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 Ravulizumab (New Therapeutic Indication: Atypical Haemolytic Uremic Syndrome (aHUS))

of 21 January 2021

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1. Legal basis

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

1. Approved therapeutic indications,
2. Medical benefit,
3. Additional medical benefit in relation to the appropriate comparator therapy,
4. Number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. Treatment costs for 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 ravulizumab (Ultomiris) was listed for the first time on 1 August 2019 in the “LAUER-TAXE®”, the extensive German registry of available drugs and their prices.

On 26 June 2020, ravulizumab received marketing authorisation for a new therapeutic indication:

“Ultomiris is indicated in the treatment of patients with a body weight of 10 kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab”.

On 24 July 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 ravulizumab 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 came to a resolution on whether an additional benefit of ravulizumab 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 presented on this in the written and oral hearing procedure. In order to determine the extent of the additional benefit, the G-BA 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 used in the benefit assessment of ravulizumab.

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 Ravulizumab (Ultomiris) in accordance with the product information

Ultomiris is indicated in the treatment of patients with a body weight of 10 kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab.

Therapeutic indication of the resolution (resolution of 21 January 2021):

See new approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Patients with a body weight of 10 kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab

- Eculizumab

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.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.

[1] General Methods, Version 5.0 dated 10 July 2017. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care), Cologne.

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. Eculizumab is approved in the present therapeutic indication.

On 2. Non-medicinal treatment that can be provided within the framework of the SHI system is not considered.

On 3. No corresponding resolutions have been passed.

On 4. The generally state of medical knowledge for the indication was established by means of a systematic search for guidelines and reviews of clinical studies.

Overall, the evidence in this therapeutic indication is quite limited. In accordance with the only available guideline from the Society for Paediatric Nephrology (GPN)[2], eculizumab should be used as first-line treatment for complement-mediated (atypical) haemolytic uraemic syndrome (HUS). Although this guideline addresses children and adolescents, eculizumab is also approved for the treatment of adults with aHUS and, as described in Section 1, is the only approved active ingredient.

In the overall view, the G-BA therefore considers it appropriate to define eculizumab as an appropriate comparator therapy in the present therapeutic indication. In addition to therapy with eculizumab, supportive measures should be implemented.

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 ravulizumab is assessed as follows:

For ravulizumab for the treatment of patients with a body weight of 10 kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab, an additional benefit compared with eculizumab is not proven.

Justification:

Data basis:

Because no directly comparative studies could be identified against the appropriate comparator therapy, the pharmaceutical company submitted comparisons of individual arms from different studies in the dossier to demonstrate an additional benefit. In doing so, it uses two studies each for ravulizumab and for the appropriate comparator therapy (eculizumab); for ravulizumab, the pivotal Studies 311 and 312, and for eculizumab, Studies C10-003 and C10-004. Here, the pharmaceutical company presents the comparisons separately for paediatric and adult patient populations for patients who have not previously been treated with complement inhibitors (complement inhibitor naïve patients). The comparison with paediatric patients includes Studies 312 and C10-003; the comparison with adult patients includes Studies 311 and C10-004.

[2] Society for Paediatric Nephrology. S2k guideline: haemolytic-uraemic syndrome in childhood. AWMF register No. 166/002. 2016.

On the studies on ravulizumab (Study 311, Study 312)

The currently ongoing single-arm, multi-centre Studies 311 and 312 are the pivotal studies on ravulizumab in the present therapeutic indication. Study 311 included complement inhibitor-naïve adult patients with aHUS. Study 312 included children and adolescents under 18 years of age from a body weight of 5 kg with aHUS in two cohorts. Cohort 1 included complement inhibitor naïve patients, and Cohort 2 included patients who had previously received treatment with eculizumab for at least 90 days and had a proven response to eculizumab.

Both studies included patients who had thrombotic microangiopathy (TMA) during screening or up to 28 days prior. This was determined using defined laboratory parameters on thrombocyte count, lactate dehydrogenase (LDH), and haemoglobin concentration as well as serum creatinine level. Patients with other causes of TMA, regular dialysis for end-stage kidney disease, and plasma therapy for the treatment of current TMA for ≥ 28 days before the start of screening were excluded.

Study 312 included 31 children and adolescents, including 21 in Cohort 1. 3 children and adolescents from Cohort 1 were subsequently excluded from the study because they did not meet the inclusion criteria; they were not included in the evaluation. Study 311 included 58 adults, two of whom were subsequently excluded from the study analysis because they also did not meet the inclusion criteria.

In both studies, treatment with ravulizumab was carried out largely in accordance with the requirements in the product information. Deviations from this result from the fact that, in accordance with the product information, ravulizumab may be administered only from a body weight of 10 kg. In contrast, Study 312 included 4 of 31 patients (12.9%; Cohort 1: n = 3, Cohort 2: n = 1) with a body weight < 10 kg.

The primary endpoint of both studies was complete TMA response during the 26-week initial evaluation period as measured by normalisation of haematological parameters (thrombocyte count and LDH) and an improvement in serum creatinine concentration ≥ 25% compared with the start of treatment. Secondary endpoints were other endpoints of morbidity and adverse events (AEs).

After the initial evaluation period, patients were eligible to continue receiving ravulizumab in an extension period of up to 2 years (Study 311) or 4.5 years (Study 312) or until commercial availability.

On the studies on eculizumab (C10-003, C10-004)

The single-arm, multi-centre Studies C10-003 and C10-004 included paediatric (body weight of at least 5 kg) and adult patients with aHUS. For inclusion in both studies, TMA had to be present based on defined laboratory parameters (thrombocyte count, lactate dehydrogenase (LDH) and haemoglobin concentration, and serum creatinine level).

Excluded from participation were patients with other causes of TMA, regular dialysis for end-stage kidney disease, and – only in Study C10-003 – plasma therapy for the treatment of current TMA for > 5 weeks before the start of screening.

Studies C10-003 and C10-004 included 22 paediatric and 41 adult patients; in Study C10-003, one patient was subsequently deemed ineligible for the study and excluded from the analyses.

In both studies, the treatment was given in accordance with the requirements in the product information for eculizumab.

The primary endpoint of Studies C10-003 and C10-004 was complete TMA response during the 26-week initial evaluation period as operationalised in the studies with ravulizumab. Secondary endpoints were other endpoints of morbidity and AEs.

After the initial evaluation period, patients were eligible to continue to receive eculizumab in an extension period of up to 2 years or until commercial availability.

On the comparisons of individual arms from different studies

In the dossier for the benefit assessment, the pharmaceutical company uses the single-arm Studies 311 and C10-004 for the comparison of ravulizumab with eculizumab in complement-inhibitor naïve adult patients and Cohort 1 of Study 312 and Study C10-003 for the comparison in complement-inhibitor-naïve paediatric patients.

In doing so, the pharmaceutical company first compares the results of the individual study arms descriptively for both the paediatric and the adult patients. In order to adjust for differences in the patient populations, the pharmaceutical company also compares the single-arm studies for both populations on the basis of selected patient characteristics using propensity score matching. However, the pharmaceutical company does not submit these evaluations for all endpoints considered; such evaluations are missing (e.g. for endpoints of the side effects category). For the endpoints of the side effects category, the pharmaceutical company derives the additional benefit on the basis of the descriptive comparison; for the endpoints on the benefit side, the additional benefit is derived on the basis of the comparisons after propensity score matching.

When comparing the studies with paediatric patients, there is no statistically significant difference between the treatments in any endpoint.

When comparing the studies with adult patients, statistically significant differences to the advantage of ravulizumab can be observed in the individual analyses of various endpoints. However, neither effect estimates nor confidence intervals for the evaluations were provided by the pharmaceutical company.

The pharmaceutical company does not provide comparative data for the sub-population of patients receiving eculizumab for at least 3 months and who have shown a response to eculizumab.

Assessment:

Overall, all comparisons presented have limitations that are relevant to the assessment. Thus, first of all, the comparability of the studies submitted by the pharmaceutical company can be only partially assessed because relevant information on comparability within the complement-inhibitor-naïve paediatric or adult patient populations is missing. For Study 311 (on ravulizumab) with adult patients, no information on medical history is available. For both studies with eculizumab, information on extrarenal signs and symptoms of aHUS before the start of study is missing. Furthermore, it remains unclear whether the implementation of supportive measures in addition to treatment with ravulizumab or eculizumab is sufficiently comparable in the studies. In particular, it is uncertain to what extent the use of plasma therapy, which was permitted and carried out only in the eculizumab studies, enables sufficient comparability of the studies.

Furthermore, the propensity score matching evaluations presented are incomplete for both the complement-inhibitor-naïve paediatric and the complement-inhibitor-naïve adult patient populations. Such evaluations are missing (e.g. for endpoints of the side effects category).

Furthermore, despite the partial adjustment for potentially relevant effect modifiers or prognostic factors in the evaluation, the results from a comparison of individual arms from different studies are subject to inherent uncertainty because of the lack of randomisation.

In view of these uncertainties, the statistically significant differences observed in the comparison of the studies with adult patients in individual analyses of various endpoints – irrespective of an assessment of their patient relevance – are also not large enough to rule out the possibility that they are not based solely on systematic bias.

The pharmaceutical company does not provide comparative data for the sub-population of patients receiving eculizumab for at least 3 months and who have shown a response to eculizumab.

In the overall view, the data presented for the assessment of ravulizumab for the treatment of patients with a body weight of 10 kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab are not suitable for deriving an additional benefit of ravulizumab compared with the appropriate comparator therapy.

The additional benefit of ravulizumab compared with the appropriate comparator therapy is thus not proven.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the medicinal product Ultomiris with the active ingredient ravulizumab:

“Ultomiris is indicated in the treatment of patients with a body weight of 10 kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab”.

Eculizumab was determined as the appropriate comparator therapy.

The pharmaceutical company presented comparisons of individual arms from different studies in the dossier. For ravulizumab, the pharmaceutical company refers to the pivotal Studies 311 and 312, and for eculizumab, to Studies C10-003 and C10-004. Here, the pharmaceutical company presents the comparisons separately for paediatric and adult patient populations for patients who have not previously been treated with complement inhibitors (complement inhibitor naïve patients). The comparison with paediatric patients includes Studies 312 and C10-003; the comparison with adult patients includes Studies 311 and C10-004. The pharmaceutical company does not provide comparative data for the sub-population of patients receiving eculizumab for at least 3 months and who have shown a response to eculizumab.

Overall, all of the comparisons presented have limitations that are relevant to the evaluation, in particular because of the limited comparability of the studies and the lack of randomisation. Thus, the data presented are not suitable for deriving an additional benefit of ravulizumab compared with the appropriate comparator therapy. The additional benefit of ravulizumab compared with the appropriate comparator therapy is thus 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 G-BA bases its resolution on the information from the dossier of the pharmaceutical company. Although the derivation of the patient numbers carried out by the pharmaceutical company is mathematically comprehensible, it is subject to uncertainties. These arise in particular from the fact that the estimate of the lower limit is based on data from the global non-interventional aHUS registry initiated by the pharmaceutical company, although presumably not all patients in Germany are included in this registry. With regard to the estimation of the upper limit, the transferability of proportional values and their suitability for extrapolation is unclear, especially from the source used for this purpose.

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 Ultomiris (active ingredient: ravulizumab) at the following publicly accessible link (last access: 28 October 2020):

https://www.ema.europa.eu/documents/product-information/ultomiris-epar-product-information_de.pdf

Treatment with ravulizumab should only be initiated and monitored by specialists who are experienced in the therapy of patients with haematological or kidney diseases.

In accordance with the specifications of the European Medicines Agency (EMA) regarding additional measures for risk minimisation, the pharmaceutical company must provide training materials to all doctors and patients expected to use ravulizumab.

In addition to the product information, the training material for doctors contains a guide for the prescribing doctor. In addition to the package leaflet, the training material for patients contains a guide for patients as well as a patient card.

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 January 2021).

In general, initial induction schemes are not taken into account for the cost representation because the present indication is a disease with a continuous need for therapy and, as a rule, no new titration or dose adjustment is required after initial titration. The costs are calculated on the basis of the maintenance doses.

The doses of the medicinal product to be assessed with the active ingredient ravulizumab and the appropriate comparator therapy eculizumab follow a dosing scheme based on body weight. The annual treatment costs are given on the basis of a range between the lowest possible range of body weight and the maximum possible range of body weight in accordance with the information in the product information.

Treatment duration:

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.

Designation of the therapy	Treatment mode	Number of treatments/patient/year	Treatment duration/treatment (days)	Treatment days/patient/year
Medicinal product to be assessed				
Ravulizumab Lowest possible range of body weight:	1 × every 28 days	13.0	1	13.0

Designation of the therapy	Treatment mode	Number of treatments/patient/year	Treatment duration/treatment (days)	Treatment days/patient/ year
≥ 10 to < 20 kg BW Maximum possible range of body weight: ≥ 100 kg BW	1 × every 56 days	6.5	1	6.5
Appropriate comparator therapy				
Eculizumab Lowest possible range of body weight: 10 to < 20 kg BW	1 × every 14 days	26.1	1	26.1
Maximum possible range of body weight: ≥ 40kg BW	1 × every 14 days	26.1	1	26.1

Usage and consumption:

Designation of the therapy	Dosage/ application	Dose/patient/treatment days	Consumption by potency/treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Ravulizumab Lowest possible range of body weight: ≥ 10 to < 20 kg BW	600 mg	600 mg	2 × 300 mg	13.0	26 × 300 mg
Maximum possible range of body weight: ≥ 100 kg BW	3600 mg	3600 mg	3 × 1100 mg + 1 × 300 mg	6.5	19.5 × 1100 mg + 6.5 × 300 mg
Appropriate comparator therapy					
Eculizumab					

Designation of the therapy	Dosage/ application	Dose/patient/treatment days	Consumption by potency/treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Lowest possible range of body weight: ≥ 10 to < 20 kg BW	300 mg	300 mg	1 × 300 mg	26.1	26.1 × 300 mg
Maximum possible range of body weight: ≥ 40 kg BW	1200 mg	1200 mg	4 × 300 mg	26.1	104.4 × 300 mg

Costs:

In order to improve comparability, the costs of the medicinal products were approximated based on the pharmacy sales price level as well as less the statutory rebates according to 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.

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					
Ravulizumab 300 mg	1 CIS	€ 5,265.85	€ 1.77	€ 0.00	€ 5,264.08
Ravulizumab 1100 mg	1 CIS	€ 19,280.92	€ 1.77	€ 0.00	€ 19,279.15
Appropriate comparator therapy					
Eculizumab 300 mg	1 CIS	€ 5,877.61	€ 1.77	€ 335.09	€ 5,540.75
Abbreviations: CIS = concentrate for the preparation of an infusion solution					

Pharmaceutical selling price (LAUER-TAXE®) as last revised: 1 January 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.

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

Other services covered by SHI funds:

The special agreement on contractual unit costs of retail pharmacist services (*Hilfstaxe*; contract on price formation for substances and preparations of substances; Sections 4 and 5 Pharmaceutical Price Ordinance) of 1 October 2009 is not fully used to calculate the costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131, paragraph 4 SGB V is a suitable basis for a standardised calculation.

According to the *Hilfstaxe* in its currently valid version, surcharges for the production of parenteral preparations containing cytostatic agents of a maximum of € 81 per ready-to-use preparation and for the production of parenteral solutions containing monoclonal antibodies of a maximum of € 71 per ready-to-use unit are to be payable. These additional costs are not added to the pharmacy sales price but rather follow the rules for calculating the *Hilfstaxe*. The cost representation is based on the pharmacy sales price and the maximum surcharge for the preparation and is only an approximation of the treatment costs. This presentation does not take into account, for example, the rebates on the pharmacy sales price of the active ingredient, the invoicing of discards, the calculation of application containers and carrier solutions according to the regulations in Annex 3 of the *Hilfstaxe*.

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.

4. Process sequence

At its session on 29 October 2019, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 24 July 2020, the pharmaceutical company submitted a dossier for the benefit assessment of ravulizumab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

By letter dated 28 July 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 ravulizumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 29 October 2020, and the written statement procedure was initiated with publication on the website of the G-BA on 2 November 2020. The deadline for submitting written statements was 23 November 2020.

The oral hearing was held on 7 December 2020.

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 12 January 2021, and the proposed resolution was approved.

At its session on 21 January 2021, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	29 October 2019	Determination of the appropriate comparator therapy
Working group Section 35a	2 December 2020	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	7 December 2020	Conduct of the oral hearing
Working group Section 35a	15 December 2020 5 January 2021	Consultation on the dossier assessment by the IQWiG, evaluation of the written statement procedure
Subcommittee on Medicinal Products	12 January 2021	Concluding discussion of the draft resolution
Plenum	21 January 2021	Adoption of the resolution on the amendment of Annex XII of the AM-RL

Berlin, 21 January 2021

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

Prof. Hecken