Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V)
Enalapril (heart failure, from birth to ≤ 17 years)

of 15 August 2024

At its session on 15 August 2024, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. Annex XII shall be amended in alphabetical order to include the active ingredient Enalapril as follows:

Enalapril

Resolution of: 15 August 2024
Entry into force on: 15 August 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 15 November 2023):

AQUMELDI is indicated for the treatment of heart failure in children from birth to less than 18 years.

Therapeutic indication of the resolution (resolution of 15 August 2024):

See therapeutic indication according to marketing authorisation.

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

a) Children and adolescents from 1 to ≤ 17 years of age with heart failure

Appropriate comparator therapy for enalapril:

- Captopril or sacubitril/ valsartan

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

An additional benefit is not proven.

b) Children from birth to < 1 year of age with heart failure

Appropriate comparator therapy for enalapril:

- Captopril

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

An additional benefit is not proven.

Study results according to endpoints:

a) Children and adolescents from 1 to ≤ 17 years of age with heart failure

No assessable data submitted.

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		

b) Children from birth to < 1 year of age with heart failure

No assessable data submitted.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
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Health-related quality of life	∅	No data available.
Side effects	n.a.	There are no assessable data.
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2. Number of patients or demarcation of patient groups eligible for treatment

a) Children and adolescents from 1 to ≤ 17 years of age with heart failure

Approx. 3,000 children and adolescents

b) Children from birth to < 1 year of age with heart failure

Approx. 70 children

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 Aqumeldi (active ingredient: enalapril) agreed upon in the context of the marketing authorisation at the following publicly accessible link (last access: 8 July 2024):

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

Treatment with enalapril should only be initiated and monitored by doctors experienced in treating children and adolescents with heart failure.

4. Treatment costs

Annual treatment costs:

a) Children and adolescents from 1 to ≤ 17 years of age with heart failure

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Enalapril	€ 3,381.03 - € 38,640.36
Appropriate comparator therapy:	
Captopril in total:	€ 60.94 - € 9,626.80
Captopril OS 1 year	€ 5,434.49
Captopril OS 5 years	€ 9,626.80
Captopril TAB 5 or 6 years	€ 60.94
Captopril TAB 17 years	€ 182.81
Sacubitril/ valsartan	€ 840.96 - € 5,072.53
Abbreviations: OS = oral solution; TAB = tablets	

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

Costs for additionally required SHI services: not applicable

b) Children from birth to < 1 year of age with heart failure

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Enalapril	€ 966.01 - € 4,347.04
Appropriate comparator therapy:	
Captopril	€ 776.36 - € 1,707.98

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

Costs for additionally required SHI services: not applicable

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:

a) Children and adolescents from 1 to ≤ 17 years of age with heart failure

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

b) Children from birth to < 1 year of age with heart failure

– No medicinal product with new active ingredients that can be used in a combination therapy that 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.

II. **The resolution will enter into force on the day of its publication on the website of the G-BA on 15 August 2024.**

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 15 August 2024

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

Prof. Hecken