Justification

Gemeinsamer Bundesausschuss

to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Resolutions on the Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V – Olaratumab

of 18 May 2017

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.

For medicinal products for the treatment of a rare disease (orphan drugs) that are approved in accordance with Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999, according to Section 35a, paragraph 1, sentence 10, 1st half of the sentence SGB V, the additional medical benefit is considered to be proven through the grant of the marketing authorisation. Evidence of the medical benefit and the additional medicinal benefit in relation to the appropriate comparator therapy need not be submitted (Section 35a, paragraph 1, sentence 10, 2nd half of the sentence SGB V). Section 35a, paragraph 1, sentence 10 1st half of the sentence SGB V thus guarantees an additional benefit for an approved orphan drug, although an assessment of the orphan drug in accordance with the principles laid down in Section 35a, paragraph 1, sentence 3, Nos. 2 and 3 SGB V in conjunction with Chapter 5, Sections 5 et seq. of the Rules of Procedure, G-BA (VerfO) has not been carried out. Only the extent of the additional benefit has to be demonstrated.

However, the restrictions on the benefit assessment of orphan drugs resulting from the statutory obligation to the marketing authorisation do not apply if the turnover of the medicinal product with the SHI at pharmacy retail prices including VAT exceeds € 50 million in the last 12 calendar months. According to Section 35a, paragraph 1, sentence 11 SGB V, the pharmaceutical company must then, within three months of being requested to do so by the G-BA, submit evidence according to Chapter 5, Section 5, paragraphs 1–6 VerfO, in particular regarding the additional medical benefit in relation to the appropriate comparator therapy as defined by the G-BA according to Chapter 5, Section 6 VerfO and prove the additional benefit in comparison with the appropriate comparator therapy.

In accordance with Section 35a, paragraph 2 SGB V, the G-BA decides whether to carry out the benefit assessment itself or to commission the Institute for Quality and Efficiency in Health Care (IQWiG). On the basis of the statutory requirement in Section 35a, paragraph 1, sentence 10 SGB V that the additional benefit of an orphan drug is deemed to have been proven through the grant of marketing authorisation, the G-BA modified the procedure for the benefit assessment of orphan drugs at its session on 15 March 2012 to the effect that, in the case of orphan drugs, the G-BA initially no longer independently determines an appropriate comparator therapy as the basis for the solely legally permissible assessment of the extent of an additional benefit to be assumed by law. Rather, the extent of the additional benefit provided by the G-BA is assessed exclusively on the basis of the approval studies.

Accordingly, at its session on 15 March 2012, the G-BA amended the mandate issued to the IQWiG by resolution of 1 August 2011 for the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a, paragraph 2 SGB V in such a way that, in the case of orphan drugs, the IQWiG is only commissioned to carry out a benefit assessment in the case of a previously defined comparator therapy when the sales volume of the medicinal product concerned has exceeded the legal limit of € 50 million and is therefore subject to an unrestricted benefit assessment (*cf* Section 35a, paragraph, 1 sentence 11 SGB V). According to Section 35a, paragraph 2 SGB V, the assessment of the G-BA 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 shall pass a resolution 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 olaratumab in accordance with Chapter 5, Section 8, number 1, sentence 2 of the Rules of Procedure of the G-BA (VerfO) is 1 December 2016. 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, number 1 VerfO on 1 December 2016.

Olaratumab for the treatment of soft tissue sarcoma is approved as a medicinal product for the treatment of a rare disease in accordance with Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999.

According to Section 35a, paragraph 1, sentence 10, 1st half of the sentence SGB V, the additional benefit is considered to be already proven by the marketing authorisation. The extent of the additional benefit is assessed on the basis of the approval studies by the G-BA.

The G-BA carried out the benefit assessment and commissioned the IQWiG to evaluate the information provided by the pharmaceutical company in Module 3 of the dossier on treatment costs and patient numbers. The benefit assessment was published together with the IQWiG assessment on the website of the G-BA (www.g-ba.de) on 1 March 2017, thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA has adopted its resolution on the basis of the dossier of the pharmaceutical company, the dossier evaluation carried out by the G-BA, the assessment of treatment costs and patient numbers (IQWiG G16-13) prepared by the IQWiG, and the statements submitted in the written statement and oral hearing procedure.

In order to determine the extent of the additional benefit, the G-BA has evaluated the studies relevant for marketing authorisation with regard to their therapeutic relevance (qualitative) in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7, sentence 1 numbers 1 through 4 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of olaratumab.

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

2.1.1 Approved therapeutic indication of olaratumab (Lartruvo®) in accordance with product information

Lartruvo is indicated in combination with doxorubicin for the treatment of adult patients with advanced soft tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin (see Section 5.1 of the product information).

[1] General Methods, Version 4.2 dated 22 April 2015. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen [Institute for Quality and Efficiency in Health Care], Cologne.

2.1.2 Extent of the additional benefit

In summary, the additional benefit of olaratumab in combination with doxorubicin is assessed as follows:

for patients with advanced soft tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin, there is a considerable additional benefit.

Justification:

For the benefit assessment, the pharmaceutical company submits the results of the JGDG pivotal study in the dossier.

The JGDG study is an open, multi-centric Phase 1b/2 study that includes adult patients with advanced or metastasised soft tissue sarcoma who are not considered for a curative treatment with surgery or radiotherapy and who had not yet received anthracycline. The study comprises a Phase 1b section to investigate the safety and pharmacokinetics of olaratumab in combination with doxorubicin and a Phase 2 section to investigate the efficacy and safety of olaratumab in combination with doxorubicin in an open randomised controlled comparison. The patients examined in Phase 1b did not switch to Phase 2 of the study.

The benefit assessment is based on the JGDG Phase 2 study in which olaratumab + doxorubicin was compared with doxorubicin monotherapy. For this purpose, 133 patients were randomised 1:1 to the treatment group with olaratumab + doxorubicin (N = 66) or the doxorubicin control group (N = 67). The randomisation was stratified for the four factors: (1) PDGFRα status (positive vs negative), (2) number of systemic previous therapies (0 vs ≥ 1), (3) histological tumour type (leiomyosarcoma vs synovial sarcoma vs others), and (4) ECOG-PS (0–1 vs 2).

Patients who showed no progress after eight therapy cycles of olaratumab + doxorubicin were subsequently given olaratumab monotherapy. In the control group, monotherapy with doxorubicin was performed for a maximum of eight cycles (24 weeks). Patients in the control group with a progression during or after doxorubicin monotherapy were able to subsequently receive olaratumab monotherapy (crossover population).

The study was conducted exclusively in the US at 16 study centres between October 2010 and May 2015.

Limitations in the significance of the study results:

In general, the study has limitations in the significance of the data because of the small sample size of only 133 included patients. In addition, some of the statistical criteria of the analyses conducted were not adequately defined *a priori*. The study results are subject to a high risk of bias, especially because of the unblinded study design.

With more than 20 sub-types of soft tissue sarcoma, the study population was characterised by a large histological heterogeneity. The most common subtypes were leiomyosarcoma, liposarcoma, and undifferentiated pleomorphic sarcoma. In this respect, the baseline characteristics of the study population show a striking difference between the study arms; the intervention group shows a broader histological heterogeneity in the sub-type than the control group. An imbalance between intervention and control group is also striking in the proportion of women (61 vs 51%), in patients who had received ≥ 1 previous systemic therapy (39 vs 30%), in the age ≥ 65 years (27 vs 36%), and in patients with > 2 metastasis sites (35 vs 51%).

From the control group, 30 patients with a progression during or after doxorubicin monotherapy received olaratumab monotherapy (crossover population), thereby further hindering a valid assessment of the treatment effect of olaratumab + doxorubicin.

Mortality

Overall survival

For the overall survival endpoint, there was a statistically significant increase in overall survival in the treatment group with olaratumab + doxorubicin compared with doxorubicin monotherapy (26.5 months vs 14.7 months median), thus resulting in a median extension of the survival of 11.8 months (hazard ratio: 0.46 [0.30; 0.71], p = 0.0003). The result was confirmed by sensitivity analyses addressing the influence of follow-up therapies, baseline characteristics, or the number of therapy cycles.

Morbidity

Progression-free survival

For the endpoint progression-free survival (PFS), there was no statistically significant difference between treatment groups: 8.2 months (olaratumab + doxorubicin) vs 4.4 months (doxorubicin) median (hazard ratio: 0.67 [0.40;1.12], p = 0.1208).

The PFS endpoint is a combined endpoint composed of endpoints of the mortality and morbidity categories. In the JGDG study, the mortality endpoint component was calculated as an independent endpoint via the overall survival endpoint. The morbidity component – radiologically determined disease progression according to the RESIST criteria – was not surveyed on a symptom-related basis but rather exclusively using imaging techniques. Taking the aforementioned factors into consideration, there are differing opinions within the G-BA regarding the relevance for patients of the PFS endpoint. The overall statement on the extent of the additional benefit remains unaffected.

Symptomatology

The effects of the therapies in the JGDG study on disease-specific symptomatology were not investigated. For the benefit assessment, no data on symptomatology are available for the combination olaratumab + doxorubicin compared with doxorubicin monotherapy.

Quality of life

The health-related quality of life was not investigated in the JGDG study. For the benefit assessment, no data are available on the effects of olaratumab + doxorubicin on quality of life compared with doxorubicin monotherapy.

Side effects

Adverse events occurred at least once in almost every patient in this trial – those treated with the combination of olaratumab + doxorubicin as well as those treated with doxorubicin monotherapy. The results on the overall rate of adverse events are used only as a supplement.

Adverse events classified as “severe adverse events” (CTCAE grade ≥ 3) occurred at least once (79.7% and 69.2%, respectively) in most patients in both treatment groups without statistically significant difference. 42.2% of patients in the olaratumab + doxorubicin and 38.5% of patients in the doxorubicin monotherapy treatment group were affected by “serious adverse events (SAE)” at least once. There is also no statistically significant difference for

this endpoint. In addition, there is no statistically significant difference between the treatment groups in the number of therapy discontinuations because of adverse events.

With regard to the frequently documented adverse events (≥ 10% of patients in one study arm), olaratumab + doxorubicin was associated in particular with increased occurrence of severe neutropoenia (CTCAE grade ≥ 3); however, this was not associated with an increased occurrence of febrile neutropoenia or severe infections.

When interpreting these results, the longer observation period for adverse events in the intervention group with olaratumab + doxorubicin must be taken into account. The present consideration of event frequencies therefore leads to a conservative result because the longer observation period in the intervention group alone may lead to more frequent documentation of adverse events.

Overall assessment

To assess the extent of the additional benefit of olaratumab in combination with doxorubicin for the treatment of advanced soft tissue sarcoma, the JGDG pivotal study provides results on mortality (overall survival), morbidity, and side effects compared with doxorubicin monotherapy.

The results for the overall survival endpoint show that treatment with olaratumab in combination with doxorubicin resulted in a statistically significant median survival extension of 11.8 months vs doxorubicin monotherapy; this is considered a significant improvement with a significant magnitude.

There is a lack of data for an assessment of health-related quality of life. Statements on quality of life are given high priority, especially in the present palliative therapy situation. There are also no data on disease-specific symptomatology.

The endpoints on side effects show neither an advantage nor a clear disadvantage. In the study, the increase of severe neutropoenia (CTCAE grade ≥ 3) in the olaratumab + doxorubicin treatment group was not associated with an increased incidence of febrile neutropoenia or severe infections.

Overall, the results available on patient-relevant outcomes show an additional benefit for olaratumab in combination with doxorubicin compared with doxorubicin monotherapy because of the prolongation in overall survival, which is assessed as considerable in scope.

The limitations in the significance of the study results described result in relevant uncertainties in the interpretation of the results. However, the extent of these uncertainties is not estimated to such an extent that they would not allow quantification of the additional benefit. However, the result is subject to relevant uncertainties.

As a result, the G-BA classifies the extent of the additional benefit of olaratumab in combination with doxorubicin as considerable based on the criteria in Section 5, paragraph 7 AM-NutzenV, taking into account the severity of the disease and the therapeutic objective in the treatment of the disease.

2.1.3 Limitation of the period of validity of the resolution

The limitation of the period of validity of the resolution on the benefit assessment of olaratumab (in combination with doxorubicin) has 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 this 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 significance of the study results available from the JGDG Phase 1b/2 study is limited, especially because of the small sample size of only 133 patients and the resulting limited statistical significance. This gives rise to relevant uncertainties in the interpretation of the available results, which means that the extent of the additional benefit identified in this resolution is subject to uncertainties.

To investigate the efficacy and safety of olaratumab in combination with doxorubicin in the present therapeutic indication, a blinded controlled, randomised Phase 3 study is currently under way (Study I5B-MC-JGDJ; "ANNOUNCE"). This study is planned to include 460 patients. This Phase 3 study is potentially relevant for assessing the additional benefit of olaratumab in combination with doxorubicin. In addition, there is a legitimate expectation that the results of this study will be more significant than the existing data basis.

Against the background that the medicinal product Lartruvo® with the active ingredient olaratumab was approved under "special conditions", the European Medicines Agency (EMA) requires, among other things, that the results of the currently ongoing phase 3 ANNOUNCE study be submitted as part of the evidence to be provided by the pharmaceutical company. The clinical study report on this study is expected to be submitted to the EMA by 31 January 2020.[2]

Against this background, it is justified to limit the duration of this resolution. For this purpose, the G-BA considers a limitation of the resolution until 1 May 2020 to be appropriate. In principle, an extension may be granted if it is justified and clearly demonstrated that the period of the limitation is not sufficient.

Conditions of the limitation:

For the renewed benefit assessment after the deadline, the study results from the currently ongoing Phase 3 study I5B-MC-JGDJ ("ANNOUNCE") are to be presented in the dossier.

In accordance with Section 3, number 5 AM-NutzenV in conjunction with Chapter 5 Section 1, paragraph 2, number 7 VerfO, the procedure for the benefit assessment of olaratumab shall recommence when the deadline has expired. For this purpose, the pharmaceutical company must submit a dossier on the benefit assessment of olaratumab to the G-BA at the latest on the day of expiry of the deadline (Section 4, paragraph 3, number 5 AM-NutzenV in conjunction with Chapter 5, Section 8, number 5 VerfO). The possibility that a benefit assessment of olaratumab can be carried out at an earlier point in time for other reasons (*cf* Chapter 5, Section 1, paragraph 2 VerfO) remains unaffected by this.

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

approx. 1,200–1,400 patients

The information on the number of patients is based on the target population in statutory health insurance (SHI).

The G-BA bases the resolution on the patient numbers stated in the dossier of the pharmaceutical company; these are subject to uncertainties based on the data available. The patient numbers are based on the incidence of patients with advanced soft tissue sarcoma. This

[2] European Medicines Agency. Assessment report: Lartruvo; 15 September 2016

may result in an underestimation because the marketing authorisation for olaratumab is not limited to newly diagnosed patients. Another underestimation lies in the derivation of the incidence via the mortality rate. Because the 1-year survival rate in the advanced stage is 50% and thus only half of the newly diagnoses patients have died after one year, these patients would not be included in the total number of patients.

Overall, it can be assumed that the number of patients is overestimated because the present therapeutic indication includes only patients who cannot be treated curatively and who had also not been treated with doxorubicin. However, the number of patients indicated includes all patients with advanced soft tissue sarcoma. Including the mortality rate in the calculation also leads to an overestimation of the number of patients because patients in earlier stages of the disease can also die of soft tissue sarcoma.

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 Lartruvo® (active ingredient: olaratumab) at the following publicly accessible link (last access: 10 April 2017):

http://www.ema.europa.eu/docs/de_DE/document_library/EPAR_-_Product_Information/human/004216/WC500216869.pdf

Treatment with olaratumab should only be initiated and monitored by specialists in internal medicine, haematology, and oncology who are experienced in the treatment of patients with soft tissue sarcomas.

This medicinal product was approved under “special conditions”. This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

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 May 2017).

Treatment duration:

If no maximum treatment duration is specified in the product information, the treatment duration is assumed to be one year, even if the actual treatment duration is patient-individual and/or is shorter on average.

Designation of the therapy	Treatment mode	Number of treatments per patient per year	Treatment duration per treatment (days)	Treatment days per patient per year
Olaratumab	Day 1 and 8 of a 21-day cycle	17 cycles	2	34
Doxorubicin	Day 1 of a 21-day	8 cycles	1	8

	cycle			

Usage and consumption:

The (daily) doses recommended in the product information are used as the basis for calculation.

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements from the official representative statistics "Microcensus 2013 – body measurements of the population" were used as a basis (average height: 1.72 m, average body weight: 76.3 kg). From this, a body surface area of 1.89 m² is calculated (calculation according to Du Bois 1916).

Designation of the therapy	Dosage	Dose per patient per treatment day	Consumption by potency per treatment day	Treatment days per patient per year	Mean annual consumption by potency
Olaratumab	15 mg/kg BW	1144.50 mg	3 × 500 mg	34	102 × 500 mg
Doxorubicin[3]	75 mg/m² BSA	141.75 mg	1 × 50 mg 1 × 100 mg	8	8 × 50 mg 8 × 100 mg

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy retail price level and also deducting the statutory rebates in accordance with Sections 130 and 130 a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates.

Costs of the medicinal product:

[3] The doxorubicin dosage corresponds to the information given in the product information of Lartruvo Section 5.1. Regarding dose adjustments, please refer to the product information of doxorubicin. According to the product information of doxorubicin, there is a cumulative maximum dose that should not be exceeded.

Designation of the therapy[4]	Costs (pharmacy selling price according to potency and package size)	Costs after deduction of statutory rebates
Olaratumab	€ 1,937.05 500 mg	€ 1827.93 [€ 1.77[5]; € 107.35[6]]
Doxorubicin[3]	€ 150.93[7] 50 mg € 285.46[7] 100 mg	€ 138.09 [€ 1.77[5]; € 11.07[6]] € 261.98 [€ 1.77[5]; € 21.71[6]]

Pharmaceutical retail price (LAUER-TAXE®) as last revised: 1 May 2017

Costs for additionally required SHI services:

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 or package information, the costs incurred for this must be taken into account as costs for additionally required SHI services. Only costs directly related to the use of the medicinal product are taken into account. Medical treatment costs, hospital costs incurred for application of the medicinal product (e.g. infusion vials, infusion equipment), for monitoring the success of the treatment or the course of the disease, costs incurred for routine investigations (e.g. standard laboratory services such as blood counts, that do not exceed standard expenditure over the course of oncological treatment), and medical fee-based services are not shown.

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) is not fully used to calculate costs because a) it is negotiated dynamically, b) it is not representative of the care because of the large number of billing modalities for cytostatic agents existing in SHI provision, most of which are regulated in non-public contracts, which are not tied to the Hilfstaxe, and c) it may not include all relevant active ingredients at a certain point in time and for these reasons is not suitable for standardised cost survey overall. On the other hand, the pharmacy retail price publicly accessible in the directory services in accordance with Section 131, paragraph 4 SGB V is a suitable basis for a standardised calculation.

According to the special agreement on contractual unit costs of retail pharmacist services [Hilfstaxe"] (last revised: 7. Supplementary Agreement to the Agreement on Pricing of Substances and Preparations of Substances of 1 March 2016), surcharges for the preparation of parenteral preparations containing cytostatics of a maximum of € 81 per ready-to-use preparation and for the preparation of parenteral solutions containing monoclonal antibodies of a maximum of € 71 per ready-to-use unit shall apply. These amounts can be undercut in contracts. These additional costs are not added to the pharmacy retail price but rather follow the rules for calculating the Hilfstaxe. The cost representation is based on the pharmacy retail price and the maximum surcharge for production and is only an approximation of the

[4] From the 2nd year of treatment onwards, the costs for olaratumab monotherapy apply.
[5] Rebate according to Section 130 SGB V
[6] Rebate according to Section 130a SGB V
[7] Fixed reimbursement rate

treatment costs. This presentation does not take into account, for example, the rebates on the pharmacy purchase price of the active ingredients, the invoicing of discards, and the calculation of application containers and carrier solutions according to the regulations of Annex 3 of the Hilfstaxe.

Designation of the therapy[4]	Costs per unit	Number per cycle	Number per patient per year	Costs per patient per year
Olaratumab	€ 71	2	34	€ 2,414
Doxorubicin	€ 81	1	8	€ 648 Total: € 3,062

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

On 1 December 2016, the pharmaceutical company submitted a dossier for the benefit assessment of olaratumab to the G-BA in due time in accordance with Chapter 5, Section 8, number 1, sentence 2 VerfO.

The benefit assessment of the G-BA was published on 1 March 2017 together with the IQWiG assessment of treatment costs and patient numbers on the G-BA website (www.g-ba.de), thus initiating the written statement procedure. The deadline for submitting written statements was 22 March 2017.

The oral hearing was held on 11 April 2017.

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 23 May 2017, and the proposed resolution was approved.

At its session on 18 May 2017, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal Products	21 February 2017	Information of the benefit assessment of the G-BA
Working group Section 35a	28 March 2017	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal Products	11 April 2017	Conduct of the oral hearing
Working group Section 35a	18 April 2017; 2 May 2017	Consultation on the dossier evaluation by the G-BA, the assessment of treatment costs and patient numbers by the IQWiG, and the evaluation of the written statement procedure
Subcommittee Medicinal Products	9 May 2017	Concluding consultation of the proposed resolution
Plenum	18 May 2017	Adoption of the resolution on the amendment of Annex XII of the AM-RL

Berlin, 18 May 2017

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

Prof. Hecken