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 (new therapeutic indication)

From 3 September 2015

In its session on 3 September 2015, 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 16 July 2015 (Federal Gazette, AT 11 September 2015 B1) as follows:

I.

In Appendix XII, the following information shall be added after number 4 to the benefit assessment of aflibercept in the therapeutic indication "age-related macular degeneration" (therapeutic indication initially authorized) in accordance with the resolution of 6 June 2013, "metastatic colorectal cancer" of 15 August 2013, "macular oedema secondary to retinal vein occlusion" of 20 March 2014, and the benefit assessment of aflibercept in the therapeutic indication "visual impairment due to diabetic macular oedema" of 5 March 2014:

Aflibercept

Therapeutic indication authorized from 24 February 2015:

Aflibercept (Eylea®) is indicated in adults for the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion.

1. Additional benefit of the pharmaceutical over appropriate comparator

   Appropriate comparator:

   Ranibizumab

   Extent and probability of additional benefit over appropriate comparator:

   An additional benefit has not been proved.

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

   Approx. 23,100 to 60,000 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 contents of the product information for Eylea® (active ingredient: aflibercept) at the following public link (last accessed: 27 July 2015): http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002392/WC500135815.pdf

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

   Administering physicians must follow the information requested and to be supplied by the pharmaceutical company in accordance with the EPAR (see p. 65 http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Assessment_Report_-_Variation/human/002392/WC500185971.pdf)

4. Costs of treatment

Duration of treatment:

Designation of therapy	Mode of treatment	Number of treatments per patient per year	Duration per treatment (days)	Number of treatment days per patient per year
Aflibercept first year	Monthly injections until maximum vision is achieved and/or no more signs of disease activity can be detected.	3 – 12	1	3 – 12
Aflibercept following years	Monthly injections or prolongation of injection intervals depending on disease progression	0[1] – 12	1	0 – 12
Ranibizumab first year	Monthly injections until maximum visual acuity is achieved and/or no signs of disease activity; continued treatment based on disease activity as measured by visual acuity and/or morphological criteria	3 – 12	1	3 – 12
Ranibizumab following years	Continued treatment based on disease activity as measured by visual acuity and/or morphological criteria	0[1] – 12	1	0 – 12

Consumption:

Designation of therapy	Strength (mg)	Number per pack (mg)	Average annual consumption (packs)
Aflibercept	2	4	First year 3 – 12 Following years 0 – 12
Ranibizumab	0.5	2.3	First year 3 – 12 Following years 0 – 12

Costs:

Cost of pharmaceutical:

Designation of therapy	Cost (pharmacy retail price)	Cost after legally mandated rebates
Aflibercept	€1,099.08	€1,037.07 [€1.77[2]; €60.24[3]]
Ranibizumab	€1,262.96	€1,191.87 [€1.77[2]; €69.32[3]]

"Lauer-Taxe", effective: 1 August 2015

Costs for additional, necessary SHI benefits: not quantifiable

Costs for additional, necessary SHI expense items: Designation of therapy	Type of benefit	Costs per unit[4]	Number per patient per year	Cost per patient per year
Aflibercept	Intravitreal injection and follow-up examinations[5]	Not quantifiable[6, 7, 8]	First year: 3 – 12 Following years: 0	not quantifiable
Ranibizumab	Intravitreal injection and follow-up examinations[5]	Not quantifiable[6, 7, 8]	First year: 3 – 12 Following years: 0	not quantifiable

[1] If progression findings are stable for 12 months after the previous treatment year, no further injections are administered in the following year.

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

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

[4] In accordance with the German Uniform Value Scale (EBM). Reference value for 2015: 10.2718 euro cents.

[5] Follow-up examinations are determined by the attending physician (see Eylea® product information, effective February 2015; Lucentis®, effective November 2014).

[6] No EBM codes are available for part of the post-operative check-ups (e.g. optical coherence tomography (OCT)).

[7] Vision check-ups included in basic price

[8] EBM codes for the intravitreal injection: either GOP 31371/36371 (right eye) or GOP 31372/36372 (left eye) or GOP 31373/36373 (both eyes).

Annual treatment costs:

Designation of therapy	Annual treatment costs per patient[9]
Aflibercept	First year: €3,111.21 – €12,444.84 Following years: €0 – €14,444.84
Ranibizumab	First year: €3,575.61 – €14,302.44 Following years: €0 – €14,302.44

II.

This resolution takes effect on the day of its publication in the internet on the website of the Federal Joint Committee on 3 September 2015.

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

Berlin, 3 September 2015

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

The Chair
Prof. Hecken

[9] Costs for additional SHI expenses not quantifiable