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 Naldemedin (Treatment of Opioid-induced Constipation in Adult Patients who Have Previously Been Treated with a Laxative)

of 5 November 2020

Contents

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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 naldemedin (Rizmoic) in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the G-BA (VerfO) is 15 May 2020. 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 12 May 2020.

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 17 August 2020, 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 naldemedin 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,

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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 naldemedin.

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 naldemedin (Rizmoic) in accordance with the product information

Rizmoic is indicated for the treatment of opioid-induced constipation (OIC) in adult patients who have previously been treated with a laxative.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

a) Adult patients with opioid-induced constipation who have previously been treated with a laxative

Another non-prescription laxative (in accordance with AM-RL Annex I No. 1) or a prescribable medical product to treat constipation (in accordance with AM-RL Section J and Annex V) or combinations thereof

b) Adult patients with opioid-induced constipation for whom a non-prescription laxative or a prescribable medical product to treat constipation are no longer suitable

Methylnaltrexone or naloxegol

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 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.

[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.

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

On 1. The peripheral opioid receptor antagonists methylnaltrexone and naloxegol have been explicitly approved to treat opioid-induced constipation.

The following medicinal products have also been approved to treat constipation: lubricant laxatives, contact laxatives, swelling agents, osmotic laxatives, sorbitol/docusate, glycerol, carbonate and E. coli preparations, and prucalopride.

On 2. Annex V of the pharmaceutical directive specifies that medical products with a laxative effect may be prescribed in the therapeutic indication of naldemedin.

On 3. No resolutions have been reached on the benefit assessment for the therapeutic indication of opioid-induced constipation.

On 4. The general state of medical knowledge was illustrated by systematic research for guidelines and reviews of clinical studies in the present indication.
This revealed no evidence suggesting that a particular substance or class of substances was preferable for non-prescription laxatives or prescribable medical products. Consequently, as appropriate comparative therapy for adult patients with opioid-induced constipation who have previously been treated with a laxative, reimbursable laxatives (in accordance with AM-RL Annex I No. 1) and prescribable medical products (in accordance with AM-RL Section J and Annex V) or a combination of these without further restriction are equally suitable as therapeutic options. Treatment for opioid-induced constipation must take account the fact that a decision must be made in line with a staged approach as to when therapy with non-prescription laxatives or prescribable medical products to treat constipation has already reached its limits and the use of prescription laxatives is indicated. A balanced decision of this kind – taking into account the authorisation of prescription medicinal products and the potential side effects – can be made after the failure of one or more laxatives, or possibly a combination.

Patients with opioid-induced constipation for whom such a non-prescription laxative or a prescribable medical product to treat constipation is no longer an option, for example due to an insufficient response, can be treated with opioid receptor antagonists in accordance with the relevant marketing authorisation. The active ingredients methylnaltrexone or naloxegol are equally appropriate therapeutic options.
As specified by the staged approach of the S3 guideline for palliative care updated in September 2020, the prokinetic serotonin receptor agonist prucalopride can only be used as a subordinate therapeutic alternative if the above-mentioned OIC therapy strategy fails. In addition, in the written and oral statements the clinicians also considered subordinate use of prucalopride. New evidence from the described patient population thus renders prucalopride no longer appropriate.

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 naldemedin is assessed as follows:

For adult patients with opioid-induced constipation who have previously been treated with a laxative and for whom a non-prescription laxative or prescribable medical product to treat constipation is no longer an option, an additional benefit is not proven.

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Justification for patient group a):

For this patient population, the pharmaceutical company did not present any study that would have been suitable for the assessment of the additional benefit of naldemedin in the present therapeutic indication compared with the appropriate comparator therapy.

Justification for patient group b):

In its dossier to evaluate the additional benefit of naldemedin, the pharmaceutical company has not presented any directly comparative studies compared to the appropriate comparator therapy, but rather an indirect comparison (naldemedin vs naloxegol via the bridge comparator, standard therapy) based on the two RCT COMPOSE 3 and KODIAC-08.

COMPOSE 3

The COMPOSE 3 study is a double-blind, randomised, multicentre trial comparing naldemedin with placebo over 52 weeks. A total of 1246 adult patients with OIC following opioid therapy for chronic non-cancer pain were included and the primary endpoint was adverse events. To be included, patients had to be pre-treated with laxatives. Inclusion was permissible for patients with existing, stable laxative therapy, even with dose adjustments or in the context of emergency medication, both in the verum and the comparator arm.

KODIAC-08

The KODIAC-08 study is an open-label, randomised, multicentre study comparing naloxegol to 52-week standard care in 844 adult patients with OIC following opioid therapy for non-cancer chronic pain. The primary endpoints were various adverse events. Before randomisation, all laxatives had to be discontinued and patients in the comparator arm received standard care consisting of a regimen of laxatives selected by the investigator. Laxative therapy was prohibited in the intervention arm.

Suitability of the studies for an indirect comparison

The indirect comparison on the basis of these studies is not appropriate for the current benefit assessment, however, for the following reasons.
The KODIAC-08 study considered by the pharmaceutical company is a long-term safety study, whose only recorded endpoints are adverse events. As a result, it is not possible to perform a risk-benefit comparison on the basis of this study.
In addition, the study populations of the two trials are not sufficiently comparable. In KODIAC-08, the study population only partially corresponds to the approved therapeutic indication for naldemedin, since pre-treatment with laxatives was not necessary for inclusion into the study. In addition, the proportion of patients in both trials who are no longer eligible for treatment with another laxative is unclear.
Standard therapy, as a bridge comparator for indirect comparison, is also not sufficiently comparable in the two studies; in contrast to the KODIAC-08 study, no newly defined laxative therapy was used as standard therapy in the COMPOSE 3 study at the beginning of the study.
Based on the aforementioned factors, the studies drawn on by the pharmaceutical company are not well suited to making an indirect comparison.

Overall assessment/conclusion:

The pharmaceutical company has not provided any relevant data in its dossier to evaluate the additional benefit of naldemedin compared to the appropriate comparator therapy for adult patients with opioid-induced constipation who have previously been treated with a laxative.

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The G-BA considers the indirect comparisons presented for adult patients with opioid-induced constipation, for whom a non-prescription laxative or a prescribable medical product to treat constipation is no longer an option, to be, in their totality, unsuitable to derive patient-relevant effects for the additional benefit of naldemedin.
For adult patients with opioid-induced constipation who have previously been treated with a laxative and for whom a non-prescription laxative or prescribable medical product to treat constipation is no longer an option, an additional benefit compared to the appropriate comparator therapy is therefore not proven.

2.1.4 Summary of the assessment

The present assessment refers to the benefit assessment of the new medicinal product with the active ingredient naldemedin. The active ingredient naldemedin is approved for the treatment of opioid-induced constipation (OIC) in adult patients who have previously been treated with a laxative. In the therapeutic indication to be considered, two patient groups were distinguished:

a) Adult patients with opioid-induced constipation who have previously been treated with a laxative

b) Adult patients with opioid-induced constipation for whom a non-prescription laxative or a prescribable medical product to treat constipation are no longer suitable

a) Adult patients with opioid-induced constipation who have previously been treated with a laxative

The G-BA determined the appropriate comparator therapy to be another non-prescription laxative (in accordance with AM-RL Annex I No. 1) or a prescribable medical product to treat constipation (in accordance with AM-RL Section J and Annex V) or combinations thereof.

For this patient population, the pharmaceutical company did not present any study that would have been suitable for the assessment of the additional benefit of naldemedin compared with the appropriate comparator therapy.

Overall, for adult patients with opioid-induced constipation who have been previously treated with a laxative, an additional benefit for naldemedin compared to the appropriate comparator therapy is not proven.

b) Adult patients with opioid-induced constipation for whom a non-prescription laxative or a prescribable medical product to treat constipation are no longer suitable

Methylnaltrexone or naloxegol was determined as an appropriate comparator therapy by the G-BA.

In the absence of directly comparative studies, the pharmaceutical company presented an indirect comparison (naldemedin vs naloxegol via the bridge comparator, standard therapy) based on the two RCTs COMPOSE 3 and KODIAC-08.

The indirect comparison on the basis of these studies is not appropriate for the current benefit assessment, however, for the following reasons.

The KODIAC-08 study considered by the pharmaceutical company is a long-term safety study, whose only generated endpoints are adverse events. As a result, it is not possible to perform a risk-benefit comparison on the basis of this study.

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In addition, the study populations of the two trials are not sufficiently comparable. In KODIAC-08, the study population only partially corresponds to the approved therapeutic indication for naldemedin, since pre-treatment with laxatives was not necessary for inclusion into the study. In addition, the proportion of patients in both trials who are no longer eligible for treatment with another laxative is unclear.

Standard therapy, as a bridge comparator for indirect comparison, is also not sufficiently comparable in the two studies; in contrast to the KODIAC-08 study, no newly defined laxative therapy was used as standard therapy in the COMPOSE 3 study at the beginning of the study.

Overall, for adult patients with opioid-induced constipation for whom a non-prescription laxative or a prescribable medical product to treat constipation are no longer suitable, an additional benefit for naldemedin compared to the appropriate comparator therapy is 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 takes into account the patient numbers given in the dossier of the pharmaceutical company. However, these are subject to uncertainties because of the limited epidemiological data basis on incidence and prevalence in the present indication as well as the lack of information on projections and adjustments in the dossier. Overall, the patient numbers can be assumed to be underestimated.

Based on module 3 and module 5 of the dossier, differentiation of the SHI target population is not possible on the basis of classifying the patients into those who are candidates for a non-prescription laxative or a prescribable medical product to treat constipation (patient group a) or those who are no longer candidates (patient group b).

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 Rizmoic (active ingredient: naldemedin) at the following publicly accessible link (last access: 15 October 2020):

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

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: 15 October 2020).

Since opioid-induced constipation can be assumed to be associated with long-term administration in the context of chronic pain therapy with opioids, care was taken in the selection of medicinal products to ensure that they were suitable for long-term use following confirmed diagnosis. Hence, medicinal and medical products for acute or short-term treatment of constipation were not included.

As the active ingredient macrogol is available both as an approved non-prescription medicinal product in accordance with Annex I No. 1 AM-RL and as a prescribable medical product in accordance with Annex V AM-RL, the cheapest alternative is considered regardless of the marketing form.

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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.

Various dosage forms are available for the active ingredients bisacodyl, lactulose and sodium picosulphate. The most inexpensive dosage forms were selected in the presentation of treatment costs.

For the calculation of the dosages as a function of body weight, the average body measurements from the official representative statistics “Microcensus 2017 – body measurements of the population” were used as a basis (average body weight): 77.0 kg).[2]

Treatment duration:

Designation of the therapy	Treatment mode	Number of treatments/patient/year	Treatment duration/treatment (days)	Treatment days/patient/ year
Medicinal product to be assessed				
Naldemedin	1 × daily	365	1	365
Appropriate comparator therapy				
Patient population a)				
Bisacodyl	1 × daily	365	1	365
Escherichia coli	1 × daily	365	1	365
Psyllium husks, Indian	2–3 × daily	365	1	365
Lactulose	1–2 × daily	365	1	365
Macrogol 4000	1–2 × daily	365	1	365
Macrogol (+ electrolytes)	1–3 × daily	365	1	365
Sodium picosulphate	1 × daily	365	1	365
Patient population b)				
Methylnaltrexone	1 × every 2 days	182.5	1	182.5
Naloxegol	1 × daily	365	1	365

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

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Usage and consumption:

Designation of the therapy	Dosage/ application	Dose/patient/treatment days	Consumption by potency/treatment day	Treatment days/ patient/ year	Annual average consumption by potency
Medicinal product to be assessed					
Naldemedin	200 µg	200 µg	1 × 200 µg	365	365 × 200 µg
Appropriate comparator therapy					
Patient population a)					
Bisacodyl (oral)	5–10 mg	5–10 mg	1–2 × 5 mg	365	365–730 × 5 mg
Escherichia coli	2–4 capsules	2–4 capsules	2–4 capsules	365	730–1460 capsules
Psyllium husks, Indian	5 g	10–15 g	2–3 × 5 g	365	730–1095 × 5 g
Lactulose (OSL)	7.5–15 ml (5–10 mg)	7.5–15 ml up to 15–30 ml	1 x 7.5–15 ml up to 2 x 7.5–15 ml	365	365 x 7.5–15 ml up to 730 x 7.5–15 ml
Macrogol 4000	1 sachet (10 g)	1–2 sachets (10–20 g)	1–2 sachets (1–2 x 10 g)	365	365–730 × 1 sachet (10 g)
Macrogol (+ electrolytes)	1 sachet	1–3 sachets	1–3 sachets	365	365–1095 × 1 sachet
Sodium picosulphate	5–10 mg	5–10 mg	1–2 × 5 mg	365	365–730 × 5 mg
Patient population b)					
Methylnaltrexone	12 mg	12 mg	1 × 12 mg	182.5	182.5 × 12 mg
Naloxegol	25 mg	25 mg	1 × 25 mg	365	365 × 25 mg

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Sections 130 and 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.

Non-prescription medicinal products that are reimbursable by the statutory health insurance in accordance with Annex I of the Pharmaceuticals Directive (OTC exemption list) are not subject to the current medicinal product price regulation. Instead, for these, in accordance with Section 129, paragraph 5a SGB V when a non-prescription medicinal product is sold and invoiced in accordance with Section 300 SGB V, for the insured person, a pharmaceutical selling price in the amount of the selling price of the pharmaceutical company – plus the surcharges according

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to Sections 2 and 3 of the Pharmaceutical Price Ordinance in the 31 December 2003 version – shall apply.

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					
Naldemedin	100 FCT	€ 438.64	€ 1.77	€ 24.30	€ 412.57
Appropriate comparator therapy					
Bisacodyl[3]	100 GRT	€ 6.69	€ 0.33	€ 0.91	€ 5.45
Escherichia coli[3]	100 GHC	€ 102.35	€ 5.12	€ 5.84	€ 91.39
Psyllium husks, Indian[3]	60 GOS	€ 14.33	€ 0.72	€ 0.49	€ 13.12
Lactulose[3,4]	OSL 1000 ml (10g = 15ml)	€ 17.77	€ 0.89	€ 0.88	€ 16.00
Macrogol 4000[3]	50 POS; 10 g	€ 32.46	€ 1.62	€ 2.97	€ 27.87
Macrogol, electrolytes[3]	50 POS	€ 26.11	€ 1.31	€ 2.19	€ 22.61
Methylnaltrexone	7 SFI	€ 327.12	€ 1.77	€ 17.97	€ 307.38
Naloxegol	100 FCT	€ 403.91	€ 1.77	€ 22.33	€ 379.81
Sodium picosulphate[3]	40 LOZ	€ 9.71	€ 0.49	€ 1.62	€ 7.60
Abbreviations: FCT = film-coated tablets, GOS = granules for preparation of an oral suspension, GHC = gastric juice resistant hard capsules, GRT = gastric juice resistant tablets, LOZ = lozenges, OSL = oral solution, POS = powder for preparation of an oral solution, SFI = solution for injection					

Pharmaceutical retail price (LAUER-TAXE®) as last revised: 15 October 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 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.

[3] OTC as per Annex I AM-RL
[4] Fixed reimbursement rate

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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 22 August 2017, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

After the positive opinion was issued, the appropriate comparator therapy determined by the G-BA was reviewed. At its session on 29 January 2019, the Subcommittee on Medicinal Products redefined the appropriate comparator therapy.

On 12 May 2020, the pharmaceutical company submitted a dossier for the benefit assessment of naldemedin to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 12 May 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 naldemedin.

The dossier assessment by the IQWiG was submitted to the G-BA on 13 August 2020, and the written statement procedure was initiated with publication on the website of the G-BA on 17 August 2020. The deadline for submitting written statements was 7 September 2020.

The oral hearing was held on 21 September 2020.

By letter dated 6 October 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 16 October 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 27 October 2020, and the proposed resolution was approved.

On 5 November 2020, the G-BA resolved by written statement to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	22 August 2017	Determination of the appropriate comparator therapy
Subcommittee on Medicinal Products	29 January 2019	Redefinition of the appropriate comparator therapy

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Working group Section 35a	16 September 2020	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	21 September 2020	Conduct of the oral hearing
Subcommittee on Medicinal Products	6 October 2020	Commissioning of the IQWiG with the supplementary assessment of documents
Working group Section 35a	30 September 2020 14 October 2020 21 October 2020	Consultation on the dossier assessment by the IQWiG, evaluation of the written statement procedure
Subcommittee on Medicinal Products	27 October 2020	Concluding discussion of the draft resolution
Plenum	5 November 2020	Written resolution on the amendment of Annex XII of the AM-RL

Berlin, 5 November 2020

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

Prof. Hecken

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