA must be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy must 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 GBA 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 for 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 for the therapeutic indication.

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

On 1. In addition to dupilumab, H1 antihistamines of the first generation (e.g. hydroxyzine) and of the second generation (e.g. cetirizine, loratadine) are approved for the

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treatment of chronic spontaneous urticaria in children under 12 years of age. Systemic glucocorticoids (e.g. prednisolone) are approved for acute treatment.

On 2. Non-medicinal treatment options are not considered in the present therapeutic indication as a rule.

On 3. No GBA resolutions are available for the therapeutic indication - chronic spontaneous urticaria.

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 indication according to Section 35a, paragraph 7 SGB V (see "Information on Appropriate Comparator Therapy").

The approved treatment options and the evidence for the therapy of chronic spontaneous urticaria in children are limited. Guidelines 2,3 generally recommend applying the same treatment algorithm for children with urticaria as for adults (exercise caution: for example, regarding weight-adjusted dosages).

H1 antihistamines are generally approved for the treatment of chronic spontaneous urticaria in children under 12 years of age. Due to their marketing authorisation and side-effect profile, systemic glucocorticoids are only available for the acute treatment of an acute exacerbation of chronic spontaneous urticaria. Consequently, these are not considered as the appropriate comparator therapy for the long-term treatment of patients in the intended therapeutic indication. The biologic agent omalizumab, by contrast, is only approved for patients 12 years and above.

Based on the evidence available in the therapeutic indication and the guidelines, H1 antihistamines of the 2nd generation are initially recommended for the treatment of chronic spontaneous urticaria in adults. These should initially be administered at the standard dose (according to the marketing authorisation). If there is no response, dose escalation to up to four times the approved dose is recommended. If there is a continued inadequate response to antihistamines of the 2nd generation, a combination of H1 antihistamines of the 2nd generation and omalizumab is recommended. These therapy recommendations are also applied to the paediatric patient cohort in this context.

The international guideline "The International Guideline for the Definition, Classification, Diagnosis and Management of Urticaria" 2, on which the German S3 guideline3 – currently under revision – is based, it is recommended applying the same

[2] Zuberbier T et al. The International Guideline for the Definition, Classification, Diagnosis and Management of Urticaria. Allergy. 2026 Feb 6. doi: 10.1111/all.70210. Epub ahead of print. PMID: 41649409.

[3] S3 guideline on the classification, diagnosis and treatment of urticaria; p. 43: "For patients with chronic urticaria who do not respond to a standard-dose H1 antihistamine of the 2nd generation, dose escalation up to four times* is recommended as a second-line therapy option prior to consideration of other treatments."

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treatment algorithm for children with urticaria as for adults (exercise caution: for example, with regard to weight-adjusted dosages) (weak level of recommendation).

Dose escalation to up to four times the approved dose is recommended for the treatment of chronic urticaria in adults if they do not respond to a standard-dose H1 antihistamine of the 2nd generation. This recommendation is consensus- and evidence-based and has the highest possible level of recommendation (evidence basis: relevant RCTs4). This recommendation is also set out in a UK guideline5.

According to current therapy recommendations, dose escalation of H1 antihistamines of the 2nd generation to up to four times the approved dose for adults must be considered the therapy standard for the treatment of patients with chronic spontaneous urticaria who do not respond to a standard-dose H1 antihistamine of the 2nd generation.

This is a paediatric therapeutic indication. There is no significant evidence from clinical studies regarding the off-label use of H1 antihistamines of the 2nd generation in children at a dose escalated to up to four times the approved dose. Taking into account the generally available marketing authorisation of H1 antihistamines of the 2nd generation in this therapeutic indication, the medical necessity as well as the aforementioned recommendations on the treatment algorithm for children, the described dose escalation of H1 antihistamines can still be considered the therapy standard for the pediatric patient cohort in healthcare.

In accordance with the generally recognised state of medical knowledge, it can be concluded in the overall assessment that the off-label use of H1 antihistamines of the 2nd generation at a dose up to four times the approved dose for the treatment of urticaria is the therapy standard in the therapeutic indication under assessment for patients with inadequate response to H1 antihistamines of the 2nd generation at the standard dose, and must generally be preferred to the use of the approved dose; Section 6, paragraph 2, sentence 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV).

If the dose escalation of H1 antihistamines of the 2nd generation has an inadequate effect, the international guideline[1] recommends the additional administration of omalizumab. Omalizumab is approved as an add-on therapy for the treatment of chronic spontaneous urticaria in adults and adolescents (12 years and above).

Given the condition - stipulated within the therapeutic indication of dupilumab - that the therapy options with H1 antihistamines of the 2nd generation including dose escalation up to four times the approved dosage are exhausted prior to administration of dupilumab, no approved therapy options are available for patients ≥ 2 years to < 12 years of age within this therapeutic indication. Furthermore, this is a paediatric therapeutic indication for which there is no significant evidence from clinical studies. However, chronic spontaneous urticaria has a significant negative impact on the quality of life and daily living of those affected.

[4] Evidence report on the relevant S3 guideline: Reference to multiple RCTs, page 24 et seq.

[5] Sabroe RA, Lawlor F, Grattan CEH, Ardern-Jones MR, Bewley A, Campbell L, et al. British Association of Dermatologists guidelines for the management of people with chronic urticaria 2021. Br J Dermatol 2022;186(3):398-413.

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The use of unapproved therapy options is medically necessary in this therapeutic indication. According to the generally recognised state of medical knowledge, the off-label use is considered the therapy standard in the therapeutic indication to be assessed. The medicinal product under assessment will be the first to be approved for this therapeutic indication (treatment of children 2–11 years of age with CSU who have an inadequate response to H1 antihistamines) (Section 6, paragraph 2, sentence 3, number 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV)). It is therefore appropriate in accordance with Section 6, paragraph 2, sentence 3, number 1 AM-NutzenV to designate the off-label use of omalizumab as the appropriate comparator therapy in the therapeutic indication for this patient cohort. This is supported both by the recommendations set out in the available guidelines and by the joint written statement issued by the DDG and the DGAKI, which designates the active ingredient omalizumab as the current treatment standard in the present treatment setting.

Consequently, the appropriate comparator therapy for the active ingredient dupilumab for the treatment of moderate to severe chronic spontaneous urticaria in children (≥ 2 years to < 12 years of age) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU is therefore determined to be omalizumab in combination with H1 antihistamines of the 2nd generation.

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

Any change to the appropriate comparator therapy requires a decision by the GBA based on a prior review of the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO.

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2.1.3 Extent and probability of the additional benefit

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

The additional benefit over the appropriate comparator therapy is not proven for the treatment of moderate to severe chronic spontaneous urticaria in children (≥ 2 years to < 12 years of age) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU.

Justification:

In their dossier, the pharmaceutical company did not present any data for the assessment of the additional benefit of dupilumab compared with the appropriate comparator therapy.

Overall, no data are therefore available to enable an assessment of the additional benefit of dupilumab for the treatment of moderate to severe chronic spontaneous urticaria in children (≥ 2 years to < 12 years of age) with moderate to severe chronic spontaneous urticaria with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU. An additional benefit is therefore not proven.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient dupilumab.

The therapeutic indication assessed here is: "for the treatment of moderate to severe CSU in children (2 – 11 years) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU".

The appropriate comparator therapy was determined to be "Omalizumab, in combination with H1 antihistamines of the 2nd generation".

The pharmaceutical company did not present any data to prove the additional benefit of dupilumab compared to the appropriate comparator therapy. Consequently, an additional benefit of dupilumab is not proven for the treatment of moderate to severe chronic spontaneous urticaria in children (≥ 2 years to < 12 years of age) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU.

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 information is based on the data provided by the pharmaceutical company in the dossier.

Definitive assessment of the estimate is not possible as it is subject to various uncertainties overall. There are uncertainties regarding routine data during the collection of prevalence data and pretreatment with H1 antihistamines, owing to the ICD codes used and over-the-counter availability of antihistamines, as well as regarding the operationalisation of severity based on an inadequate response to treatment with H1 antihistamines. The determination of the inadequate response is also subject to uncertainties due to different operationalisations

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as well as the fluctuating nature of the disease. It is not possible to make a definitive assessment of the presented estimate of the number of patients who are naive to anti-IgE antibodies.

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 Dupixent (active ingredient: dupilumab) at the following publicly accessible link (last access: 21 September 2026):

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

Treatment with dupilumab must be initiated and monitored by specialists experienced in treating patients with chronic spontaneous urticaria (CSU).

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 September 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

In general, initial induction regimens are not taken into account for the cost representation, since the present indication is a chronic disease with a continuous need for therapy and, as a rule, no new titration or dose adjustment is required after initial titration. Dupilumab is approved for the treatment of moderate to severe chronic spontaneous urticaria in patients (2 years and above) and may be used in combination with H1 antihistamines. Omalizumab is used as an add-on therapy to H1 antihistamines. The use of H1 antihistamines of the 2nd generation is recommended. For the treatment costs of H1 antihistamines, the range from the single dose up to four times the standard dose (OLU) is determined by a more cost-effective and a more cost-intensive therapy option.

For the treatment of severe chronic urticaria in children, the "S3 guideline on the classification, diagnosis and treatment of urticaria" recommends escalating the approved dose of H1 antihistamines of the 2nd generation to up to four times the standard dose, as well as combination therapy with omalizumab[6]. Use of omalizumab constitutes an off-label therapy option. Accordingly, the off-label therapy option of the appropriate comparator therapy was taken into account in the cost representation. The calculation was based on the standard dosages specified in the publications cited.

[6] German S3 guideline on the classification, diagnosis and treatment of urticaria, adapted from the international S3 guideline; AWMF guidelines registry (013-028) [online]. 2022; URL: https://register.awmf.org/assets/guidelines/013-028l_S3_Klassifikation-Diagnostik-Therapie-Urtikaria_2022-04.pdf.

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Children ≥ 2 years to < 12 years of age with moderate to severe chronic spontaneous urticaria with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU

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:				
Dupilumab	Children ≥ 2 years and < 30 kg BW			
	Continuously, 1 x every 28 days	13.0	1	13.0
	Children ≥ 6 years and > 30 kg BW			
	Continuously, 1 x every 14 days	26.1	1	26.1
if applicable, in combination with H1 antihistamines of the 2nd generation:				
Cetirizine	Continuously, 2 x daily	365.0	1	365.0
Rupatadine	Continuously, 1 x daily	365.0	1	365.0
Appropriate comparator therapy				
Omalizumab[7, 8]	Continuously, 1 x every 28 days	13.0	1	13.0
in combination with H1 antihistamines of the 2nd generation:				
Cetirizine	Continuously, 2 x daily	365.0	1	365.0
Rupatadine	Continuously, 1 x daily	365.0	1	365.0

Consumption:

For dosages depending on body weight (BW), the average body measurements from the official representative statistics "2025 Microcensus – body measurements of the population"[9] were used as a basis. The active ingredient dupilumab is dosed in children according to body weight. Standard patients with an average body weight of 14.8 kg (for children aged 2 years)

[7] Zhu W-F, Wang C, Qiao J-J, Li L-J. Safety and efficacy of omalizumab for antihistamine-resistant chronic urticaria in children: a case series and literature review. World J Pediatr. 2024; 20(3): 294–8. https://doi.org/10.1007/s12519-023-00760-4.

[8] Alomari O, Ozceker D, Mokresh ME, Topçak AB, Ertan SN, Şahin MK, Çalışkan N, Karadag SIK, Erbay MF, Yıldırım G, Bologur H, Güngör H, Kaplan O, Tunç HS, Kocatürk E. Omalizumab in paediatric chronic spontaneous urticaria: A systematic review and meta-analysis of efficacy and safety. Pediatr Allergy Immunol. 2025 Jun;36(6):e70132. doi: 10.1111/pai.70132. PMID: 40545961.

[9] Federal Health Reporting. Average body measurements of the population (2025, both sexes), www.gbe-bund.de

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or 43.6 kg (for children aged 11 years) are considered for the cost calculation. The dupilumab dosage recommendations for these body weights can be found in the product information.

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:					
Dupilumab	Children ≥ 2 years				
	5 kg to < 15 kg: 200 mg 15 kg to < 30 kg 300 mg	5 kg to < 15 kg: 200 mg 15 kg to < 30 kg 300 mg	1 x 200 mg 1 x 300 mg	13.0	13 x 200 mg 13 x 300 mg
	Children ≥ 6 years				
	30 kg to < 60 kg: 200 mg	30 kg to < 60 kg: 200 mg	1 x 200 mg	26.1	26.1 x 200 mg
if applicable, in combination with H1 antihistamines of the 2nd generation:					
Cetirizine 2 – 5 years	2.5 mg -	5 mg -	2 x 2.5 mg -	365.0	1,825 ml -
	10 mg	20 mg	4 x 5 mg		7,300 ml
Cetirizine 6 – 11 years	5 mg -	10 mg -	1 x 10 mg -	365.0	365 x 10 mg -
	20 mg	40 mg	4 x 10 mg		1,460 x 10 mg
Rupatadine	2.5 mg = 2.5 ml -	2.5 mg -	1 x 2.5 mg -	365.0	912.5 ml -
	20 mg = 20 ml	20 mg	1 x 20 mg		7,300 ml
Appropriate comparator therapy					
Omalizumab[2,3]	150 mg – 300 mg	150 mg – 300 mg[6]	1 x 150 mg - 2 x 150 mg	13.0	13 - 26 x 150 mg
in combination with H1 antihistamines of the 2nd generation:					
Cetirizine 2 – 5 years	2.5 mg -	5 mg -	2 x 2.5 mg -	365.0	1,825 ml -
	10 mg	20 mg	4 x 5 mg		7,300 ml
Cetirizine 6 – 11 years	5 mg -	10 mg -	1 x 10 mg -	365.0	365 x 10 mg -
	20 mg	40 mg	4 x 10 mg		1,460 x 10 mg

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Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Rupatadine	2.5 mg = 2.5 ml -	2.5 mg -	1 x 2.5 mg -	365.0	912.5 ml -
	20 mg = 20 ml	20 mg	1 x 20 mg		7,300 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.

Non-prescription medicinal products that are reimbursable at the expense of the statutory health insurance according to Annex I of the Pharmaceuticals Directive (so-called OTC exception list) are not subject to the current medicinal products price regulation. Instead, in accordance with Section 129 paragraph 5aSGB V, when a non-prescription medicinal product is dispensed and invoiced in accordance with Section 300, a medicinal product dispensing price in the amount of the dispensing price of the pharmaceutical company plus the surcharges in accordance with Sections 2 and 3 of the Pharmaceutical Price Ordinance in the version valid on 31 December 2003 applies to the insured.

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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:					
Dupilumab 200 mg	6 SFI	€ 3,840.76	€ 1.77	€ 216.01	€ 3,622.98
Dupilumab 300 mg	6 SFI	€ 3,840.76	€ 1.77	€ 216.01	€ 3,622.98
Cetirizine 5 mg[10]	150 ml SYR	€ 12.72	€ 0.64	€ 0.58	€ 11.50
Cetirizine 10 mg[10]	100 FCT	€ 25.57	1.28	1.31	22.98
Rupatadine solution	120 ml OS	€ 28.24	€ 1.77	€ 0.89	€ 25.58
Appropriate comparator therapy					
Omalizumab 150 mg	10 SFI	€ 4,172.95	€ 1.77	€ 234.98	€ 3,936.20
Cetirizine 5 mg[10]	150 ml SYR	€ 12.72	€ 0.64	€ 0.58	€ 11.50
Cetirizine 10 mg[10]	100 FCT	€ 25.57	1.28	1.31	22.98
Rupatadine solution	120 ml OS	€ 28.24	€ 1.77	€ 0.89	€ 25.58
Abbreviations: FCT = film-coated tablets; SFI = solution for injection; SYR = syrup					

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<u>Costs for additionally required SHI services:</u>

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.

[10] Fixed reimbursement rate

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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 12 May 2026, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 5 May 2026, the pharmaceutical company submitted a dossier for the benefit assessment of dupilumab to the GBA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2, sentence 2 VerfO.

By letter dated 13 May 2026 in conjunction with the resolution of the GBA 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 GBA commissioned the IQWiG to assess the dossier concerning the active ingredient dupilumab.

The dossier assessment by the IQWiG was submitted to the GBA on 7 August 2026, and the written statement procedure was initiated with publication on the GBA website on 17 August 2026. The deadline for submitting written statements was 7 September 2026.

The oral hearing was held on 21 September 2026.

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 Subcommittee's session on 27 October 2026, and deliberation of the draft resolution was concluded.

At their session on 5 November 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	12 May 2026	Determination of the appropriate comparator therapy
Working group Section 35a	16 September 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on	21 September 2026	Conduct of the oral hearing

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Medicinal Products		
Working group Section 35a	30 September 2026 14 October 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	27 October 2026	Concluding discussion of the draft resolution
Plenum	5 November 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 5 November 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Dr Optendrenk

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