Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive: Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V Pegcetacoplan (paroxysmal nocturnal haemoglobinuria, pretreated patients)

of 15 September 2022

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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.

For medicinal products for the treatment of rare diseases (orphan drugs) that are approved according to Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999, the additional medical benefit is considered to be proven through the grant of the marketing authorisation according to Section 35a, paragraph 1, sentence 11, 1st half of the sentence German Social Code, Book Five (SGB V). Evidence of the medical benefit and the additional medical benefit in relation to the appropriate comparator therapy do not have to be submitted (Section 35a, paragraph 1, sentence 11, 2nd half of the sentence SGB V). Section 35a, paragraph 1, sentence 11, 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, No. 2 and 3 SGB V in conjunction with Chapter 5 Sections 5 et seq. of the Rules of Procedure (VerfO) of the G-BA has not been carried out. In accordance with Section 5, paragraph 8 AM-NutzenV, only the extent of the additional benefit is to be quantified indicating the significance of the evidence.

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 sales prices and outside the scope of SHI-accredited medical care, including VAT exceeds € 50 million in the last 12 calendar months. According to Section 35a paragraph 1, sentence 12 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, subsection 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). Based on the legal requirement in Section 35a paragraph 1 sentence 11 SGB V that the additional benefit of an orphan drug is considered to be proven through the grant of the 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, for 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 is assessed exclusively on the basis of the approval studies by the G-BA indicating the significance of the evidence.

Accordingly, at its session on 15 March 2012, the G-BA amended the mandate issued to the IQWiG by the 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 to that effect 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 12 SGB V). According to Section 35a paragraph 2 SGB V, the assessment by 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 decides on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The relevant date for the first placing on the (German) market of the active ingredient pegcetacoplan 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 April 2022. 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 28 March 2022.

Pegcetacoplan for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least 3 months is approved as a medicinal product for the treatment of rare diseases under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999.

In accordance with Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V, the additional benefit is considered to be proven through the grant of the marketing authorisation. The extent of the additional benefit and the significance of the evidence are assessed on the basis of the marketing authorisation 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 on 1 July 2022 together with the IQWiG assessment on the website of the G-BA (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA 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 G22-07) and the statements made in the written statement and oral hearing procedure, as well of the amendment drawn up by the G-BA on the benefit assessment.

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

[1] General Methods, version 6.1 from 24.01.2022. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of Pegcetacoplan (Aspaveli) in accordance with the product information

Aspaveli is indicated in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least 3 months.

Therapeutic indication of the resolution (resolution of 15 September 2022):

See the approved therapeutic indication.

2.1.2 Extent of the additional benefit and significance of the evidence

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

Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification.

Justification:

The pharmaceutical company has submitted data from the completed, pivotal, multicentre, randomised, controlled, open-label phase III PEGASUS study for benefit assessment.

Adult patients with PNH who had been on stable eculizumab treatment for at least 3 months prior to screening and had a haemoglobin (Hb) level below 10.5 g/dl were enrolled. In addition, vaccinations against Neisseria meningitidis types A, C, W, Y and B, Streptococcus pneumoniae and Haemophilus influenzae type B had to have been given within 2 years before the 1st treatment day or within 14 days of starting pegcetacoplan treatment.

The study included an 8-week screening period, a 52-week treatment period and a 12-week follow-up. The treatment period was divided into an uncontrolled 4-week run-in period (day -28 to ≤ day -1), a 16-week, open-label, randomised controlled period (RCP) and an uncontrolled, open-label treatment period (OLP) in which all participants were treated with pegcetacoplan (week 17 to week 48).

During the run-in period, all patients were treated with a combination therapy of pegcetacoplan and eculizumab. For RCP, patients were then randomised to the intervention arm (pegcetacoplan; N = 41) and the control arm (eculizumab; N = 39) stratified by number of red cell concentrate (RCC) transfusions within 12 months prior to day -28 (< 4 vs ≥ 4) and platelet count at screening (< 100,000 vs ≥ 100,000).

After the 16-week RCP, all patients in the OLP were treated with pegcetacoplan. Patients in the control arm again received a combination therapy of pegcetacoplan and eculizumab for the first 4 weeks of OLP, before pegcetacoplan was administered as monotherapy from week 21.

The primary endpoint of the study was the change in Hb from baseline to week 16; additional endpoints were collected on symptomatology, health-related quality of life and adverse events.

Several data cut-offs were carried out for the PEGASUS study. A primary data cut-off to evaluate the run-in period and RCP from 24.02.2020, a non-pre-specified second data cut-off from 23.09.2020 and a final data cut-off from 06.11.2020 for OLP. This assessment is based on the results of the primary data cut-off for RCP, as this is controlled data.

Uncertainties of the PEGASUS study

PNH is a chronic disease. Treatment with pegcetacoplan or eculizumab is recommended for life, as stated in the product information. Accordingly, as already stated in the G-BA's resolution on ravulizumab, a comparative study duration of at least 24 weeks is generally considered necessary by the G-BA in the therapeutic indication of PNH. Against this background, the RCP duration of 16 weeks in the PEGASUS study is considered too short overall to be able to derive reliable statements on the extent of the additional benefit from the available data.

Furthermore, the design of the PEGASUS study is subject to significant uncertainties and limitations. Thus, all patients were treated with a combination therapy of pegcetacoplan and eculizumab during the run-in period. This initial combination regimen is part of the use in accordance with the product information when switching from a C5 inhibitor to pegcetacoplan. Subsequently, for the RCP, those study participants randomised to the comparator arm were withdrawn from the intervention under investigation after 4 weeks of combination therapy and treatment with eculizumab was continued. Thus, on the one hand, an influence of carry-over effects on the RCP results cannot be ruled out due to the combination regimen during the run-in period. On the other, in view of the open-label study design, it can be assumed that the withdrawal from the intervention in the comparator arm significantly increases the risk of bias, especially with regard to subjectively collected endpoints.

The available data are therefore not assessable, especially due to the short duration of the RCP (16 weeks), and are therefore not suitable for quantifying the extent of the additional benefit.

Mortality

Overall survival was not collected as a separate endpoint in the PEGASUS study. Fatalities were recorded as part of the assessment of the adverse events. Not a single death occurred in any study arm during the RCP. From the available data, there is therefore no relevant difference between the treatment arms.

Morbidity

Transfusion independence

The endpoint of transfusion independence during RCP describes the percentage of patients who did not receive any transfusions (whole blood, red cell concentrates [RCC] or other blood transfusions) between day 1 and week 16. Study participants without transfusion who discontinued the study before week 16 were counted as having transfusion for the analysis of transfusion independence during the RCP.

Patients in the present therapeutic indication require frequent transfusions. A long-term or sustainable avoidance of transfusions (transfusion independence) while maintaining a defined minimum value of haemoglobin represents a relevant therapeutic objective in the present therapeutic indication, with which a control of anaemia and anaemia-related symptoms is

achieved, while avoiding transfusions. Thus, long-term transfusion independence may represent a patient-relevant endpoint in the present therapeutic indication.

PNH is a chronic disease. Thus, no statements on the long-term avoidance of transfusions can be derived from a transfusion independence after only 16 weeks according to the comparator survey in the RCP of the study. The results for the endpoint of transfusion independence are therefore not assessable in the present case and thus not suitable for quantifying the extent of the additional benefit. The endpoint is only presented additionally.

Thrombotic and cardiovascular events

No thrombotic or cardiovascular event occurred in any study arm during the RCP. From the available data, there is therefore no relevant difference between the treatment arms.

Fatigue (FACIT-Fatigue)

In the PEGASUS study, the fatigue perceived by the patients was recorded with the FACIT-Fatigue.

In the dossier on FACIT-Fatigue (as well as on the other patient-reported endpoints), the pharmaceutical company presents both responder analyses for improvement and deterioration as well as analyses for mean change. With regard to the responder analyses, the pharmaceutical company clarified in the written statement that day -28 (i.e., before administration of the first dose of pegcetacoplan) was taken as the reference point for the assessment of the change and that the responder analyses refer to the change at week 16. In addition, with regard to the responder analyses for deterioration, the pharmaceutical company submitted analyses with the statement in which subjects with missing values were evaluated as responders in the analyses (worst case imputation). As a result, the responder analyses for improvement and deterioration of FACIT-fatigue (and the other patient-reported endpoints) are considered suitable and used for the assessment.

The responder analysis for deterioration does not show a statistically significant difference. The responder analysis for improvement shows a statistically significant difference between the treatment arms to the advantage of pegcetacoplan. Nevertheless, the results cannot be assessed against the background of the uncertainties of the PEGASUS study described above and are therefore not suitable for quantifying the extent of the additional benefit.

Symptomatology (EORTC QLQ-C30)

The symptomatology of the patients was assessed using the symptom scales of the EORTC-QLQ-C30 questionnaire in the PEGASUS study.

The EORTC QLQ-C30 is a generic measurement tool for assessing the symptomatology and quality of life of patients with oncological diseases. The relevance of individual items of the questionnaire for the symptomatology of the present therapeutic indication is unclear. The symptom scales of the EORTC QLQ-C30 are therefore not used for the present assessment.

Quality of life

LASA

Data on health-related quality of life were collected in the PEGASUS study using the Linear Analogue Scale Assessment (LASA). Due to the lack of validation of the LASA total score, the individual scales are used for the benefit assessment.

There is no statistically significant difference in the responder analyses for deterioration. In the responder analyses for improvement, all three individual scales of the LASA (activity level, ability to perform daily activities and general quality of life) show statistically significant differences between the treatment arms to the advantage of pegcetacoplan. The results cannot be assessed against the background of the uncertainties of the PEGASUS study described above and are therefore not suitable for quantifying the extent of the additional benefit.

EORTC QLQ-C30

Further data on health-related quality of life from the PEGASUS study are available using the functional scales and the global health status scale of the EORTC QLQ-C30 questionnaire.

There is no statistically significant difference in the responder analyses for deterioration. The responder analyses for improvement show statistically significant differences in the role functioning and physical functional scales well as in the global health status scale to the advantage of pegcetacoplan. The results cannot be assessed against the background of the uncertainties of the PEGASUS study described above and are therefore not suitable for quantifying the extent of the additional benefit.

Side effects

Adverse events (AEs) in total

AEs occurred in about 88% of patients in the intervention arm and about 85% of patients in the comparator arm. The results were only presented additionally.

Serious AEs (SAEs), severe AEs and therapy discontinuations due to AEs

There were no statistically significant differences between the treatment arms for the endpoints of SAEs, severe AEs and therapy discontinuations due to AEs.

AEs of special interest

In detail, statistically significant differences to the disadvantage of pegcetacoplan are shown with regard to the AEs of special interest "injection site reaction" and "infusion-related reaction".

In the overall assessment, the results for the endpoint category of side effects cannot be assessed against the background of the uncertainties of the PEGASUS study described above and are therefore not suitable for quantifying the extent of the additional benefit.

Overall assessment

Results of the PEGASUS study are available for the benefit assessment of pegcetacoplan for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least 3 months. The 16-week, open-label, randomised controlled period (RCP) of the study compared pegcetacoplan with eculizumab.

PNH is a chronic disease. Treatment with pegcetacoplan or eculizumab is recommended for life, as stated in the product information. Accordingly, as already stated in the G-BA's resolution on ravulizumab, a comparative study duration of at least 24 weeks is generally considered necessary by the G-BA in the therapeutic indication of PNH. Against this background, the RCP duration of 16 weeks in the PEGASUS study is considered too short overall to be able to derive reliable statements on the extent of the additional benefit from the available data.

Furthermore, the design of the PEGASUS study is subject to significant uncertainties and limitations. Thus, all patients were treated with a combination therapy of pegcetacoplan and eculizumab during the run-in period. This initial combination regimen is part of the use in accordance with the product information when switching from a C5 inhibitor to pegcetacoplan. Subsequently, for the RCP, those study participants randomised to the comparator arm were withdrawn from the intervention under investigation after 4 weeks of combination therapy and treatment with eculizumab was continued. Thus, on the one hand, an influence of carry-over effects on the RCP results cannot be ruled out due to the combination regimen during the run-in period. On the other, in view of the open-label study design, it can be assumed that the withdrawal from the intervention in the comparator arm significantly increases the risk of bias, especially with regard to subjectively collected endpoints.

In summary, the available data on mortality, morbidity, quality of life and side effects do not allow quantification of the extent of the additional benefit of pegcetacoplan, especially against the background of the too short RCP duration of 16 weeks.

As a result, a non-quantifiable additional benefit is determined for pegcetacoplan for the treatment of adult patients with PNH who are anaemic after treatment with a C5 inhibitor for at least 3 months, since the scientific data basis does not allow quantification.

Significance of the evidence

The present assessment is based on the results of the open-label, randomised, controlled period of the pivotal phase III PEGASUS study.

The available results from the PEGASUS study do not allow a quantification of the extent of the additional benefit in the overall assessment. The significance of the evidence is categorised as 'hint'.

2.1.3 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Aspaveli with the active ingredient pegcetacoplan. Aspaveli was approved as an orphan drug in the following therapeutic indication:

"Aspaveli is indicated for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least 3 months."

The pharmaceutical company submitted data from the pivotal phase III PEGASUS study for the benefit assessment. In the open-label, randomised controlled period (RCP) of the study, pegcetacoplan was compared with eculizumab.

PNH is a chronic disease. Against this background, the RCP duration of 16 weeks in particular is assessed as too short overall to be able to quantify the extent of the additional benefit.

Furthermore, the study design is subject to significant uncertainties and limitations.

Overall, it is therefore not possible to quantify the extent of the additional benefit of pegcetacoplan.

As a result, a non-quantifiable additional benefit is identified for pegcetacoplan since the scientific data basis does not allow quantification. The significance of the evidence is categorised as 'hint'.

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 patient numbers from the dossier submitted by the pharmaceutical company. The procedure of the pharmaceutical company is mathematically comprehensible, but is subject to uncertainties in the individual calculation steps. In particular, the insufficient consideration of the criterion of a minimum interval of 3 months after the start of treatment with a C5 inhibitor, which is required according to the therapeutic indication, leads to a tendency to overestimate patients who are still anaemic.

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 Aspaveli (active ingredient: pegcetacoplan) at the following publicly accessible link (last access: 9 August 2022):

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

Treatment with pegcetacoplan should only be initiated and monitored by specialists who are experienced in the treatment of patients with haematological diseases.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients as well as a patient card. The training material as well as the patient card contain instructions in particular regarding the increased risk of infection with encapsulated bacteria under pegcetacoplan. The patient card should be made available to the patients.

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 August 2022).

Treatment period:

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 patient-individual and/or is shorter on average. The time unit "days" is used to calculate the "number of treatments/ patient/ year", time intervals between individual treatments and for 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				
Pegcetacoplan	continuously, 2 x every 7 days	104.3	1	104.3

Consumption:

For the cost representation only the dosages of the general case are considered. Patient-individual dose adjustments (e.g., because of side effects or comorbidities) are not taken into account when calculating the annual treatment costs.

In general, initial induction regimens are not taken into account for the cost representation, since the present indication is a chronic disease with a continuous need for therapy and, as a rule, no new titration or dose adjustment is required after initial titration.

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Pegcetacoplan	1080 mg	1080 mg	1 x 1080 mg	104.3	104.3 x 1080 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 Section 130 and Section 130a 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 products:

Designation of the therapy	Packaging 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					
Pegcetacoplan 1,080 mg	8 INF	€ 34,673.22	€ 1.77	€ 1,979.60	€ 32,691.85
Abbreviations: INF = infusion solution					

LAUER-TAXE® last revised: 15 August 2022

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 the standard expenditure in the course of the treatment are not shown.

No additionally required SHI services are taken into account for the cost representation.

3. Bureaucratic costs calculation

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 28 March 2022, the pharmaceutical company submitted a dossier for the benefit assessment of pegcetacoplan to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

The benefit assessment of the G-BA was published on 1 July 2022 together with the IQWiG assessment of treatment costs and patient numbers on the website of the G-BA (www.g-ba.de), thus initiating the written statement procedure. The deadline for submitting written statements was 22 July 2022.

The oral hearing was held on 8 August 2022.

An amendment to the benefit assessment with a supplementary assessment of data submitted in the written statement procedure was submitted on 24 August 2022.

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 6 September 2022, and the draft resolution was approved.

At its session on 15 September 2022, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	27 June 2022	Information of the benefit assessment of the G-BA
Working group Section 35a	2 August 2022	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal products	8 August 2022	Conduct of the oral hearing
Working group Section 35a	16 August 2022 30 August 2022	Consultation on the dossier assessment 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	6 September 2022	Concluding discussion of the draft resolution
Plenum	15 September 2022	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 15 September 2022

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken