

Resolution
by the Federal Joint Committee
on an amendment to the Pharmaceutical Directive (AM-RL):
Appendix XII – Resolutions on the benefit assessment of pharmaceuticals
with new active ingredients, in accordance with the German Social Code,
Book Five (SGB V), section 35a
Aliskiren/amlodipine

from 3 May 2012

In its session on 3 May 2012, the Federal Joint Committee resolved to amend the Pharmaceutical Directive (AM-RL), version published 18 December 2008/22 January 2009 (Federal Gazette, number 49a of 31 March 2009), last amended on 3 May 2012 (Federal Gazette, AT 1 June 2012, B6), as follows:

I.

Appendix XII shall be amended in alphabetical order to include the active ingredient combination aliskiren/amlodipine:

Aliskiren/amlodipine

Therapeutic indication:

Rasilamlo® is indicated for the treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled with aliskiren or amlodipine used alone.

1. Additional benefit of the pharmaceutical over appropriate comparator

Appropriate comparator: combination therapy comprising an

– Angiotensin-converting-enzyme inhibitor (lisinopril or ramipril or enalapril)

and

– A calcium canal antagonist of the type dihydropyridine (amlodipine oder nitrendipine).

Extent and probability of an additional benefit over a combination therapy comprising an angiotensin-converting-enzyme inhibitor (lisinopril or ramipril or enalapril) and a calcium canal antagonist of the type dihydropyridine (amlodipine oder nitrendipine): as the necessary proof documents for the benefit assessment were not submitted in their entirety, an additional benefit over the appropriate comparator is considered not proved (SGB V, section 35a, paragraph 1, sentence 5).

2. Number of patients and criteria for defining patients eligible for treatment

Number: approx. 156,000 – 565,900 patients

3. Requirements for quality-assured administration

The specifications outlined in the product information are to be followed.

4. Costs of treatment

Duration of treatment:

Description of therapy	Mode of treatment	Number of treatments per patient per year	Duration per treatment (days)	Number of treatment days per patient per year
Pharmaceutical evaluated				
Aliskiren/amlodipine	ongoing, 1 x daily	ongoing	365	365
Appropriate comparator				
Lisinopril + amlodipine	ongoing, 1 – 2 x daily	ongoing	365	365
Lisinopril + nitrendipine	ongoing, 1 x daily	ongoing	365	365
Lisinopril + nitrendipine	ongoing, 1 – 2 x daily	ongoing	365	365
Lisinopril + amlodipine	ongoing, 1 x daily	ongoing	365	365

Description of therapy	Mode of treatment	Number of treatments per patient per year	Duration per treatment (days)	Number of treatment days per patient per year
Ramipril + amlodipine	ongoing, 1 x daily	ongoing	365	365
Ramipril + nitrendipine	ongoing, 1 x daily	ongoing	365	365
Enalapril + amlodipine	ongoing, 1 x daily	ongoing	365	365
Enalapril + nitrendipine	ongoing, 1 x daily	ongoing	365	365
	ongoing, 1 – 2 x daily	ongoing	365	365

Consumption:

Description of therapy	Strength (mg)	Number per pack (tablets) ¹	Average annual consumption (tablets)
Pharmaceutical evaluated			
Aliskiren/amlodipine	150/5 300/10	98	365
Appropriate comparator			
Lisinopril ² amlodipine	5 – 40 5 – 10	100 100	365 – 730 365
Lisinopril ² nitrendipine ³	5 – 40 20 – 40	100 100	365 – 730 365 – 730
Ramipril + amlodipine	2.5 – 10 5 – 10	100 100	365 365
Ramipril + nitrendipine	2.5 – 10 20 – 40	100 100	365 365 – 730
Enalapril + amlodipine	5 – 40 5 – 10	100 100	365 365
Enalapril + nitrendipine	5 – 40 20 – 40	100 100	365 365 – 730

¹ Largest pack

² In accordance with the product information, the effective maintenance dosage is between 5 – 40 mg/day

³ In accordance with the product information, the effective maintenance dosage is between 20 – 40 mg/day

Costs:

Cost of pharmaceutical:

Description of therapy	Cost (pharmacy retail price ¹)	Cost after legally mandated rebates
Pharmaceutical evaluated		
Aliskiren/amlodipine	€126.01 – €148.24	€109.7 € – €128.76 [€2.05 ³ , €14.62 – €17.43 ⁴]

Description of therapy	Cost (pharmacy retail price ¹)	Cost after legally mandated rebates
Appropriate comparator		
Lisinopril ^{2;5} + amlodipine ²	€13.26 – €16.05 €15.33 – €17.33	€10.99 – €13.56 [€2.05 ³ ; €0.22 – €0.44 ⁴] €12.90 – €14.74 [€2.05 ³ ; €0.38 – €0.54 ⁴]
Lisinopril ^{2;5} + nitrendipine ^{2;6}	€13.26 – €16.05 €16.51	€10.99 – €13.56 [€2.05 ³ ; €0.22 – €0.44 ⁴] €13.98 [€2.05 ³ ; €0.48 ⁴]
Ramipril ² + amlodipine ²	€12.90 – €15.10 €15.33 – €17.33	€10.66 – €12.69 [€2.05 ³ ; €0.19 – €0.36 ⁴] €12.90 – €14.74 [€2.05 ³ ; €0.38 – €0.54 ⁴]
Ramipril ² + nitrendipine ^{2;6}	€12.90 – €15.10 €16.51	€10.66 – €12.69 [€2.05 ³ ; €0.19 – €0.36 ⁴] €13.98 [€2.05 ³ ; €0.48 ⁴]
Enalapril ² + amlodipine ²	€13.26 – €18.71 €15.33 – €17.33	€10.99 – €16.01 [€2.05 ³ ; €0.22 – €0.65 ⁴] €12.90 – €14.74 [€2.05 ³ ; €0.38 – €0.54 ⁴]
Enalapril ² + nitrendipine ^{2;6}	€13.26 – €18.71 €16.51	€10.99 – €16.01 [€2.05 ³ ; €0.22 – €0.65 ⁴] €13.98 [€2.05 ³ ; €0.48 ⁴]

¹ Largest pack

² Reference price

³ Rebate in accordance with SGB V, section 130

⁴ Rebate in accordance with SGB V, section 130a

⁵ Strengths 5 mg – 20 mg

⁶ Strength 20 mg

"Lauer-Taxe", effective 15 March 2012

Costs for additional, necessary statutory health insurance (SHI) benefits: none

Annual treatment costs:

Description of therapy	Annual treatment costs per patient after legally mandated rebates	
Pharmaceutical evaluated		
Aliskiren/amlodipine	€408.58 – €479.57	
Appropriate comparator		
Lisinopril + amlodipine	€40.11 – €98.99 €47.09 – €53.80	€87.20 – €152.79
Lisinopril + nitrendipine	€40.11 – €98.99 €51.03 – €102.05	€91.14 – €201.04
Ramipril + amlodipine	€38.91 – €46.32 €47.09 – €53.80	€86.00 – €100.12
Ramipril + nitrendipine	€38.91 – €46.32 €51.03 – €102.05	€89.94 – €148.37
Enalapril + amlodipine	€40.11 – €58.44 €47.09 – €53.80	€87.20 – €112.24
Enalapril + nitrendipine	€40.11 – €58.44 €51.03 – €102.05	€91.14 – €160.49

II.

This resolution takes effect on the day of its publication in the internet on the website of the Federal Joint Committee on 3 May 2012.

The justification for this resolution will be published on the website of the Federal Joint Committee at www.g-ba.de.

Berlin, 3 May 2012

The Federal Joint Committee
in accordance with SGB V,
section 91

The Chair
Hess