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
Ixekizumab (new therapeutic indication: juvenile psoriatic arthritis (JpsA), ≥ 6 years)

From 19 March 2026

**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. requirement 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 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 ixekizumab (Taltz) was listed for the first time on 1 March 2017 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 22 August 2025, ixekizumab 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 18 September 2025, 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, No. 2 of the Rules of Procedure (VerfO) of the G-BA concerning the active ingredient ixekizumab with the new therapeutic indication "Taltz, alone or in combination with methotrexate, is indicated for the treatment of active JpsA in patients 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy.".

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 2 January 2026 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 ixekizumab 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 ixekizumab.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA 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 Ixekizumab (Taltz) in accordance with the product information

Taltz, alone or in combination with methotrexate, is indicated for the treatment of active JpsA in patients 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy.

**Therapeutic indication of the resolution (resolution of 19.03.2026):**

See the approved therapeutic indication

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

### 2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Children and adolescents 6 years of age and older with active juvenile psoriatic arthritis and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy

**Appropriate comparator therapy for ixekizumab, alone or in combination with methotrexate:**

- Etanercept (≥ 12 years) or secukinumab or tofacitinib

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 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 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 ixekizumab, glucocorticoids, non-steroidal anti-inflammatory drugs (NSAIDs), conventional synthetic disease-modifying antirheumatic drugs (csDMARDs; including methotrexate (MTX) and hydroxychloroquine), biologic DMARDs (bDMARDs; here etanercept and secukinumab) and the JAK inhibitors tofacitinib and baricitinib are approved for the treatment of juvenile psoriatic arthritis (JPsA) in the therapeutic indication. For the approved therapeutic indications of csDMARDs and bDMARDs, some specifications on the approved age have to be additionally considered.

On 2. Non-medicinal measures as sole appropriate comparator therapy are not considered in the present therapeutic indication.

On 3. In the therapeutic indication to be considered here, there are three G-BA resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V:

- Tofacitinib from 3 March 2022
- Secukinumab from 5 January 2023
- Baricitinib from 2 May 2024

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 therapeutic indication.

The scientific-medical societies and the Drugs Commission of the German Medical Association 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.

For the treatment of patients 6 years of age and older with JPsA, it can first be stated that different diseases are distinguished within the juvenile idiopathic arthritis (JIA) indication; JPsA represents one of these subtypes, usually without a polyarticular course. In addition, taking into account the comments of the clinical experts in the previous benefit assessment procedure for the active ingredient baricitinib[2], it is established that the diagnosis of JIA relates to children and adolescents and that it is not continued in adulthood. It is therefore assumed that the marketing authorisation of ixekizumab in the therapeutic indication of JPsA covers children and adolescents aged 6 to 17 years.

[2] G-BA resolution on the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a SGB V for baricitinib dated 3 May 2024.

The two identified German AWMF S2k guidelines on the therapy of psoriasis in children and adolescents[3] and on the treatment of juvenile idiopathic arthritis, published by the German Society for Paediatrics and Adolescent Medicine,[4] only partly address JPsA and primarily refer to evidence from plaque psoriasis and polyarticular juvenile idiopathic arthritis (pJIA).

In the overall assessment, the guidelines recommend the use of MTX for the therapy of JPsA after failure of (symptomatic) NSAIDs and, if applicable, short-term use of glucocorticoids. If there is an inadequate response or intolerance to csDMARDs, the guidelines recommend the use of TNF-α inhibitors. Currently, in case of inadequate response or intolerance to csDMARDs, the therapeutic significance of MTX in combination with a TNF-α inhibitor (here etanercept) is not assessable.

The TNF-α inhibitor etanercept is approved for the treatment of active JPsA in adolescents 12 years of age and older who have had an inadequate response to csDMARDs. In addition, the IL-17 inhibitor secukinumab for patients 6 years of age and older as well as the JAK inhibitors tofacitinib and baricitinib for patients 2 years of age and older hold a marketing authorisation in this therapeutic indication. The three active ingredients are relatively new therapy options in this therapeutic indication and are not yet explicitly mentioned in the guidelines. However, secukinumab and tofacitinib for the treatment of patients with JPsA from 6 years and 2 years of age respectively have become established in the healthcare.

In the overall assessment, taking into account the specifications on the approved age, the appropriate comparator therapy for children and adolescents 6 years of age and older with active JPsA and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy was determined to be treatment with etanercept (≥ 12 years) or secukinumab or tofacitinib.

The appropriate comparator therapy determined here includes several therapeutic alternatives. In this context, individual therapy options only represent a comparator therapy for the part of the patient population that has the patient characteristics specified in brackets. The therapeutic alternatives are only to be considered equally appropriate in the therapeutic indication, where the patient populations have the same characteristics.

It is assumed that the patients covered by the therapeutic indication are not (or no longer) eligible for (symptomatic) therapy with NSAIDs and/or glucocorticoids alone. Irrespective of this, the use of glucocorticoids (systemic and/or intra-articular) should always be possible in the context of flare therapy.

The relevant 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 G-BA based on a prior review of the criteria set out in Chapter 5 Section 6, paragraph 3 VerfO.

[3] German Dermatological Society. Therapy of psoriasis in children and adolescents; S2k guideline, extended version, version 2.1 [online]. AWMF registry number 013-094. Last revised: 01.01.2022. Berlin (GER): Association of the Scientific-Medical Societies (AWMF) [valid till 31.12.2026]

[4] German Society of Paediatrics and Adolescent Medicine. Therapy of Juvenile Idiopathic Arthritis; S2k guideline, extended version, 3rd edition [online]. AWMF registry number 027-020. Last revised: 30.11.2019. Berlin (GER): Association of the Scientific-Medical Societies (AWMF); 2019. [valid till 29.11.2024 (currently under revision)]

### 2.1.3 Extent and probability of the additional benefit

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

Children and adolescents 6 years of age and older with active juvenile psoriatic arthritis and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy

An additional benefit is not proven.

Justification:

The pharmaceutical company did not present any data for the assessment of the additional benefit of ixekizumab compared to the appropriate comparator therapy.

The label-enabling COSPIRIT-JIA study is an open-label, randomised study comparing ixekizumab with adalimumab. In accordance with the pharmaceutical company's approach in the dossier, this study is not considered for the present benefit assessment due to the lack of comparison with the appropriate comparator therapy. 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 ixekizumab.

The therapeutic indication assessed here is as follows: "Taltz, alone or in combination with methotrexate, is indicated for the treatment of active JpsA in patients 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy."

The G-BA determined the appropriate comparator therapy to be a therapy with etanercept (≥ 12 years) or secukinumab or tofacitinib.

In accordance with the pharmaceutical company’s approach, no studies could be identified in the dossier that would allow a comparison of ixekizumab with the appropriate comparator therapy.

An additional benefit of ixekizumab compared to 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 (SHI).

The resolution is based on the information from the resolution on the benefit assessment of the active ingredient secukinumab[5] in a similar therapeutic indication.

The patient number determined by the pharmaceutical company is subject to uncertainties. The upper limit is of a similar order of magnitude, whilst the lower limit is lower than the patient numbers in the previous procedure for secukinumab. In the event of deviation from the lower limit, it can be assumed that the patient numbers of the pharmaceutical company tend to be an underestimation.

Despite the procedure for secukinumab being subject to uncertainty, the number of patients in the SHI target population is given preference.

## 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 Taltz (active ingredient: ixekizumab) at the following publicly accessible link (last access: 17 November 2025):

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

Treatment with ixekizumab should only be initiated and monitored by specialists who are experienced in the treatment of patients with juvenile psoriatic arthritis.

## 2.4 Treatment costs

The treatment costs are based on the requirements in the product information and the information listed in the LAUER-TAXE® (last revised: 15 January 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

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.

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.

[5] G-BA resolution on the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a SGB V for secukinumab dated 5 January 2023.

Treatment period:

Children and adolescents 6 years of age and older with active juvenile psoriatic arthritis and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy

| Designation of the therapy | Treatment mode | Number of treatments/ patient/ year | Treatment duration/ treatment (days) | Treatment days/ patient/ year |
|---|---|---|---|---|
| Medicinal product to be assessed | | | | |
| Ixekizumab | Continuously<br>1 x every 28 days | 13.0 | 1 | 13.0 |
| Methotrexate, if applicable | Continuously,<br>1 x every 7 days | 52.1 | 1 | 52.1 |
| Appropriate comparator therapy | | | | |
| Etanercept (≥ 12 years) or secukinumab or tofacitinib | | | | |
| Etanercept | Continuously,<br>2 x in 7 days<br>or<br>Continuously,<br>1 x in 7 days | 104.3<br>or<br>52.1 | 1<br>or<br>1 | 104.3<br>or<br>52.1 |
| Secukinumab | Continuously,<br>1 x monthly | 12.0 | 1 | 12.0 |
| Tofacitinib | Continuously,<br>2 x daily | 730.0 | 1 | 365.0 |
| Methotrexate, if applicable | Continuously,<br>1 x every 7 days | 52.1 | 1 | 52.1 |

Consumption:

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

Methotrexate is available on the market in both oral and parenteral dosage forms. For cost representation, it is assumed that patients 6 years of age and older generally receive the more economical option (tablets). As it is not always possible to achieve the exact calculated dose per day with the commercially available dosage strengths, in these cases rounding up or down to the next higher or lower available dose that can be achieved with the commercially available dosage strengths as well as the scalability of the respective dosage form.

For the calculation of the dosages depending on body weight, the minimum body weight of 25 kg applicable according to the therapeutic indication to be assessed and the average body measurements from the official representative statistics "Microcensus 2017 – body measurements of the population[6]" (average body weight of 12-year-olds at 47.1 kg, as well as body height of 6-year-olds at 1.22 m). This results in a body surface area of 0.92 m² for 6-year-olds (calculated according to Du Bois 1916). The "Microcensus 2021 – body measurements of the population[7]" was applied for the 17-year-olds (average body weight: 67.2 kg, average body height: 1.74 m). This results in a body surface area of 1.81 m² (calculated according to Du Bois 1916).

Children and adolescents 6 years of age and older with active juvenile psoriatic arthritis and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy

| 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 | | | | | |
| Ixekizumab | Children ≥ 6 years (25 to ≤ 50 kg) | | | | |
| | 40 mg | 40 mg | 1 x 40 mg | 13.0 | 13.0 x 40 mg |
| | Adolescents ≤ 17 years (> 50 kg) | | | | |
| | 80 mg | 80 mg | 1 x 80 mg | 13.0 | 13.0 x 80 mg |
| Methotrexate, if applicable | 10-15 mg/m² BSA<br>9.2 mg – 27.15 mg | 9.2 mg – 27.15 mg | 1 x 10 mg – 2 x 10 mg + 1 x 7.5 mg | 52.1 | 52.1 x 10 mg – 104.2 x 10 mg + 52.1 x 7.5 mg |
| Appropriate comparator therapy | | | | | |
| Etanercept (≥ 12 years) or secukinumab or tofacitinib | | | | | |
| Etanercept | 0.4 – 0.8 mg/kg BW<br>18.84 mg – 50.00 mg[8] | 18.84 mg – 50.00 mg | 2 x 10 mg – 1 x 50 mg | 104.3 – 52.1 | 208.6 x 10 mg – 52.1 x 50 mg |
| Secukinumab | Children ≥ 6 years (< 50 kg) | | | | |
| | 75 mg | 75 mg | 1 x 75 mg | 12.0 | 12.0 x 75 mg |

[6] Federal Health Reporting. Average body measurements of the population (2017, both sexes, 1 year and older), www.gbe-bund.de

[7] Federal Health Reporting. Average body measurements of the population (2021, both sexes, 15 years and older), www.gbe-bund.de

[8] The maximum daily dose of etanercept is 50 mg when administered once a week and 25 mg when administered twice a week.

| Designation of the therapy | Dosage/ application | Dose/ patient/ treatment days | Consumption by potency/ treatment day | Treatment days/ patient/ year | Average annual consumption by potency |
|---|---|---|---|---|---|
| | Adolescents ≤ 17 years (≥ 50 kg) | | | | |
| | 150 mg | 150 mg | 1 x 150 mg | 12.0 | 12.0 x 150 mg |
| Tofacitinib | Children ≥ 6 years (25 to < 40 kg) | | | | |
| | 4 mg | 8 mg | 2 x 4 mg | 365.0 | 730 x 4 mg |
| | Adolescents ≤ 17 years (≥ 40 kg) | | | | |
| | 5 mg | 10 mg | 2 x 5 mg | 365.0 | 730 x 5 mg |
| Methotrexate, if applicable | 10-15 mg/m² BSA 9.2 mg – 27.15 mg | 9.2 mg – 27.15 mg | 1 x 10 mg – 2 x 10 mg + 1 x 7.5 mg | 52.1 | 52.1 x 10 mg – 104.2 x 10 mg + 52.1 x 7.5 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. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

**Costs of the medicinal products:**

Children and adolescents 6 years of age and older with active juvenile psoriatic arthritis and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy

| 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 | | | | | |
| Ixekizumab 40 mg | 1 SFI | € 687.25 | € 1.77 | € 0.00 | € 685.48 |
| Ixekizumab 80 mg | 3 IPFS | € 3,989.32 | € 1.77 | € 0.00 | € 3,987.55 |
| Methotrexate 7.5 mg[9] | 30 TAB | € 33.75 | € 1.77 | € 1.77 | € 30.21 |
| Methotrexate 10 mg[9] | 30 TAB | € 41.63 | € 1.77 | € 2.40 | € 37.46 |
| Appropriate comparator therapy | | | | | |

[9] 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 |
|---|---|---|---|---|---|
| Etanercept 10 mg | 4 DSS | € 194.34 | € 1.77 | € 10.13 | € 182.44 |
| Etanercept 50 mg[9] | 12 SFI | € 2,548.84 | € 1.77 | € 203.25 | € 2,343.82 |
| Secukinumab 75 mg | 1 SFI | € 352.09 | € 1.77 | € 0.00 | € 350.32 |
| Secukinumab 150 mg | 6 PEN | € 4,022.03 | € 1.77 | € 0.00 | € 4,020.26 |
| Tofacitinib 240 mg | 1 OS | € 791.11 | € 1.77 | € 0.00 | € 789.34 |
| Tofacitinib 5 mg | 182 FCT | € 2,924.03 | € 1.77 | € 0.00 | € 2,922.26 |
| Methotrexate 7.5 mg[9] | 30 TAB | € 33.75 | € 1.77 | € 1.77 | € 30.21 |
| Methotrexate 10 mg[9] | 30 TAB | € 41.63 | € 1.77 | € 2.40 | € 37.46 |
| Abbreviations: FCT = film-coated tablets; SFI = solution for injection; IPFS = solution for injection in a pre-filled syringe; PEN = solution for injection in a pre-filled pen; TAB = tablets; DSS = dry substance with solvent | | | | | |

LAUER-TAXE® last revised: 15 January 2026

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.

The calculation of the additionally required SHI services is based on packs in distribution with the LAUER-TAXE® last revised on 15 September 2025 and fee structure items (FSI) - last revised in the 3rd quarter of 2025 of the uniform value scale (UVS 2025/Q3).

*Diagnosis of tuberculosis*

For active ingredients of the appropriate comparator therapy (etanercept, tofacitinib), costs are regularly incurred for examination of both active and inactive ("latent") tuberculosis infections. The costs presented are a blood test (quantitative determination of an in vitro interferon-gamma release after ex vivo stimulation with antigens specific for Mycobacterium tuberculosis-complex (except BCG)) and a chest radiograph. The tuberculin skin test is not presented due to lack of sensitivity and specificity as well as the possibility of "sensitisation". In contrast, these investigations are not required when secukinumab is used, and, furthermore, do not generally arise when ixekizumab is used as the medicinal product to be assessed.

*Diagnosis of chronic hepatitis B*

In addition, patients must be tested for the presence of HBV infection before initiating treatment with etanercept or tofacitinib. These investigations are not required when using ixekizumab and secukinumab. Diagnostics to rule out chronic hepatitis B requires sensibly coordinated steps. A step-by-step serological diagnosis initially consists of the examination of HBs antigen and anti-HBc antibodies. If both are negative, a past HBV infection can be

excluded. In certain case constellations, further steps may be[10] necessary in accordance with current guideline recommendations.

In total, additionally required SHI services are required for the diagnosis of suspected chronic hepatitis B and examinations for tuberculosis infections which usually differ between the medicinal product to be assessed and the appropriate comparator therapy and are consequently considered as additionally required SHI services in the resolution.

| Designation of the therapy | Designation of the service | Number | Costs per unit | Costs/ patient/ year |
|---|---|---|---|---|
| Tuberculosis screening | | | | |
| Etanercept<br>Tofacitinib | Quantitative determination of an in vitro interferon-gamma release after ex vivo stimulation with antigens (at least ESAT-6 and CFP-10) specific for Mycobacterium tuberculosis-complex (except BCG) (FSI 32670) | 1 | € 53.36 | € 53.36 |
| Etanercept<br>Tofacitinib | Chest radiograph (FSI 34241) | 1 | € 18.60 | € 18.60 |
| HBV screening | | | | |
| Etanercept<br>Tofacitinib | HBV test<br>Hepatitis B surface antigen status (FSI 32781) | 1 | € 5.06 | € 5.06 |
| | Anti-HBc antibody (FSI 32614) | 1 | € 5.43 | € 5.43 |

## 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

[10] S3 guideline on prevention, diagnosis and therapy of hepatitis B virus infection; AWMF registry no.: 021/011 https://register.awmf.org/assets/guidelines/021-011l_S3_Prophylaxe-Diagnostik-Therapie-der-Hepatitis-B-Virusinfektion_2021-07.pdf

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 data from the product 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 statutory 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:

Children and adolescents 6 years of age and older with active juvenile psoriatic arthritis and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy

- No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

References:
Product information for ixekizumab (Taltz); Taltz 80 mg solution for injection in a pre-filled pen
Last revised: August 2025

## 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 10 September 2024, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 18 September 2025, the pharmaceutical company submitted a dossier for the benefit assessment of ixekizumab to the G-BA in accordance with Chapter 5 Section 8, paragraph 1, number 2 VerfO.

By letter dated 25 September 2025 in conjunction with the G-BA resolution 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 ixekizumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 18 December 2025, and the written statement procedure was initiated with publication on the G-BA website on 2 January 2026. The deadline for submitting statements was 23 January 2026.

The oral hearing took place on 9 February 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 10 March 2026, and the draft resolution was approved.

At their session on 19 March 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

**Chronological course of consultation**

| Session | Date | Subject of consultation |
|---|---|---|
| Subcommittee on Medicinal products | 10 September 2024 | Determination of the appropriate comparator therapy |
| Working group Section 35a | 3 February 2026 | Information on written statements received; preparation of the oral hearing |
| Subcommittee on Medicinal products | 9 February 2026 | Conduct of the oral hearing |
| Working group Section 35a | 17 February 2026<br>3 March 2026 | Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure |
| Subcommittee on Medicinal products | 10 March 2026 | Concluding discussion of the draft resolution |
| Plenum | 19 March 2026 | Adoption of the resolution on the amendment of the Pharmaceuticals Directive |

Berlin, 19 March 2026

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

Prof. Hecken