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
Aflibercept

from 6 June 2013

In its session on 6 June 2013, 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 18 April 2013 (Federal Gazette, AT 13.06.2013 B2) as follows:

I.

Appendix XII shall be amended in alphabetical order to include the active ingredient aflibercept:

Aflibercept

Therapeutic indication

Eylea® is indicated for adults for the treatment of neovascular (wet) age-related macular degeneration (AMD).

1. Additional benefit of the pharmaceutical over appropriate comparator

   Appropriate comparator:

   Ranibizumab

   Extent and probability of additional benefit over ranibizumab:

   An additional benefit over the appropriate comparator has not been proved.

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

   Number: approx. 305,000 patients

3. Requirements for quality-assured administration

   The specifications outlined in the product information are to be followed. The European Medicines Agency (EMA), the European regulatory authority, provides the product information for Eylea® (active ingredient: aflibercept) at the following public link (last accessed: 15 May 2013):

   Hyperlink product information aflibercept (Eylea®)

   Eylea® may be administered only by a qualified ophthalmologist experienced in the administration and follow-up care of intravitreal injections.

   So far no valid data are available for patients previously treated with other VEGF inhibitors.

   Administering physicians must follow the information requested and to be supplied by the pharmaceutical company in accordance with EPAR (Hyperlink EPAR aflibercept (Eylea®) p. 78).

4. Costs of treatment

   Duration of treatment:

Description of therapy	Mode of treatment[1]	Number of treatments per patient per year	Duration per treatment (days)	Treatments per patient per year
Aflibercept First year	3 injections (one per month), afterwards every 2 months	7	1	7
Aflibercept Following years	Time between injections can be extended depending on progress	1 – 6	1	1 – 6
Ranibizumab First year	Monthly injection until vision is constant for three check-ups. Continued treatment in case of loss of vision.	3 – 12	1	3 – 12

[1] Information based on product information

Description of therapy	Mode of treatment[1]	Number of treatments per patient per year	Duration per treatment (days)	Treatments per patient per year
Ranibizumab Following years	Continued treatment in case of loss of vision.	0 – 12	1	0 – 12

Consumption:

Description of therapy	Strength (mg)	Number per pack (mg)	Average annual consumption (packs)
Aflibercept	4 mg	4 mg	First year 7: Following years
Ranibizumab	2.3 mg	2.3 mg	First year 3 – 12 Following years [0 – 12]

Costs:

Cost of pharmaceutical:

Description of therapy	Cost (pharmacy retail price)	Cost after legally mandated rebates
Aflibercept	€1,136.03	€1,074.74 [€2.05[2]; €59.24[3]]
Ranibizumab	€1,262.77	€1,102.28 [€2.05[2]; €158.44[3]]

"Lauer-Taxe", effective 1 May 2013

Costs for additional, necessary statutory health insurance (SHI) benefits:

Description of therapy	Type of benefit	Cost per unit	Number per patient per	Cost per patient per year
Aflibercept	Intravitreal injection, check-ups	Not quantifiable[4, 5, 6]	First year 7 Following years [1 –	Not quantifiable[4]
Ranibizumab	Intravitreal injection	Not quantifiable[4, 6]	First year 3 – 12 Following years [0 – 12]	Not quantifiable[4]

Annual treatment costs:

Description of therapy	Annual treatment costs per patient[7]
Aflibercept	First year €7,523.18 Following years €1,074.74 – €6,448.44
Ranibizumab	First year €3,306.84 – €13,227.36 Following years €0 – €13,227.36

II.

This resolution takes effect on the day of its publication in the internet on the website of the Federal Joint Committee on 6 June 2013.

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

Berlin, 6 June 2013

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

The Chair
Hecken

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[2] Rebate in accordance with SGB V, section 130

[3] Rebate in accordance with SGB V, section 130a

[4] EBM number not available

[5] The aflibercept product information recommends basing treatment intervals on functional and morphological progress. Check-up intervals should be determined by the attending physician; they may be more frequent than injection intervals. Costs for morphological examinations, e.g. optical coherence tomography OCT, cannot be quantified at the time of resolution, as they are not reflected in the EBM.

[6] Vision check-ups included in basic price

[7] Costs for additional SHI expenses not quantifiable