

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, and Appendix IX – Reference price grouping angiotensin II antagonists, group 1, in level 2 in accordance with the German Social Code, Book Five (SGB V), section 35a, paragraph 3 along with paragraph 4, sentence 1

from 15 March 2012

In its session on 15 March 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 15 March 2012 (Federal Gazette, AT 16 April 2012, B6), as follows:

I.

Appendix XII shall be amended in alphabetical order to include the active ingredient azilsartan medoxomil (as a potassium salt):

"Azilsartan medoxomil (as a potassium salt)

A medical benefit as a therapeutic improvement in accordance with the German Social Code, Book 5 (SGB V), section 35, paragraph 1b, sentences 1 through 5, of azilsartan medoxomil (as a potassium salt) over the other active ingredients in the reference price group "angiotensin II antagonists, group 1" in level 2 is not proved in accordance with SGB V, section 35a, paragraph 1, sentences 4 and 5.

II.

The reference price group "angiotensin II antagonists, group 1" in level 2 shall be rewritten as follows:

"Level: 2

Active ingredient group: angiotensin II antagonists

Reference price group number: 1

Status: ethical

Active ingredients and prescription-related average doses:

Active ingredient	Prescription-related average dose
Azilsartan	37.5
Azilsartan medoxomil potassium salts	
Candesartan	12.5
Candesartan cilexetil	
Eprosartan	600
Eprosartan mesilat	
Irbesartan	216.9
Losartan	57.6
Losartan potassium	
Olmesartan	17.9
Olmesartan medoxomil	
Telmisartan	62.4
Valsartan	222

Group description: oral unit dosage forms

Dosage forms: coated tablets, capsules, tablets"

III.

This resolution takes effect on the day of its publication in the internet on the website of the Federal Joint Committee on 15 March 2012.

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

Berlin, 15 March 2012

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

The Chair
Hess