

Justification



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 Andexanet alfa

of 20 February 2020

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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 relevant date for the first placing on the market of the active ingredient andexanet alfa in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the G-BA (VerfO) is 1 September 2019. The pharmaceutical company submitted the final dossier to the G-BA in accordance with Section 4, paragraph 3, number 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 1 VerfO on 30 August 2019.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on the website of the G-BA (www.g-ba.de) on 2 December 2019, 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 andexanet alfa 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, the statements submitted in the written statement and oral hearing procedure, and the addenda to the benefit assessment prepared by the IQWiG. In order to determine the extent of the additional benefit, the G-BA has 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 andexanet alfa.

In the light of the above and taking into account the 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 andexanet alfa (Ondexxya®) in accordance with product information

Andexanet alfa (Ondexxya®) is indicated for adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

Appropriate comparator therapy:

- An optimised standard therapy for life-threatening or uncontrolled bleeding.

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.
3. As comparator therapy, medicinal products 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.

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.

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

- On 1. No specific medicinal product is currently approved for the treatment of adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.
- On 2. For adult patients treated with a direct Factor Xa (FXa) inhibitor (apixaban or rivaroxaban) who have life-threatening or uncontrolled bleeding, non-medicinal treatment is not considered as the sole appropriate comparator therapy.
- On 3. No resolutions of the G-BA have been made in the present therapeutic indication.
- On 4. The generally accepted state of medical knowledge for the present indication was established by means of a search for guidelines and systematic reviews of clinical studies.

Overall, the evidence base for the treatment of bleeding complications in the prophylaxis of thrombotic events is very limited. For severe bleeding under treatment with rivaroxaban or apixaban, the administration of prothrombin concentrates is mentioned in the literature as an option. In the case of life-threatening bleeding, the administration of recombinant factor VIIa may be considered.

The present therapeutic indication refers to life-threatening or uncontrolled bleedings. In addition to the possible administration of prothrombin concentrates, further therapeutic options for the attempt of haemostasis in cases of life-threatening or uncontrolled bleeding include fluid substitution or the administration of plasma expanders or blood products. A criterion for the appropriate therapy in each case is also the localisation of the life-threatening or uncontrolled bleeding (e.g. cerebral haemorrhage, gastrointestinal bleedings).

Therefore, an optimised standard therapy for life-threatening or uncontrolled bleeding is determined as an appropriate comparator therapy for the present therapeutic indication. This may include blood products, fluid substitution, plasma expanders, or prothrombin concentrates.

It is assumed that the patients in both arms receive optimal intensive medical treatment.

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 andexanet alfa is assessed as follows:

For adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding, the additional benefit compared with the appropriate comparator therapy is not proven.

Justification:

The benefit assessment was not based on directly comparable data of andexanet alfa compared with the appropriate comparator therapy.

ANNEXA-4 study on andexanet alfa

The pharmaceutical company presents the single-arm multi-centre ANNEXA-4 pivotal study for andexanet alfa. The study included 352 adult patients treated with an FXa inhibitor

(apixaban, rivaroxaban, edoxaban, enoxaparin). The patients had to suffer from an acute severe bleeding, and it had to be necessary to stop the anticoagulation. The bleedings requiring the suspension of anticoagulation were (severe) intracranial haemorrhages in 64.5% of the included patients and gastrointestinal haemorrhages in 25.6% of the patients. Treatment with andexanet alfa for haemostasis was administered in compliance with the marketing authorisation with an initial intravenous bolus followed by a continuous intravenous infusion in two different dosing schemes depending on the last dose and the time of the last intake of the FXa inhibitor. The follow-up time of the patients was 30 days.

The primary endpoints of the study were the percentage change in anti-FXa activity and the achievement of effective haemostasis 12 hours after treatment with andexanet alfa. Secondary endpoints of the study were effects of intracranial haemorrhage on the neurological status of patients, the need for blood transfusions, and the occurrence of renewed bleeding as well as endpoints related to mortality and adverse events.

Propensity-score-adjusted comparison

As part of the written statement procedure, the pharmaceutical company presented a propensity-score(PS)-adjusted comparison of individual arms from different studies for the comparison of andexanet alfa with the appropriate comparator therapy in patients with intracerebral bleedings. The pharmaceutical company included the single-arm ANNEXA-4 study for the intervention and the single-arm RETRACE-II study for the appropriate comparator therapy. Although the RETRACE II study was already part of the study pool for the appropriate comparator therapy in the benefit assessment dossier, the pharmaceutical company did not yet have the complete data set of the study and thus the patient-individual data at the time the dossier was submitted.

The RETRACE II study is a retrospective German observational (registry) study involving 1,338 patients from 19 university centres who experienced vitamin K antagonist-associated or non-vitamin K-dependent oral anticoagulant-associated intracerebral bleeding between 1 January 2011 and 31 December 2015. Patients with intracerebral bleeding associated with trauma, tumour, arteriovenous malformation, aneurysmatic subarachnoid haemorrhage, acute thrombolysis, or other coagulopathies were excluded from the study.

Endpoints of the study were haematoma enlargement, occurrence of intracranial and extracranial complications (ischaemic and haemorrhagic adverse events) during hospitalisation, mortality before leaving hospital or after three months, and neurological functionality after three months.

For the PS-adjusted comparison, the pharmaceutical company only considers those patients who were treated with apixaban or rivaroxaban within the last 18 hours and suffered intracerebral, non-trauma, or tumour-associated bleeding. To further align the patient collectives, patients in the RETRACE II study with abnormal liver function or alcohol abuse are excluded and not considered in the PS-adjusted comparison. The sub-population selected for comparison (85 patients from the ANNEXA 4 study; 97 patients from the RETRACE II study) therefore does not cover all patients covered by the therapeutic indication of andexanet alfa.

From the patient characteristics presented, it is clear that bleeding in the comparator arm (RETRACE II study) was treated with vitamin K in 5.2% of the patients and with no specific therapy in 15.5% of the patients. Thus, for these patients, it is unclear whether they have received a therapy in the sense of the appropriate comparator therapy. Further information on the interventions carried out (e.g. on concomitant medication or local and intensive care measures) is missing.

To adjust for differences in the patient populations, the pharmaceutical company performed a PS-adjusted comparison of the individual arms from the two studies. The propensity score is modelled on the basis of patient characteristics. For comparison, the endpoints of 30 days mortality before discharge from hospital, volume change (baseline to follow-up) of intracerebral haemorrhage lesion, and neurological status measured by the Modified Rankin

Scale after treatment are used. On the other hand, the pharmaceutical company does not present any evaluations of the endpoints on health-related quality of life and side effects because there is insufficient data from the RETRACE II study for these endpoints.

Despite adjustment for potentially relevant effect modifiers or prognostic factors, the results from a comparison of individual arms from different studies are subject to inherent uncertainty due to the lack of randomisation because potentially unknown confounders can systematically bias the results. In addition, in the comparison presented, some patient characteristics were not considered in the modelling of the propensity score because of missing values. For example, for the National Institute of Health Stroke Scale (NIHSS), surveys were available for only 45% of patients in the ANNEXA-4 population. An adequate adjustment for this characteristic was therefore not possible. Here, higher mean values can be seen in patients receiving the comparator therapy (8 in ANNEXA-4 vs 10 in RETRACE-II). This indicates a higher degree of severity of intracerebral bleeding in the patients on the comparator therapy side.

Notwithstanding the insufficiently comparable patient characteristics, the PS-adjusted comparison shows a statistically significant difference in favour of andexanet alfa (difference of the mean volume change between the groups [ml]: -7.21; 95% confidence interval [-11.41; -2.83]; $p = 0.001$). However, the effect observed is not large enough to be explained by systematic bias alone. Moreover, it is unclear how this endpoint is reflected in directly patient-relevant outcomes such as neurological function or mortality. There is no statistically significant difference between the two groups in the endpoints neurological function and mortality. Furthermore, without a comparative evaluation of side effect endpoints, it is not possible to weigh the benefits and harms of the intervention against the appropriate comparator therapy.

Overall, the data of the PS-adjusted comparison are not suitable to derive an additional benefit for andexanet alfa compared with the appropriate comparator therapy.

2.1.4 Limitation of the period of validity of the resolution

The limitation of the period of validity of the resolution on the benefit assessment of andexanet alfa finds its legal basis in Section 35a, paragraph 3, sentence 4 SGB V. Thereafter, the G-BA may limit the validity of the resolution on the benefit assessment of a medicinal product. In the present case, the limitation is justified by objective reasons consistent with the purpose of the benefit assessment according to Section 35a, paragraph 1 SGB V.

The resolution is not based on directly comparative data from a randomised controlled trial of andexanet alfa compared with the appropriate comparator therapy.

As part of the conditional marketing authorisation of andexanet alfa, the pharmaceutical company is required by the European Medicines Agency to submit directly comparative data on andexanet alfa compared with current standard care by 30 June 2023.

In accordance with this EMA requirement, a randomised controlled trial comparing andexanet alfa to standard care in patients treated with a direct FXa inhibitor and suffering from intracranial haemorrhage was initiated in 2019 (*Study 18-513*). The study is expected to be completed in 2023.

Against the background that directly comparative clinical data that are, in principle, relevant for the benefit assessment of andexanet alfa in the present indication are expected, it is justified to limit the period of validity of the present resolution. However, it must be taken into account that the commissioned study will only generate data on patients with intracranial bleedings. Consequently, based on this study, no conclusions can be drawn regarding the additional benefit of andexanet alfa in patients with extracranial bleeding.

For the renewed benefit assessment after the deadline, the results of the direct comparative study of andexanet alfa compared with the standard therapy commissioned by the EMA are to be presented in the dossier. A limitation of the resolution until 1 November 2023 is considered to be appropriate.

The G-BA is able, in principle, to revise the limitation if it has been presented with clear justification that it is insufficient or too long.

In accordance with Section 3, paragraph 1 No. 5 AM-NutzenV in conjunction with Chapter 5, Section 1, paragraph 2, No. 7 VerfO, the procedure for the benefit assessment of the medicinal product andexanet alfa shall recommence when the deadline has expired. For this purpose, the pharmaceutical company must submit a dossier to the G-BA at the latest on the day of expiry of the deadline to prove the extent of the additional benefit of andexanet alfa (Section 4, paragraph 3, No. 5 AM-NutzenV in conjunction with Chapter 5, Section 8, No. 5 VerfO). The possibility that a benefit assessment for andexanet alfa can be carried out for other reasons (*cf* Chapter 5, Section 1, paragraph 2 VerfO) remains unaffected.

2.1.5 Summary of the assessment

The present benefit assessment concerns the benefit assessment of the new medicinal product Ondexxya[®] with the active ingredient active andexanet alfa. Ondexxya[®] was conditionally approved with “specific obligations” for the treatment of adult patients treated with a direct factor Xa inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

The G-BA determined the appropriate comparator therapy to be an optimised standard therapy for life-threatening or uncontrolled bleeding.

No direct comparative data are available for andexanet alfa compared with the appropriate comparator therapy. For the benefit assessment, the pharmaceutical company presents a propensity-score-adjusted comparison of individual arms from different studies for the comparison of andexanet alfa with the appropriate comparator therapy in patients with intracerebral bleedings. The single-arm pivotal ANNEXA-4 study is included for the intervention and the German retrospective observational (registry) study RETRACE-II for the appropriate comparator therapy.

The patient characteristics of the studies used for the propensity score adjusted comparison do not show sufficient similarity, especially with regard to the severity of intracerebral bleeding. Although there is a statistically significant difference in favour of andexanet alfa for the endpoint volume change in intracerebral haemorrhage lesion, the effect is not large enough to be explained by systematic bias alone. Moreover, it is unclear how this endpoint is reflected in directly patient-relevant outcomes such as neurological function or mortality. There is no statistically significant difference between the two groups in the endpoints neurological function and mortality. Furthermore, no comparative data on side effect endpoints are available. It is therefore not possible to weigh the benefit and harm of the intervention against the appropriate comparator therapy.

Overall, the data presented are not suitable to derive an additional benefit of andexanet alfa compared with the appropriate comparator therapy.

The resolution is limited until 1 November 2023.

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

The number of patients is the target population in the statutory health insurance (SHI). These are based on the data from the pharmaceutical company's dossier.

Because of unconsidered diagnostic codes, potentially divergent patient numbers for 2019, and the inclusion of persons with controllable or non-life-threatening bleeding for the upper limit as well as the exclusion of further individuals with life-threatening bleeding for the lower limit, the range of the number of patients in the SHI target population indicated is subject to uncertainties overall.

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 Ondexxya® (active ingredient: andexanet alfa) at the following publicly accessible link (last access: 7 November 2019):

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

Andexanet alfa is intended exclusively for use in hospitals.

This medicinal product was approved with "specific obligations". This means that further evidence of the benefit of the medicinal product is anticipated. The EMA will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

After the administration of andexanet alfa, monitoring for signs and symptoms of thrombosis is highly recommended.

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 2020).

Adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) and who suffer a life-threatening or uncontrolled bleeding are always treated within the framework of an optimised standard therapy. The treatment costs for an optimised standard therapy are different for each individual patient.

Because an optimised standard therapy for life-threatening or uncontrolled bleeding has been determined as an appropriate comparator therapy, an optimised standard therapy is also represented for the medicinal product under evaluation.

The type and scope of an optimised standard therapy may vary between the medicinal product to be evaluated and the comparator therapy.

Treatment duration:

Designation of the therapy	Treatment mode	Number of treatments/patient/year	Treatment duration/treatment (days)	Treatment days/patient/year
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Designation of the therapy	Treatment mode	Number of treatments/patient/year	Treatment duration/treatment (days)	Treatment days/patient/year
Medicinal product to be assessed				
Andexanet alfa	Single dose	1	1	1
An optimised standard therapy for life-threatening or uncontrolled bleeding	different for each individual patient			
Appropriate comparator therapy				
An optimised standard therapy for life-threatening or uncontrolled bleeding	different for each individual patient			

Usage and consumption:

To illustrate the costs of therapy with andexanet alfa, it is assumed that anticoagulation only needs to be stopped once a year per patient. This does not take into account the fact that there may be more than one bleeding per year, thus making it necessary to stop anticoagulation several times.

Andexanet alfa² is administered as an intravenous bolus followed by a continuous infusion. The low dosing scheme allows for an initial bolus of 400 mg andexanet alfa followed by a continuous infusion of 480 mg andexanet alfa.

The high dosing scheme allows for an initial bolus of 800 mg andexanet alfa followed by a continuous infusion of 960 mg andexanet alfa.

The recommended dosing scheme (low dose vs high dose) of andexanet alfa is based on the current dose of apixaban or rivaroxaban taken by the patient at the time of discontinuation of anticoagulation as well as on the time elapsed since the last intake of apixaban or rivaroxaban.

Designation of the therapy	Dosage/use	Dose/patient/treatment day	Consumption by potency/treatment day	Treatment days/patient/year	Annual average consumption by potency
Medicinal product to be assessed					
Andexanet alfa	(400 mg + 480 mg) – (800 mg + 960 mg)	(400 mg + 480 mg) – (800 mg + 960 mg)	5 × 200 mg – 9 × 200 mg	1	5 × 200 mg – 9 × 200 mg
An optimised	different for each individual patient				

² Andexanet alfa is intended exclusively for use in hospitals.

Designation of the therapy	Dosage/use	Dose/patient/treatment day	Consumption by potency/treatment day	Treatment days/patient/year	Annual average consumption by potency
standard therapy for life-threatening or uncontrolled bleeding					
Appropriate comparator therapy					
An optimised standard therapy for life-threatening or uncontrolled bleeding	different for each individual patient				

Costs:

Andexanet alfa is listed in the LAUER-TAXE® but is only sold as a hospital pack. The active ingredient is therefore currently not subject to the Pharmaceutical Price Ordinance, and there are no rebates according to Section 130 or Section 130a SGB V. The calculation is based on the purchase price of the clinic package plus 19% value added tax. This differs from the information usually taken into account in LAUER-TAXE®.

Costs of the medicinal product:

Designation of the therapy	Package size	Costs (purchase price of clinic pack)	Value added tax of 19%	Costs
Medicinal product to be assessed				
Andexanet alfa	4 DFL	€ 12,800	€ 2,432	€ 15,232
An optimised standard therapy for life-threatening or uncontrolled bleeding	different for each individual patient			
Appropriate comparator therapy				
An optimised standard therapy for life-threatening or uncontrolled bleeding	different for each individual patient			
Abbreviations: DFL = glass vial (german "Durchstechflasche")				

Pharmaceutical retail price (LAUER-TAXE®) as last revised: 1 February 2020

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 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.

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

The Subcommittee on Medicinal Products determined the appropriate comparator therapy at its session on 12 June 2019.

On 30 August 2019, the pharmaceutical company submitted a dossier for the benefit assessment of andexanet alfa to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 30 August 2019 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 andexanet alfa.

The dossier assessment by the IQWiG was submitted to the G-BA on 28 November 2019, and the written statement procedure was initiated with publication on the website of the G-BA on 2 December 2019. The deadline for submitting written statements was 23 December 2019.

The oral hearing was held on 6 January 2020.

By letter dated 6 January 2020, the IQWiG was commissioned with a supplementary assessment of data submitted in the written statement procedure. The addendum prepared by IQWiG was submitted to the G-BA on 31 January 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 11 February 2020, and the proposed resolution was approved.

At its session on 20 February 2020, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal Products	12 June 2019	Determination of the appropriate comparator therapy
Subcommittee Medicinal Products	6 January 2020	Conduct of the oral hearing, Commissioning of the IQWiG with the supplementary assessment of documents
Working group Section 35a	14 January 2020 4 February 2020	Consultation on the dossier evaluation by the IQWiG, evaluation of the written statement procedure
Subcommittee Medicinal Products	11 February 2020	Concluding discussion of the draft resolution
Plenum	20 February 2020	Adoption of the resolution on the amendment of Annex XII of the AM-RL

Berlin, 20 February 2020

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

Prof. Hecken