Justification

Gemeinsamer Bundesausschuss

to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Secukinumab (New Therapeutic Indication: Plaque Psoriasis, from the Age of 6 to <18 Years)

of 18 February 2021

Contents

1. Legal basis

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

1. Approved therapeutic indications,
2. Medical benefit,
3. Additional medical benefit in relation to the appropriate comparator therapy,
4. Number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. Treatment costs for statutory health insurance funds,
6. Requirements for a quality-assured application.

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

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

2. Key points of the resolution

The active ingredient secukinumab (Cosentyx) was listed for the first time on 1 June 2015 in the “LAUER-TAXE®”, the extensive German registry of available drugs and their prices.

On 31 July 2020, Cosentyx received marketing authorisation for a new therapeutic indication classified as a major variation of Type 2 according to Annex 2, number 2a to Regulation (EC) No. 1234/2008 of the Commission from 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12 December 2008, p. 7).

On 27 August 2020, the pharmaceutical company submitted a dossier 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 G-BA on the active ingredient secukinumab with the new therapeutic indication in due time (i.e. at the latest within four weeks after informing the pharmaceutical company about the approval for a new therapeutic indication).

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 December 2020 on the website of the G-BA (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 secukinumab 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 written statements submitted in the written and oral hearing procedure as well as the addendum to the benefit assessment prepared by the IQWiG. In order to determine the extent of the additional benefit, the G-BA has assessed the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative) according to 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 set aside in the benefit assessment of secukinumab.

In light of the above and taking into account the written statements received and the oral hearing, the G-BA has arrived at 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 secukinumab (Cosentyx) in accordance with the product information

Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years who are candidates for systemic therapy.

Therapeutic indication of the resolution (resolution of 18 February 2021):

New therapeutic indication according to marketing authorisation

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Children and adolescents from the age of age of 6 years and with moderate to severe plaque psoriasis who are candidates for systemic therapy

Appropriate comparator therapy:

- Adalimumab or etanercept or ustekinumab

Criteria according to Chapter 5, Section 6 of the Rules of Procedure of the G-BA:

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

[1] General Methods, Version 6.0 dated 5 November 2020. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care), Cologne.

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 applications or non-medicinal treatments for which the patient-relevant benefit has already been determined by the Federal Joint Committee shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

Justification based on the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO:

On 1. In the present therapeutic indication, the following active ingredients are generally approved for children and adolescents:

- Cyclosporine
- Methotrexate
- The *TNF-alpha inhibitors* adalimumab and etanercept
- The *interleukin inhibitors* ustekinumab and ixekizumab

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

On 3. No resolutions of the G-BA have been made in the therapeutic indication (plaque psoriasis in children and adolescents) considered here.

On 4. The general accepted state of medical knowledge on which the decision of the G-BA are based was illustrated by systematic research for guidelines and reviews of clinical studies in this indication.

For the treatment of plaque psoriasis in children and adolescents who are eligible for systemic therapy, the TNF-alpha inhibitors adalimumab and etanercept (severe form of plaque psoriasis) and the interleukin inhibitor ustekinumab (moderate to severe plaque psoriasis) are approved in Germany. The evidence does not support a clinical advantage for any of the three active ingredients that would support a preference in the determination as an appropriate comparator therapy.

The IL-17 inhibitor ixekizumab was only recently granted marketing authorisation in plaque psoriasis in children and adolescents. It can therefore not yet be considered established in care in this indication.

The use of the active ingredient cyclosporine (severe form of plaque psoriasis) is not recommended for children under 16 years of age in accordance with marketing authorisation. Because cyclosporine is therefore not a treatment option for a predominant proportion of children and adolescents and is also not recommended, cyclosporine is not part of the appropriate comparator therapy.

Accordingly, for children and adolescents aged 6 years and older with plaque psoriasis who are eligible for systemic therapy, the active ingredients adalimumab, etanercept, and ustekinumab are determined to be equally appropriate comparator therapies.

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

2.1.3 Extent and probability of the additional benefit

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

For the treatment of children and adolescents with moderate to severe plaque psoriasis who are candidates for systemic therapy, there is a hint of a minor additional benefit for secukinumab compared with the appropriate comparator therapy etanercept.

Justification:

The pharmaceutical company presented the results of the CAIN457A2310 study to prove the additional benefit of secukinumab.

CAIN457A2310 is a randomised, parallel-group study comparing secukinumab at two different doses with etanercept and placebo in children and adolescents from 6 to under 18 years of age with severe plaque psoriasis. In the opinion of the investigator, systemic therapy should be indicated either on account of the patients not responding adequately to topical therapies, systemic therapies or phototherapy, or because they did not tolerate the latter two. Treatment in the secukinumab arms and the placebo arm was double-blinded at the outset over a 12-week period, while treatment with etanercept was blinded only to those ascertaining the objective endpoints. Patients in the placebo arm who had not experienced a response of a Psoriasis Area Severity Index (PASI) score of 75 at the end of the double-blind study phase were randomly assigned to (low dose/high dose) secukinumab (secondary secukinumab arms). The data directly comparing secukinumab and etanercept is therefore collected over 52 weeks (primary secukinumab arms) or 40 weeks (secondary secukinumab arms). Disease severity in the study was defined on the basis of a PASI score of ≥ 20, an Investigator's Global Assessment (IGA) score of 4 and an affected body surface area (BSA) of ≥ 10 %. Systemic therapy should be indicated as assessed by the investigator. The total study population comprised 162 children and adolescents who were randomly assigned to the four study arms at a ratio of 1:1:1:1.

The benefit assessment only takes into account the data collected on the lower dosage of secukinumab, as this is the only dosage that broadly corresponds to the approved dosage.

The data from the secondary secukinumab arms are subject to uncertainty. The treatment period was 12 weeks shorter than in the primary secukinumab arm or etanercept arm, and data from the initial treatment with placebo were also included in the analysis. Due to potential interfering effects on the outcomes of all endpoints, the data from the secondary secukinumab arms are not drawn upon for the benefit assessment.

The assessment of additional benefit continued to be based predominantly on the sub-population of patients for whom the appropriate comparator therapy etanercept was approved as based on pre-treatment (sensitivity analysis C). Etanercept is approved for the treatment of chronic severe plaque psoriasis in children from 6 years of age who have responded inadequately to or have not tolerated other systemic therapy or phototherapy. The study results of the total population (main analysis) are also presented. These include the comparison of the primary secukinumab treatment arms with the etanercept arm. In contrast to sensitivity analysis C, the comparator arm includes all patients treated with etanercept who were candidates for systemic therapy as assessed by the investigator.

Hence, data are available comparing secukinumab with the appropriate comparator therapy etanercept for a period of 52 weeks. However, according to the product information for etanercept, patients are to be treated for a maximum period of 24 weeks, and therefore the benefit assessment primarily draws on the 24-week data. The study results for the 52-week period are presented as a supplement.

Extent and probability of the additional benefit

Mortality

No deaths occurred in the CAIN457A2310 study.

Morbidity

Psoriasis Area and Severity Index (PASI)

In the German healthcare context, the PASI is a standard instrument for the classification of the degree of severity by the physician and is highly relevant for the diagnosis and monitoring of the severity of the disease in healthcare. PASI is used in conjunction with other instruments to determine the severity of psoriasis. The symptoms redness, thickness, and scaling of the skin for the body regions head, trunk, arms, and legs are evaluated by the physician with a score between 0 (not present) and 4 (very severe). The proportion of the affected body surface is estimated by the investigator as a percentage of the total surface area of the body region. An overall score is formed based on the evaluation of the symptoms and the assessment of the affected body surface. The PASI score can range from 0 (no signs of psoriasis) to 72.

For this benefit assessment, the results on the percentage of patients with a PASI score improvement from the start of the study to week 24 of 100% (PASI 100), 90% (PASI 90) and 75% (PASI 75) are drawn on.

For the remission endpoint, a PASI score of 100, both analyses (sensitivity analysis C and main analysis) demonstrated a statistically significant effect at week 24 to the benefit of secukinumab over etanercept. The proportion of patients with an improvement in PASI score from the start of study at week 24 of 75% (PASI 75) and 90% (PASI 90) also demonstrated a statistically significant benefit for secukinumab compared with etanercept in both analyses.

The percentage of patients in the relevant population (sensitivity analysis C) with a PASI score improvement at week 52 of 100%, 75% (PASI 75) and 90% (PASI 90), respectively, reveals no statistically significant differences between secukinumab and etanercept. In the additional presented data at week 52 in the main analysis, a statistically significant benefit for secukinumab was only established for a PASI score of 90.

Quality of life

Children's Dermatology Life Quality Index (CDLQI) response

In this study, the health-related quality of life was assessed using CDLQI. The CDLQI instrument is a validated questionnaire used to determine disease-specific health-related quality of life children and adolescents over 16 years of age with dermatological diseases. For CDLQI (CDLQI 0 or 1), no statistically significant difference was revealed between the treatment groups.

Side effects

For the endpoints SAEs, discontinuation due to AEs and infections, there is no statistically significant difference between the treatment groups.

Overall assessment/conclusion

For the benefit assessment of secukinumab for the treatment of children and adolescents with moderate to severe plaque psoriasis who are candidates for systemic therapy, the study CAIN457A2310 was submitted.

For children and adolescents with severe plaque psoriasis, both the sensitivity analysis and the main analysis in the endpoint category morbidity revealed a statistically significant benefit in favour of secukinumab compared to the appropriate comparator therapy etanercept, both in terms of remission, as defined by a PASI score of 100, and in terms of improvement of PASI scores of 75% and 90%, respectively, at week 24.

In the endpoint categories quality of life and side effects, neither a benefit nor a detriment was revealed for secukinumab compared to etanercept.

Overall, the positive effects of secukinumab compared to the appropriate comparator therapy on the investigated morbidity endpoints are deemed to constitute an improvement to therapy-relevant benefit. The extent of this additional benefit is classified as minor.

Reliability of data (probability of additional benefit)

The assessment of the additional benefit is based on the study CAIN457A2310, a randomised parallel-group study with an open-label design in which the investigators of the objective endpoints were blinded.

A portion of the enrolled patients could not be included in the benefit assessment, as the appropriate comparator therapy etanercept was not used during pre-treatment in accordance with the marketing authorisation. For this reason, the assessment was restricted to the evaluation of the sensitivity analysis C.

In accordance with the marketing authorisation of etanercept, therapy is to be discontinued after 12 weeks in the absence of a response. The data from CAIN457A2310 show that approximately one third of patients did not experience a PASI 75 response at week 12. This results in a potentially high risk of bias, as patients may have continued to be treated with etanercept instead of switching to another potentially more effective therapy.

Overall, uncertainties remain as to whether the investigated study population comprehensively covers the patients in the therapeutic indication. The reliability of the finding is, hence, categorised as a hint.

2.1.4 Summary of the assessment

The present assessment refers to the benefit assessment of a new therapeutic indication for the active ingredient secukinumab. The therapeutic indication assessed here is as follows:

Treatment of children and adolescents from the age of age of 6 years with moderate to severe plaque psoriasis who are candidates for systemic therapy.

The G-BA determined adalimumab or etanercept or ustekinumab as appropriate comparator therapies.

For the benefit assessment of secukinumab for the treatment of children and adolescents with moderate to severe plaque psoriasis who are candidates for systemic therapy, the study CAIN457A2310 was submitted. In the morbidity endpoint category, a statistically significant advantage to the benefit of secukinumab is shown at week 24 both in remission, based on a PASI score of 100, and in the improvement of PASI score of 75% and 90%. In the categories quality of life and side effects, neither a benefit nor a detriment was revealed for secukinumab compared to etanercept.

Thus, for children and adolescents with severe plaque psoriasis, secukinumab has a positive effect on morbidity with no detriments to quality of life and the side effect profile.

Taking into account the uncertainties associated with the limitations of the etanercept comparator arm, the overall conclusion is that there a hint exists for a minor additional benefit of secukinumab compared to etanercept.

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 figures are based on the data from the G-BA resolution on ixekizumab[2] in the therapeutic indication plaque psoriasis in children and adolescents from 6 years of age. The figures are based on prevalence and incidence data from diagnosed patients. In the overall

[2] Resolution of the G-BA on the Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V dated 21 January 2021

view, the calculation of the number is subject to uncertainties; at least for the upper limit, an overestimation of the patient numbers must be assumed.

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 Cosentyx (active ingredient: secukinumab) at the following publicly accessible link (last accessed: 26 January 2021):

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

In patients who have not responded to therapy in up to 16 weeks of treatment, the discontinuation of treatment should be considered. Some patients with an initially partial response improve over time if treatment is continued beyond 16 weeks.

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 February 2021).

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 for each individual patient and/or is shorter on average. The time unit “days” is used to calculate the “number of treatments/patient/year”, the time between individual treatments, and the maximum treatment duration if specified in the product information.

According to the product information, the use of etanercept for the treatment of plaque psoriasis is intended for 24 weeks; however a renewed treatment with etanercept may be indicated.

Treatment duration:

Designation of the therapy	Treatment mode	Number of treatments/patient/year	Treatment duration/treatment (days)	Treatment days/patient/year
Medicinal product to be assessed				
Secukinumab	1 × monthly	12	1	12
Appropriate comparator therapy				
Adalimumab	1 × every 14 days	26.1	1	26.1
Etanercept	1 × every 7 days	24	1	24
Ustekinumab	1 × every 84 days	4.3	1	4.3

Usage and consumption:

For the calculation of the dosages as a function of body weight, the average body measurements from the official representative statistics "Microcensus 2017 – body measurements of the population" were used as a basis (average body weight of 6–7 year olds: 23.6 kg und of 17–18 year olds: 67.0 kg).[3]

In general, initial induction schemes are not taken into account for the cost representation because this 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.

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					
Secukinumab	< 50 kg / BW: 75 mg	75 mg	1 × 150 mg	12	12 × 150 mg
	≥ 50 kg / BW: 150 mg – 300 mg	150 mg – 300 mg	1 × 150 mg – 2 × 150 mg		12 × 150 mg – 24 × 150 mg
Appropriate comparator therapy					
Adalimumab	20 mg – 40 mg	20 mg – 40 mg	1 × 20 mg – 1 × 40 mg	26.1 26.1	26.1 × 20 mg – 26.1 × 40 mg
Etanercept	0.8 mg/kg BW from 62.5 kg BW	20 mg – 50 mg	1 × 25 mg – 1 × 50 mg	24 24	24 × 25 mg – 24 × 50 mg
Ustekinumab	18.8 mg– 45 mg	18.8 mg– 45 mg	1 × 45 mg	4.3	4.3 × 45 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 Sections 130 and 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined based on consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated based on the costs per pack after deduction of the statutory rebates.

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

Costs of the medicinal product:

Designation of the therapy	Package 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					
Secukinumab 150 mg	1 PIJ	€ 890.58	€ 1.77	€ 0.00	€ 888.81
Secukinumab 150 mg	6 PEN	€ 5,173.49	€ 1.77	€ 0.00	€ 5,171.72
Appropriate comparator therapy					
Adalimumab 20 mg	1 SFI	€ 255.95	€ 1.77	€ 13.56	€ 240.62
Adalimumab 40 mg	6 SFI	€ 2,804.66	€ 1.77	€ 156.90	€ 2,645.99
Etanercept 25 mg[4]	24 DSS	€ 4,290.44	€ 1.77	€ 345.36	€ 3,943.31
Etanercept 50 mg[4]	12 SFI	€ 4,231.41	€ 1.77	€ 340.54	€ 3,889.10
Ustekinumab 45 mg	1 IFE	€ 5,258.42	€ 1.77	€ 297.03	€ 4,959.62
Ustekinumab 45 mg	1 SFI	€ 5,258.42	€ 1.77	€ 297.03	€ 4,959.62
Abbreviations: IFE = injection solution for prefilled syringe; SFI = solution for injection; PEN = injection solution in a prefabricated pen; PIC = powder for the preparation of an infusion solution; DSS = dry substance with solvent					

Pharmaceutical selling price (LAUER-TAXE®) as last revised: 1 February 2021

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 assessed 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 standard expenditure in the course of the treatment are not shown.
For some of the active ingredients of the appropriate comparator therapy (adalimumab, etanercept, and ustekinumab), costs for testing for both active and inactive (latent) tuberculosis infections are regularly incurred. The costs shown refer to 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)) as well as a thoracic X-ray. The tuberculin skin test is not mapped due to lack of sensitivity and specificity as well as the possibility of "sensitisation". These investigations are not required for the use of secukinumab.

In addition, patients should be tested for the presence of HBV infection before initiating treatment with adalimumab and etanercept. On the other hand, these examinations are not required for the use of ustekinumab and are also not usually required for the use of secukinumab as a medicinal product to be assessed. For the diagnosis of a suspected chronic hepatitis B, well coordinated steps are necessary[5]. A serological step-by-step diagnostic

[4] Fixed reimbursement rate
[5] "Update of the S3 guideline on prophylaxis, diagnosis and therapy of hepatitis B virus infection; AWMF register no.: 021/011" https://www.awmf.org/uploads/tx_szleitlinien/021-011l_S3_Hepatitis_B_Virusinfektionen_Prophylaxe_Diagnostik_Therapie_2011-abgelaufen.pdf

initially consists of the investigation of HBs antigen and anti-HBc antibodies. If both are negative, a past HBV infection can be excluded. If the HBs antigen is positive, an active HBV infection has been detected.

Overall, the following additional SHI services are necessary for the diagnosis of suspected chronic hepatitis B and for the examinations for tuberculosis infections. These regularly differ between the medicinal product to be assessed and the appropriate comparator therapy and are therefore considered additionally required SHI services in the resolution.

Designation of the therapy	Description of the service	Number	Costs per unit	Costs per patient per year
Medicinal product to be assessed: Secukinumab				
not applicable				
Appropriate comparator therapy				
Adalimumab Etanercept Ustekinumab	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 for BCG) (GOP 32670)	1	€ 58.00	€ 58.00
Adalimumab Etanercept Ustekinumab	Chest radiograph (GOP 34241)	1	€ 16.24	€ 16.24
Adalimumab Etanercept	HBs antigen (GOP 32781)	1	€ 5.50	€ 5.50
	Anti-HBs antibody (GOP 32617)[6]	1	€ 5.50	€ 5.50
	Anti-HBc antibody (GOP 32614)	1	€ 5.90	€ 5.90
	HBV-DNA (GOP 32823)[7]	1	€ 89.50	€ 89.50

3. Bureaucratic costs

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.

[6] Only if HBs antigen negative and anti-HBc antibody positive
[7] Settlement of GOP 32823 possible before or during antiviral therapy with interferon and/or nucleic acid analogues.

4. Process sequence

At its session on 7 May 2019, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 27 August 2020, the pharmaceutical company submitted a dossier for the benefit assessment of secukinumab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 27 August 2020 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefits of medicinal products with new active ingredients in accordance with Section 35a SGB V, the G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient secukinumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 27 November 2020, and the written statement procedure was initiated with publication on the website of the G-BA on 1 December 2020. The deadline for submitting written statements was 22 December 2020.

The oral hearing was held on 11 January 2021.

By letter dated 12 January 2021, the IQWiG was commissioned with a supplementary assessment of data submitted in the written statement procedure. The addendum prepared by the IQWiG was submitted to the G-BA on 29 January 2021.

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 were discussed at the session of the subcommittee on 9 February 2021, and the proposed resolution was approved.

At its session on 18 February 2021, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	7 May 2019	Determination of the appropriate comparator therapy
Working group Section 35a	6 January 2021	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	12 January 2021	Conduct of the oral hearing, Commissioning of the IQWiG with the supplementary assessment of documents
Working group Section 35a	20 January 2021 3 February 2021	Consultation on the dossier assessment by the IQWiG, evaluation of the written statement procedure
Subcommittee on Medicinal Products	9 February 2021	Concluding discussion of the draft resolution

Plenum	18 February 2021	Adoption of the resolution on the amendment of Annex XII of the AM-RL

Berlin, 18 February 2021

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

Prof. Hecken