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

Resolution of: 20 June 2024 valid until: unlimited
Entry into force on: 20 June 2024
Federal Gazette, BAnz AT 16. 07 2024 B4

Therapeutic indication (according to the marketing authorisation of 17 November 2023):

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 June 2024):

Therapeutic indication according to marketing authorisation.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

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

Appropriate comparator therapy:

Parathyroid hormone

Extent and probability of the additional benefit of palopegteriparatide compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

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

No data are available to allow an assessment of the additional benefit.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

2. Number of patients or demarcation of patient groups eligible for treatment

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

Approx. 18,300 – 20,800 patients

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: 23 May 2024):

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

1 Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-04) unless otherwise indicated.

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

4. Treatment costs

Annual treatment costs:

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

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Palopegteriparatide	€ 132,547.53 - € 265,095.07
Appropriate comparator therapy:	
Parathyroid hormone	€ 99,298.25

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2024)

Costs for additionally required SHI services:

Designation of the therapy	Designation	Costs/ year
Appropriate comparator therapy:		
Parathyroid hormone	Disposable needles	€ 47.45

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

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

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.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. 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.