

## **Evinacumab (homozygous familial hypercholesterolaemia, $\geq 12$ years)**

Resolution of: 4 July 2024 Valid until: unlimited  
Entry into force on: 4 July 2024  
Federal Gazette, BAnz AT 23 08 2024 B5

### **Therapeutic indication (according to the marketing authorisation of 17 June 2021):**

Evkeeza is indicated as an adjunct to diet and other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and adolescent patients aged 12 years and older with homozygous familial hypercholesterolaemia (HoFH).

### **Therapeutic indication of the resolution (resolution of 4 July 2024):**

See therapeutic indication according to marketing authorisation.

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

Adolescents aged 12 years and older and adults with homozygous familial hypercholesterolaemia for whom dietary and medicinal lipid-lowering options have been exhausted

#### **Appropriate comparator therapy:**

- Evolocumab, if necessary with concomitant lipid-lowering medicinal therapy, *or*
- LDL apheresis (as an "ultima ratio" for therapy-refractory courses), if necessary with concomitant lipid-lowering medicinal therapy, *or*
- evolocumab and LDL apheresis (as an "ultima ratio" for therapy-refractory courses), if necessary with concomitant lipid-lowering medicinal therapy.

#### **Extent and probability of the additional benefit of evinacumab compared to the appropriate comparator therapy:**

An additional benefit is not proven.

#### **Study results according to endpoints:<sup>1</sup>**

Adolescents aged 12 years and older and adults with homozygous familial hypercholesterolaemia for whom dietary and medicinal lipid-lowering options have been exhausted

There are no assessable data.

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<sup>1</sup> Data from the dossier evaluation of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-05) unless otherwise indicated.

## 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	∅	No data available.
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

Adolescents aged 12 years and older and adults with homozygous familial hypercholesterolaemia for whom dietary and medicinal lipid-lowering options have been exhausted

Approx. 73 – 80 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 Evkeeza (active ingredient: evinacumab) agreed upon in the context of the marketing authorisation at the following publicly accessible link (last access: 27 May 2024):

[https://www.ema.europa.eu/en/documents/product-information/evkeeza-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/evkeeza-epar-product-information_en.pdf)

This medicinal product was approved under “exceptional circumstances”. This means that due to the rarity of the disease, it was not possible to obtain complete information on this medicinal product. The EMA will assess any new information that becomes available on an annual basis, and, if necessary, the summary of product characteristics will be updated.

#### 4. Treatment costs

##### Annual treatment costs:

Adolescents aged 12 years and older and adults with homozygous familial hypercholesterolaemia for whom dietary and medicinal lipid-lowering options have been exhausted

Designation of the therapy	Annual treatment costs/ patient
<b>Medicinal product to be assessed:</b>	
Evinacumab	€ 210,556.32- € 421,112.64
Cholestyramine	€ 175.38 - € 1,322.10
Ezetimibe	€ 96.14
Simvastatin <sup>2</sup>	€ 43.00 - € 68.95
Evolocumab	€ 5,336.44 - € 11,606.76
LDL apheresis	€ 23,150.18 - € 67,522.12
<i>Evinacumab in combination with other lipid-lowering therapies</i>	
Evinacumab + simvastatin <sup>2</sup> + ezetimibe + cholestyramine	€ 210,870.84- € 422,599.83
Evinacumab + simvastatin <sup>2</sup> + evolocumab	€ 215,935.76 - € 432,788.35
Evinacumab + simvastatin <sup>2</sup> + ezetimibe + evolocumab	€ 216,031.90- € 432,884.49
Evinacumab + simvastatin <sup>2</sup> + ezetimibe + cholestyramine + evolocumab	€ 216,207.28- € 434,206.59
Evinacumab + simvastatin <sup>2</sup> + ezetimibe + cholestyramine + evolocumab + LDL apheresis	€ 239,357.46- € 501,728.71
Evinacumab + simvastatin <sup>2</sup> + LDL apheresis	€ 233,749.50- € 488,703.71
Evinacumab + simvastatin <sup>2</sup> + ezetimibe + LDL apheresis	€ 233,845.64 - € 488,799.85
Evinacumab + simvastatin <sup>2</sup> + ezetimibe + cholestyramine + LDL apheresis	€ 234,021.02- € 490,121.95
<b>Appropriate comparator therapy:</b>	
<ul style="list-style-type: none"> <li>• Evolocumab, if necessary with concomitant lipid-lowering medicinal therapy, <i>or</i></li> <li>• LDL apheresis (as an "ultima ratio" for therapy-refractory courses), if necessary with concomitant lipid-lowering medicinal therapy, <i>or</i></li> <li>• evolocumab and LDL apheresis (as an "ultima ratio" for therapy-refractory courses), if necessary with concomitant lipid-lowering medicinal therapy.</li> </ul>	
Evolocumab	€ 5,336.44 - € 11,606.76
LDL apheresis	€ 23,150.18 - € 67,522.12
Simvastatin <sup>2</sup>	€ 43.00 - € 68.95
Cholestyramine	€ 175.38 - € 1,322.10

<sup>2</sup> Simvastatin is shown as example for the statin group.

Designation of the therapy	Annual treatment costs/ patient
Ezetimibe	€ 96.14
<i>Evolocumab, if necessary + concomitant lipid-lowering medicinal therapy</i>	
Evolocumab, if necessary + simvastatin <sup>2</sup>	€ 5,379.44- € 11,675.71
Evolocumab, if necessary + simvastatin <sup>2</sup> + ezetimibe	€ 5,475.58- € 11,771.85
Evolocumab, if necessary + simvastatin <sup>2</sup> + ezetimibe + cholestyramine	€ 5,650.96- € 13,093.95
<i>LDL apheresis, if necessary + concomitant lipid-lowering medicinal therapy</i>	
LDL apheresis, if necessary + simvastatin <sup>2</sup>	€ 23,193.18- € 67,591.07
LDL apheresis, if necessary + simvastatin <sup>2</sup> + ezetimibe	€ 23,289.32- € 67,687.21
LDL apheresis, if necessary + simvastatin <sup>2</sup> + ezetimibe + cholestyramine	€ 23,464.70- € 69,009.31
<i>Evolocumab and LDL apheresis, if necessary + concomitant lipid-lowering medicinal therapy</i>	
Evolocumab + LDL apheresis	€ 28,486.62- € 79,128.88
Evolocumab + LDL apheresis, if necessary + simvastatin <sup>2</sup>	€ 28,529.62 - € 79,197.83
Evolocumab + LDL apheresis, if necessary + simvastatin <sup>2</sup> + ezetimibe	€ 28,625.76- € 79,293.97
Evolocumab + LDL apheresis, if necessary + simvastatin <sup>2</sup> + ezetimibe + cholestyramine	€ 28,801.14- € 80,616.07

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 June 2024)

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient year	Costs/ patient year
Medicinal product to be assessed:					
Evinacumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13.0	€ 1,300

**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:

Adolescents aged 12 years and older and adults with homozygous familial hypercholesterolaemia for whom dietary and medicinal lipid-lowering options have been exhausted

The following medicinal products with new active ingredients that can be used in a combination therapy with evinacumab in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Evolocumab (Repatha)

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.