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) Palopegteriparatide (chronic hypoparathyroidism, parathyroid hormone (PTH) replacement therapy)

of 20 June 2024

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. 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 the 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 is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient palopegteriparatide on 1 January 2024 in accordance with Chapter 5 Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure (VerfO) of the G-BA. 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 22 December 2023.

The active ingredient palopegteriparatide (Yorvipath) was approved by the European Commission (EC) on 17 November 2023 as a medicinal product for the treatment of rare diseases (orphan drugs) under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 for the treatment of adults with chronic hypoparathyroidism. The pharmaceutical company has irrevocably notified the Federal Joint Committee that, despite the orphan drug status for palopegteriparatide, a benefit assessment

is to be carried out with the submission of evidence in accordance with Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 2 April 2024 on the G-BA website (www.g-ba.de), 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 palopegteriparatide compared with the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, and the 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 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 palopegteriparatide.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA has come to 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 Palopegteriparatide (Yorvipath) in accordance with the product information

Yorvipath is a parathyroid hormone (PTH) replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism.

Therapeutic indication of the resolution (resolution of 20.06.2024):

See the approved therapeutic indication.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults with chronic hypoparathyroidism who are eligible for parathyroid hormone replacement therapy

Appropriate comparator therapy for palopegteriparatide:

Parathyroid hormone

Criteria according to Chapter 5 Section 6 of the Rules of Procedure of the G-BA and Section 6 paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication in accordance with the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven

1 General Methods, version 7.0 from 19.09.2023. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

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 G-BA 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.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if it determines by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved in the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved in the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

<u>Justification based on the criteria set out in Chapter 5 Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:</u>

on 1. In addition to palopegteriparatide, the following medicinal products are approved for the treatment of hypoparathyroidism in the therapeutic indication: parathyroid hormone, calcitriol, alfacalcidol and dihydrotachysterol[2]. Calcium is approved for the treatment and prevention of calcium deficiency.

on 2. A non-medicinal treatment paid by the SHI is not considered an appropriate comparator therapy in the therapeutic indication for the treatment of hypoparathyroidism in adults

2 Currently unavailable in Germany.

on 3. No resolutions of the G-BA are available for the present therapeutic indication. Approved exceptions to the legal exclusion from prescription according to Section 34, paragraph 1, sentence 2 SGB V according to Annex I of the Pharmaceuticals Directive are (OTC overview): "12. Calcium compounds as monopreparations only for pseudohypoparathyroidism and hypoparathyroidism."

on 4. The generally recognised state of medical knowledge on which the resolution of the G-BA is based, was illustrated by a systematic search for guidelines as well as reviews of clinical studies in the present therapeutic indication.

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present therapeutic indication according to Section 35a, paragraph 7 SGB V.

The evidence for the present therapeutic indication is limited overall. Only one Cochrane review could be included in the evidence synopsis. Due to a lack of higher-quality evidence, two guidelines were presented additionally (Khan AA et al., 2022; Khan AA et al., 2019).

Based on the available evidence, PTH therapy is recommended in the event of an inadequate response to conventional calcium and vitamin D therapy. As the active ingredient to be assessed, palopegteriparatide, is itself a PTH therapy, it is assumed that conventional calcium and vitamin D therapy is insufficient for the patients covered by the therapeutic indication and that they are therefore eligible for PTH replacement therapy.

For palopegteriparatide, parathyroid hormone is therefore determined to be an appropriate comparator therapy based on the available evidence.

A Direct Healthcare Professional Communication ("Rote-Hand-Brief") was published on 4 October 2022 for Natpar (parathyroid hormone) – the only medicinal product approved alongside palopegteriparatide. It states that the production of all dosage strengths of the medicinal product Natpar is to be discontinued worldwide by 2024. After 2024, the doses still available will be supplied until stocks last or have expired. The medicinal product Natpar is currently still listed in the LAUER-TAXE®.

The findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment mandate.

A change in the appropriate comparator therapy requires a resolution by the G-BA linked to the prior review of the criteria according to Chapter 5 Section 6, paragraph 3 Rules of Procedure.

2.1.3 Extent and probability of the additional benefit

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

For adults with chronic hypoparathyroidism who are eligible for parathyroid hormone replacement therapy, the additional benefit of palopegteriparatide compared with the appropriate comparator therapy is not proven.

Justification:

The pharmaceutical company does not present any data on the assessment of the additional benefit of palopegteriparatide compared to the appropriate comparator therapy.

The supportive PaTHway study presented in the dossier is a multicentre phase III study for the treatment of adults with hypoparathyroidism who have been treated with vitamin D and calcium for at least 12 weeks prior to screening. The study is divided into a randomised, double-blind, placebo-controlled phase (RCT phase) over 26 weeks and a subsequent 1-arm, open-label extension phase of up to 156 weeks.

In the comparator study phase, the active ingredient palopegteriparatide was compared with placebo. Following the RCT phase, the patients were able to move on to the single-arm, open-label extension phase of the study, with a change of treatment to palopegteriparatide for patients in the comparator arm.

The PaTHway study presented by the pharmaceutical company is unsuitable for the assessment of the additional benefit due to the lack of comparison of palopegteriparatide with the determined appropriate comparator therapy.

Overall assessment:

The results of the randomised, double-blind, placebo-controlled phase III PaTHway study are available for the assessment of the additional benefit of palopegteriparatide. The results of the PaTHway study presented are unsuitable for assessment of the additional benefit as they do not allow a comparison with the appropriate comparator therapy. Therefore, an additional benefit of palopegteriparatide for the treatment of adults with chronic hypoparathyroidism who are eligible for parathyroid hormone replacement therapy is not proven.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new active ingredient palopegteriparatide with the therapeutic indication: "Yorvipath is a parathyroid hormone (PTH) replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism."

The G-BA determined parathyroid hormone as the appropriate comparator therapy.

For the assessment of the additional benefit, the pharmaceutical company submitted the PaTHway study, in which palopegteriparatide was compared with placebo over a period of 26 weeks. However, this study is not considered for the present benefit assessment due to the lack of comparison with the appropriate comparator therapy.

An additional benefit of palopegteriparatide over the appropriate comparator therapy for the treatment of adults with chronic hypoparathyroidism who are eligible for parathyroid hormone replacement therapy is therefore 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. The information is based on data provided by the pharmaceutical company in the dossier.

The pharmaceutical company's estimate is subject to uncertainties for methodological reasons.

The operationalisation selected by the pharmaceutical company to determine the number of patients with chronic hypoparathyroidism only takes into account the percentage of patients whose hypoparathyroidism was caused by a medical intervention. This may lead to the exclusion of patients whose pathogenesis was caused by genetic predisposition or autoimmune processes, for example. Furthermore, the pharmaceutical company's assumption that patients with hypoparathyroidism do not have sufficient symptom control through conventional symptom-related therapy in the form of vitamin D administration at a dosage of vitamin D prescriptions above the defined average daily dose over the course of the year is fraught with uncertainty.

With regard to prevalence and incidence, the pharmaceutical company states that the overall number of thyroid operations is declining and is increasingly being performed in specialised treatment centres with improved surgical techniques. Contrary to its own trend calculation, the pharmaceutical company thus assumes that both the prevalence and incidence of the disease will decline and that the forecast patient numbers are therefore overestimated.

In the overall assessment, the information is therefore fraught with uncertainties.

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 Yorvipath (active ingredient: palopegteriparatide) agreed upon in the context of the marketing authorisation at the following publicly accessible link (last access: 2 February 2024):

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

Treatment with palopegteriparatide should only be initiated and monitored by doctors experienced in treating patients with hypoparathyroidism.

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 June 2024).

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 varies from patient to patient 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.

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

In accordance with the explanations on the derivation of the appropriate comparator therapy, it is assumed that conventional calcium and vitamin D therapy is insufficient for the patients in this therapeutic indication and that they are therefore eligible for PTH replacement therapy. It is therefore also assumed that patients receive calcium and vitamin D substitution (calcitriol, afacalcidol) in addition to PTH replacement therapy, if necessary. For these reasons, the corresponding costs are not presented.

Adults with chronic hypoparathyroidism who are eligible for parathyroid hormone replacement therapy

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Palopegteriparatide	Continuously, 1 x daily	365.0	1	365.0
Appropriate comparator therapy				
Parathyroid hormone	Continuously, 1 x daily	365.0	1	365.0

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Usage by potency/ treatment day[3]	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Palopegteriparatide	6 µg - 30 µg	6 µg - 60 µg	1 x 6 µg - 2 x 30 µg	365.0	365.0 x 6 µg - 730.0 x 30 µg
Appropriate comparator therapy					
Parathyroid hormone	25 µg – 100 µg	25 µg – 100 µg	1 x 25 µg – 1 x 100 µg	365.0	365.0 x 25 µg – 365.0 x 100 µg

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					
Palopegteriparatide 168 µg/ 0.56 ml	2 SFI	€ 10,782.53	€ 2.00	€ 612.50	€ 10,168.03
Palopegteriparatide 420 µg/ 1.4 ml	2 SFI	€ 10,782.53	€ 2.00	€ 612.50	€ 10,168.03
Appropriate comparator therapy					
Parathyroid hormone	2 PSI	€ 8,077.41	€ 2.00	€ 458.01	€ 7,617.40
Parathyroid hormone	2 PSI	€ 8,077.41	€ 2.00	€ 458.01	€ 7,617.40
Abbreviations: SFI = solution for injection; PSI = powder and solvent for solution for injection					

LAUER-TAXE® last revised: 1 June 2024

3 Shelf life of the injection solutions after opening is 14 days

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.

Designation of the therapy	Designation	Costs/ Pack[4]	Number	Consumption/ year
Parathyroid hormone	Disposable needles	€ 13.00	1 x daily	365.0

2.5 Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

According to Section 35a, paragraph 3, sentence 4, the G-BA designates all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act.

Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

A designation is also not considered if the G-BA has decided on an exemption as a reserve antibiotic for the assessed medicinal product in accordance with Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the G-BA has decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the G-BA. Due to the lack of an assessment mandate by the G-BA following the resolution on an exemption according to Section 35a, paragraph 1c, sentence 1 SGB V with

4 Number of lancets/pack = 100 pcs; presentation of the cheapest pack according to LAUER-TAXE®, last revised: 1 June 2024.

regard to the extent of the additional benefit and the therapeutic significance of the reserve antibiotic to be assessed, there is a limitation due to the procedural privileging of the pharmaceutical companies to the effect that neither the proof of an existing nor an expected at least considerable additional benefit is possible for exempted reserve antibiotics in the procedures according to Section 35a paragraph 1 or 6 SGB V and Section 35a paragraph 1d SGB V. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V must therefore also be taken into account at the level of designation according to Section 35a, paragraph 3, sentence 4 SGB V in order to avoid valuation contradictions.

With regard to the further examination steps, a differentiation is made between a "determined" or "undetermined" combination, which may also be the basis for a designation.

A "determined combination" exists if one or more individual active ingredients which can be used in combination with the assessed medicinal product in the assessed therapeutic indication are specifically named.

An "undetermined combination" exists if there is information on a combination therapy, but no specific active ingredients are named. An undetermined combination may be present if the information on a combination therapy:

- names a product class or group from which some active ingredients not specified in detail can be used in combination therapy with the assessed medicinal product, or
- does not name any active ingredients, product classes or groups, but the assessed medicinal product is used in addition to a therapeutic indication described in more detail in the relevant product information, which, however, does not include information on active ingredients within the scope of this therapeutic indication.

Concomitant active ingredient

The concomitant active ingredient is a medicinal product with new active ingredients that can be used in combination therapy with the assessed medicinal product for the therapeutic indication to be assessed.

For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2 paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

Based on an "undetermined combination", the concomitant active ingredient must be attributable to the information on the product class or group or the therapeutic indication according to the product information of the assessed medicinal product in the assessed therapeutic indication, whereby the definition of a product class or group is based on the corresponding information in the product information of the assessed medicinal product.

In addition, there must be no reasons for exclusion of the concomitant active ingredient from a combination therapy with the assessed medicinal product, in particular no exclusive marketing authorisation as monotherapy.

In addition, all sections of the currently valid product information of the eligible concomitant active ingredient are checked to see whether there is any information that excludes its use in combination therapy with the assessed medicinal product in the assessed therapeutic indication under marketing authorisation regulations. Corresponding information can be, for example, dosage information or warnings. In the event that the medicinal product is used as part of a determined or undetermined combination which does not include the assessed medicinal product, a combination with the assessed medicinal product shall be excluded.

Furthermore, the product information of the assessed medicinal product must not contain any specific information that excludes its use in combination therapy with the eligible concomitant active ingredient in the assessed therapeutic indication under marketing authorisation regulations.

Medicinal products with new active ingredients for which the G-BA has decided on an exemption as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V are ineligible as concomitant active ingredients. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V also applies accordingly to the medicinal product eligible as a concomitant active ingredient.

Designation

The medicinal products which have been determined as concomitant active ingredients in accordance with the above points of examination are named by indicating the relevant active ingredient and the invented name. The designation may include several active ingredients, provided that several medicinal products with new active ingredients may be used in the same combination therapy with the assessed medicinal product or different combinations with different medicinal products with new active ingredients form the basis of the designation.

If the present resolution on the assessed medicinal product in the assessed therapeutic indication contains several patient groups, the designation of concomitant active ingredients shall be made separately for each of the patient groups.

Exception to the designation

The designation excludes combination therapies for which - patient group-related - a considerable or major additional benefit has been determined by resolution according to Section 35a, paragraph 3, sentence 1 SGB V or it has been determined according to Section 35a, paragraph 1d, sentence 1 SGB V that at least considerable additional benefit of the combination can be expected. In this context, the combination therapy that is excluded from the designation must, as a rule, be identical to the combination therapy on which the preceding findings were based.

In the case of designations based on undetermined combinations, only those concomitant active ingredients - based on a resolution according to Section 35a, paragraph 3, sentence 1 SGB V on the assessed medicinal product in which a considerable or major additional benefit had been determined - which were approved at the time of this resolution are excluded from the designation.

Legal effects of the designation

The designation of combinations is carried out in accordance with the legal requirements according to Section 35a, paragraph 3, sentence 4 and is used exclusively to implement the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The designation is not associated with a statement as to the extent to which a therapy with the assessed medicinal products in combination with the designated medicinal products corresponds to the generally recognised state of medical knowledge. The examination was carried out exclusively on the basis of the possibility under Medicinal Products Act to use the medicinal products in combination therapy in the assessed therapeutic indication based on the product information; the generally recognised state of medical knowledge or the use of the medicinal products in the reality of care were not the subject of the examination due to the lack of an assessment mandate of the G-BA within the framework of Section 35a, paragraph 3, sentence 4 SGB V.

The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

Justification for the findings on designation in the present resolution:

Adults with chronic hypoparathyroidism who are eligible for parathyroid hormone replacement therapy

No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

References:
Product information for palopegteriparatide (Yorvipath); Yorvipath solution for injection in a pre-filled pen; last revised: April 2024

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

At its session on 11 July 2023, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 22 December 2023, the pharmaceutical company submitted a dossier for the benefit assessment of palopegteriparatide to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 3 January 2024 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit 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 palopegteriparatide.

The dossier assessment by the IQWiG was submitted to the G-BA on 22 December 2023, and the written statement procedure was initiated with publication on the G-BA website on 2 April 2024. The deadline for submitting statements was 23 April 2024.

The oral hearing was held on 6 May 2024.

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 was discussed at the session of the subcommittee on 11 June 2024, and the proposed resolution was approved.

At its session on 20 June 2024, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	11 July 2023	Implementation of the appropriate comparator therapy
Working group Section 35a	29 April 2024	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal products	6 May 2024	Conduct of the oral hearing
Working group Section 35a	14 May 2024 4 June 2024	Consultation on the dossier evaluation by the IQWiG and evaluation of the written statement procedure
Subcommittee Medicinal products	11 June 2024	Concluding discussion of the draft resolution
Plenum	20 June 2024	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 20 June 2024

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

Prof. Hecken